Oracle® Process Manufacturing

Quality Management User's Guide

Release 11*i*

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Oracle Process Manufacturing Quality Management User's Guide, Release 11*i*

Part No. B10626-04

Contents

3   Tests

4   Specifications

5 Samples

6 Results

7 Reports and Inquiries

8   Stability Studies

A Quality Management Navigator Paths

B Quality Management Profile Options

C Quality Management Business Rules

D Quality Management Workflows

E Oracle E-Record Events in Quality Management

Glossary

Index

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Preface

Welcome to the Oracle Process Manufacturing Quality Management User's Guide, Release 11*i*.

This guide assumes you have a working knowledge of the following:

- The principles and customary practices of your business area.

- Oracle Process Manufacturing.

  If you have never used Oracle Process Manufacturing, Oracle suggests you attend one or more of the Oracle Applications training classes available through Oracle University.

- Oracle Self-Service Web Applications.

  To learn more about Oracle Self-Service Web Applications, read the *Oracle Self-Service Web Applications Implementation Manual*.

- The Oracle Applications graphical user interface.

  To learn more about the Oracle Applications graphical user interface, read the *Oracle Applications User's Guide*.

See Other Information Sources for more information about Oracle Applications product information.

How To Use This Guide

The Oracle Process Manufacturing Quality Management User's Guide contains the information you need to understand and use the Oracle Process Manufacturing Quality Management application. This guide contains eight chapters, five appendixes, and a glossary:

- Chapter 1, Understanding Quality Management, provides an overview of Oracle Process Manufacturing Quality Management. It explains the fundamentals of quality management in the supply chain. It also explains the tasks and responsibilities offered. A process flow provides a detailed analysis for setting up and running the application.

- Chapter 2, Setting Up, describes the setup tasks that you need to perform for Oracle Process Manufacturing Quality Management, including setup of quality responsibilities, action codes, grades, hold reasons, test classes, test units, sampling plans, and quality system parameters.

- Chapter 3, Tests, describes the process of entering test methods and tests. A detailed discussion of experimental error is provided to help set up test limits and appropriate actions to take when test results fall in the experimental error region.

- Chapter 4, Specifications, explains the development of quality specifications, including how to use lot UOM conversions based on quality results. A complete explanation of the workflow that controls status approval is provided with information on how to edit status codes and status details. The chapter provides information on entering item specifications, monitoring specifications, and validity rules for each type of specification. A discussion of how to display specification summaries from the Navigator is also provided.

- Chapter 5, Samples, provides information on entering item samples and monitoring samples, and displaying sample groups. This is followed by a discussion of how to display sample summaries from the Navigator and Samples Summary window.

- Chapter 6, Results, discusses how to enter and composite test results. A brief discussion provides information on how to add tests to composited results and use the specification comparison functionality. The detailed process of changing quality disposition is provided. Instructions are provided to associate results to another sample.

- Chapter 7, Reports and Inquiries, discusses how to run several preformatted reports that assist in the analysis of test results, generating a Certificate of

Analysis or Conformance Report, making a sample storage summary inquiry, and generating labels for quality samples.

- Chapter 8, Stability Studies, provides information for stability study setup, planning, initial sampling, and testing. The complete stability study lifecycle is provided including how to approve the study plan, perform testing throughout the study, and evaluate test results.

- Appendix A, Quality Management Navigator Paths, describes how to navigate to each window.

- Appendix B, Quality Management Profile Options, provides the profile options to set up to run the application.

- Appendix C, Quality Management Business Rules, provides specification matching business rules, and outlines the steps needed to match customer specifications.

- Appendix D, Quality Management Workflows, describes the basic business needs for workflows, a technical overview of the workflows, and how to set up workflows in Quality Management.

- Appendix E, Oracle E-Record Events in Quality Management, provides a summary of events that are e-record and e-signature enabled, and references resources you can access for additional information.

- Glossary provides definitions of terms that are used in this guide.

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible, with good usability, to the disabled community. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For additional information, visit the Oracle Accessibility Program Web site at http://www.oracle.com/accessibility/

Accessibility of Code Examples in Documentation

JAWS, a Windows screen reader, may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, JAWS may not always read a line of text that consists solely of a bracket or brace.

Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Other Information Sources

You can choose from many sources of information, including documentation, training, and support services, to increase your knowledge and understanding of Oracle Process Manufacturing.

If this guide refers you to other Oracle Applications documentation, use only the Release 11*i* versions of those guides.

Online Documentation

All Oracle Applications documentation is available online (HTML or PDF).

- **PDF Documentation-** See the Online Documentation CD for current PDF documentation for your product with each release. This Documentation CD is also available on Oracle*MetaLink* and is updated frequently.

- **Online Help -** You can refer to Oracle Applications Help for current HTML online help for your product. Oracle provides patchable online help, which you can apply to your system for updated implementation and end user documentation. No system downtime is required to apply online help.

- **Release Content Document -** See the Release Content Document for descriptions of new features available by release. The Release Content Document is available on Oracle*MetaLink*.

- **About document -** Refer to the About document for information about your release, including feature updates, installation information, and new documentation or documentation patches that you can download. The About document is available on Oracle*MetaLink*.

Related Guides

Oracle Process Manufacturing shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other guides when you set up and use Oracle Process Manufacturing.

You can read the guides online by choosing Library from the expandable menu on your HTML help window, by reading from the Oracle Applications Document Library CD included in your media pack, or by using a Web browser with a URL that your system administrator provides.

If you require printed guides, you can purchase them from the Oracle Store at http://oraclestore.oracle.com.

Guides Related to All Products

Oracle Applications User's Guide

This guide explains how to enter data, query, run reports, and navigate using the graphical user interface (GUI). This guide also includes information on setting user profiles, as well as running and reviewing reports and concurrent processes.

You can access this user's guide online by choosing "Getting Started with Oracle Applications" from any Oracle Applications help file.

Guides Related to This Product

Accounting Setup User's Guide

The OPM Accounting Setup application is where users set up global accounting attributes about the way financial data will be collected by OPM. These attributes include such things as account keys, financial calendars, and account segments. Since OPM is closely integrated with Oracle General Ledger (GL), much of the attributes are defined in the Oracle GL instead of OPM, and therefore, the windows are display only within OPM. The *Oracle Process Manufacturing Accounting Setup User's Guide* describes how to setup and use this application.

Cost Management User's Guide

The OPM Cost Management application is used by cost accountants to capture and review the manufacturing costs incurred in their process manufacturing businesses. The *Oracle Process Manufacturing Cost Management User's Guide* describes how to setup and use this application.

Manufacturing Accounting Controller User's Guide

The Manufacturing Accounting Controller application is where users define the impact of manufacturing events on financials. For example, event RCPT (Inventory Receipts) results in a debit to inventory, a credit to accrued accounts payable, a debit or a credit to purchase price variance, etc. These impacts are predefined in the Manufacturing Accounting Controller application so users may begin using OPM to collect financial data out-of-the-box, however, they may also be adjusted per your business needs. The *Oracle Process Manufacturing Manufacturing Accounting Controller User's Guide* describes how to setup and use this application.

Oracle Financials Integration User's Guide

Since OPM is closely integrated with Oracle General Ledger, financial data that is collected about the manufacturing processes must be transferred to the Oracle Financials applications. The OPM Oracle Financials Integration application is where users define how that data is transferred. For example, users define whether data is transferred real time or batched and transferred at intervals. The *Oracle Process Manufacturing Oracle Financials Integration User's Guide* describes how to setup and use this application.

Inventory Management User's Guide

The OPM Inventory Management application is where data about the items purchased for, consumed during, and created as a result of the manufacturing process are tracked. The *Oracle Process Manufacturing Inventory Management User's Guide* includes information to help you effectively work with the Oracle Process Manufacturing Inventory application.

Physical Inventory User's Guide

Performing physical inventory count is the most accurate way to get an accounting of all material quantities purchased, manufactured, and sold, and update your onhand quantities accordingly. The OPM Physical Inventory application automates and enables the physical inventory process. The *Oracle Process Manufacturing Physical Inventory User's Guide* describes how to setup and use this application.

Order Fulfillment User's Guide

The OPM Order Fulfillment application automates sales order entry to reduce order cycle time. Order Fulfillment enables order entry personnel to inform customers of scheduled delivery dates and pricing. The *Oracle Process Manufacturing Order Fulfillment User's Guide* describes how to setup and use this application.

Purchase Management User's Guide

OPM Purchase Management and Oracle Purchasing combine to provide an integrated solution for Process Manufacturing. Purchase orders are entered in Oracle Purchasing and received in OPM. Then, the receipts entered in OPM are sent to Oracle Purchasing. The *Oracle Process Manufacturing Purchase Management User's Guide* describes how to setup and use this integrated solution.

Using Oracle Order Management with Process Inventory Guide

Oracle Process Manufacturing and Oracle Order Management combine to provide an integrated solution for process manufacturers. The manufacturing process is tracked and handled within Oracle Process Manufacturing, while sales orders are taken and tracked in Oracle Order Management. Process attributes, such as dual UOM and lot control, are enabled depending on the inventory organization for the item on the sales order. Order Management accepts orders entered through Oracle Customer Relationship Management (CRM). Within CRM, orders can originate from TeleSales, Sales Online, and iStore, and are booked in Order Management, making the CRM suite of products available to Process customers, through Order Management. The *Oracle Order Management User's Guide* and *Using Oracle Order Management with Process Inventory Guide* describes how to setup and use this integrated solution.

Process Execution User's Guide

The OPM Process Execution application lets you track firm planned orders and production batches from incoming materials through finished goods. Seamlessly integrated to the Product Development application, Process Execution lets you convert firm planned orders to single or multiple production batches, allocate ingredients, record actual ingredient usage, and then complete and close production batches. Production inquiries and preformatted reports help you optimize inventory costs while maintaining a high level of customer satisfaction with on-time delivery of high quality products. The *OPM Process Execution User's Guide* presents overviews of the tasks and responsibilities for the Production Supervisor and the Production Operator. It provides prerequisite setup in other applications, and details the windows, features, and functionality of the OPM Process Execution application.

Using Oracle Advanced Planning and Scheduling with Oracle Process Manufacturing

Oracle Process Manufacturing and Oracle Advanced Planning and Scheduling (APS) combine to provide a solution for process manufacturers that can help increase planning efficiency. This solution provides for constraint-based planning, performance management, materials management by exception, mixed mode manufacturing that enables you to choose the best method to produce each of your products, and combine all of these methods within the same plant/company. The *Using Oracle Advanced Planning and Scheduling with Oracle Process Manufacturing User's Guide* describes how to setup and use this application.

MPS/MRP and Forecasting User's Guide

The Oracle Process Manufacturing Material Requirements Planning (MRP) application provides long-term "views" of material demands and projected supply actions to satisfy those demands. The Master Production Scheduling (MPS) application lets you shorten that view to a much narrower and immediate time horizon, and see the immediate effects of demand and supply actions. The *Oracle Process Manufacturing MPS/MRP and Forecasting User's Guide* describes how to setup and use this application.

Capacity Planning User's Guide

The OPM Capacity Planning User's Guide describes the setup required to use OPM with the Oracle Applications Advanced Supply Chain Planning solutions. In addition, Resource setup, used by the OPM Production Execution and New Product Development applications, is also described.

Using Oracle Process Manufacturing with Oracle Manufacturing Scheduling

Oracle Process Manufacturing integrates with Oracle Manufacturing Scheduling to manage and utilize resources and materials. Through the Process Manufacturing application, you set up manufacturing, inventory, procurement and sales order data. Through the Manufacturing Scheduling application, you can optimize the schedule based on resource and component constraints and user predefined priorities. Using different optimization objectives, you can tailor Manufacturing Scheduling to meet your needs.

Using Oracle Manufacturing Scheduling helps you improve productivity and efficiency on your shop floor. By optimally scheduling shop floor jobs, and being able to quickly react to unplanned constraints, you can lower manufacturing costs, increase resource utilization and efficiency, and increase customer satisfaction through improved on-time delivery. The *Using Oracle Process Manufacturing with Oracle Manufacturing Scheduling User's Guide* describes how to setup and use this integrated solution.

Product Development User's Guide

The Oracle Process Manufacturing Product Development application provides features to manage formula and laboratory work within the process manufacturing operation. It lets you manage multiple laboratory organizations and support varying product lines throughout the organization. You can characterize and simulate the technical properties of ingredients and their effects on formulas. You can optimize formulations before beginning expensive laboratory test batches. Product Development coordinates each development function and enables a rapid,

enterprise-wide implementation of new products in your plants. The *Oracle Process Manufacturing Product Development User's Guide* describes how to setup and use this application.

Quality Management User's Guide

The Oracle Process Manufacturing Quality Management application provides features to test material sampled from inventory, production, or receipts from external suppliers. The application lets you enter specifications and control their use throughout the enterprise. Customized workflows and electronic record keeping automate plans for sampling, testing, and result processing. You can compare specifications to assist in regrading items, and match customer specifications. Aggregate test results and print statistical assessments on quality certificates. Several preformatted reports and inquiries help manage quality testing and reporting. The *Oracle Process Manufacturing Quality Management User's Guide* describes how to set up and use this application.

Implementation Guide

The *Oracle Process Manufacturing Implementation Guide* offers information on setup. That is, those tasks you must complete following the initial installation of the Oracle Process Manufacturing software. Any tasks that must be completed in order to use the system out-of-the-box are included in this manual.

System Administration User's Guide

Much of the System Administration duties are performed at the Oracle Applications level, and are therefore described in the *Oracle Applications System Administrator's Guide.* The *Oracle Process Manufacturing System Administration User's Guide* provides information on the few tasks that are specific to OPM. It offers information on performing OPM file purge and archive, and maintaining such things as responsibilities, units of measure, and organizations*.*

API User's Guides

Public Application Programming Interfaces (APIs) are available for use with different areas of the Oracle Process Manufacturing application. APIs make it possible to pass information into and out of the application, bypassing the user interface. Use of these APIs is documented in individual manuals such as the *Oracle Process Manufacturing Inventory API User's Guide, Oracle Process Manufacturing Process Execution API User's Guide, Oracle Process Manufacturing Product Development Formula API User's Guide, Oracle Process Manufacturing Product Development Recipe API User's Guide, Oracle Process Manufacturing Quality Management API User's Guide,*

and the *Oracle Process Manufacturing Cost Management API User's Guide.* Additional API User's Guides are periodically added as additional public APIs are made available.

Installation and System Administration

Oracle Applications Concepts

This guide provides an introduction to the concepts, features, technology stack, architecture, and terminology for Oracle Applications Release 11*i*. It provides a useful first book to read before an installation of Oracle Applications. This guide also introduces the concepts behind Applications-wide features such as Business Intelligence (BIS), languages and character sets, and Self-Service Web Applications.

Installing Oracle Applications

This guide provides instructions for managing the installation of Oracle Applications products. In Release 11*i*, much of the installation process is handled using Oracle Rapid Install, which minimizes the time to install Oracle Applications and the Oracle technology stack by automating many of the required steps. This guide contains instructions for using Oracle Rapid Install and lists the tasks you need to perform to finish your installation. You should use this guide in conjunction with individual product user guides and implementation guides.

Upgrading Oracle Applications

Refer to this guide if you are upgrading your Oracle Applications Release 10.7 or Release 11.0 products to Release 11*i*. This guide describes the upgrade process and lists database and product-specific upgrade tasks. You must be either at Release 10.7 (NCA, SmartClient, or character mode) or Release 11.0, to upgrade to Release 11*i*. You cannot upgrade to Release 11*i* directly from releases prior to 10.7.

"About" Document

For information about implementation and user documentation, instructions for applying patches, new and changed setup steps, and descriptions of software updates, refer to the "About" document for your product. "About" documents are available on Oracle*MetaLink* for most products starting with Release 11.5.8.

Maintaining Oracle Applications

Use this guide to help you run the various AD utilities, such as AutoUpgrade, AutoPatch, AD Administration, AD Controller, AD Relink, License Manager, and others. It contains how-to steps, screenshots, and other information that you need to run the AD utilities. This guide also provides information on maintaining the Oracle applications file system and database.

Oracle Applications System Administrator's Guide

This guide provides planning and reference information for the Oracle Applications System Administrator. It contains information on how to define security, customize menus and online help, and manage concurrent processing.

Oracle Alert User's Guide

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

Oracle Applications Developer's Guide

This guide contains the coding standards followed by the Oracle Applications development staff and describes the Oracle Application Object Library components that are needed to implement the Oracle Applications user interface described in the *Oracle Applications User Interface Standards for Forms-Based Products*. This manual also provides information to help you build your custom Oracle Forms Developer forms so that the forms integrate with Oracle Applications.

Oracle Applications User Interface Standards for Forms-Based Products

This guide contains the user interface (UI) standards followed by the Oracle Applications development staff. It describes the UI for the Oracle Applications products and how to apply this UI to the design of an application built by using Oracle Forms.

Other Implementation Documentation

Oracle Applications Product Update Notes

Use this guide as a reference for upgrading an installation of Oracle Applications. It provides a history of the changes to individual Oracle Applications products between Release 11.0 and Release 11*i*. It includes new features, enhancements, and changes made to database objects, profile options, and seed data for this interval.

Oracle Workflow Administrator's Guide

This guide explains how to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes, as well as how to monitor the progress of runtime workflow processes.

Oracle Workflow Developer's Guide

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

Oracle Workflow User's Guide

This guide describes how Oracle Applications users can view and respond to workflow notifications and monitor the progress of their workflow processes.

Oracle Workflow API Reference

This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

Oracle Applications Flexfields Guide

This guide provides flexfields planning, setup and reference information for the Oracle Process Manufacturing implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

Oracle eTechnical Reference Manuals

Each eTechnical Reference Manual (eTRM) contains database diagrams and a detailed description of database tables, forms, reports, and programs for a specific Oracle Applications product. This information helps you convert data from your existing applications, integrate Oracle Applications data with non-Oracle applications, and write custom reports for Oracle Applications products. Oracle eTRM is available on Oracle*Metalink*

Oracle Applications Message Manual

This manual describes all Oracle Applications messages. This manual is available in HTML format on the documentation CD-ROM for Release 11*i*.

Training and Support

Training

Oracle offers a complete set of training courses to help you and your staff master Oracle Process Manufacturing and reach full productivity quickly. These courses are organized into functional learning paths, so you take only those courses appropriate to your job or area of responsibility.

You have a choice of educational environments. You can attend courses offered by Oracle University at any one of our many education centers, you can arrange for our trainers to teach at your facility, or you can use Oracle Learning Network (OLN), Oracle University's online education utility. In addition, Oracle training professionals can tailor standard courses or develop custom courses to meet your needs. For example, you may want to use your organization structure, terminology, and data as examples in a customized training session delivered at your own facility.

Support

From on-site support to central support, our team of experienced professionals provides the help and information you need to keep Oracle Process Manufacturing working for you. This team includes your technical representative, account manager, and Oracle's large staff of consultants and support specialists with expertise in your business area, managing an Oracle server, and your hardware and software environment.

Do Not Use Database Tools to Modify Oracle Applications Data

Oracle STRONGLY RECOMMENDS that you never use SQL*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless otherwise instructed.

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using Oracle Applications can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL*Plus and other database tools do not keep a record of changes.

About Oracle

Oracle develops and markets an integrated line of software products for database management, applications development, decision support, and office automation, as well as Oracle Applications, an integrated suite of more than 160 software modules for financial management, supply chain management, manufacturing, project systems, human resources and customer relationship management.

Oracle products are available for mainframes, minicomputers, personal computers, network computers and personal digital assistants, allowing organizations to integrate different computers, different operating systems, different networks, and even different database management systems, into a single, unified computing and information resource.

Oracle is the world's leading supplier of software for information management, and the world's second largest software company. Oracle offers its database, tools, and applications products, along with related consulting, education, and support services, in over 145 countries around the world.

Your Feedback

Thank you for using Oracle Process Manufacturing and this user guide.

Oracle values your comments and feedback. In this guide is a reader's comment form that you can use to explain what you like or dislike about Oracle Process Manufacturing or this user guide. Mail your comments to the following address or call us directly at (650) 506-7000.

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Or, send electronic mail to appsdoc_us@oracle.com.

1

Understanding Quality Management

This topic provides the fundamentals of Quality Management. It presents the basic tasks, responsibilities, and process flow required to manage the quality of a product. An introduction to process quality management concepts, and the impact that quality has on other applications is provided.

- About This Guide
- About Quality Management
- Tasks and Responsibilities
- Process Flow
- Understanding the Interface to Other Applications
- Understanding Navigation
- Using the Navigator Find Window

About This Guide

The purpose of this guide is to provide reference information for end-level users of the OPM Quality Management application. It presents:

- Overviews of tasks and responsibilities accountable for managing quality within the enterprise.

- Process flows presented in the OPM Quality Management application.

- Navigating the Quality Workbench. This includes a discussion of using the Navigator Find window.

- Interfacing of OPM Quality Management with other Oracle applications.

- Prerequisite setup in other applications, including OPM System Administration, OPM Inventory Control, OPM Product Development, OPM Process Execution, Oracle Receivables, Oracle Order Management, OPM Order Fulfillment, and Oracle Purchasing.

- Prerequisite setup of action codes, grades, hold reasons, test classes, test units, sampling plans, and quality system parameters.

- Discussions of test methods and tests. This includes entering test methods, understanding tests, and entering test data. Additional discussions include customizing customer-specific quality certificate information, and defining experimental error action zones for tests.

- Discussions of item specifications, monitoring specifications, and their validity rules. This includes procedures for entry of base and overlay item specifications and monitoring specifications, the status approval process, editing and adding status codes, implementing specification version control, managing optional tests, creating samples automatically, and entry of item specification validity rules and monitoring specification validity rules. The use of lot UOM conversions based on quality results is presented.

- Discussions of samples. This includes information on the sampling process, entering item samples and monitoring samples, displaying sample groups, and displaying sample summaries from the Navigator. Procedures for retaining, archiving, and reserving samples are presented with business rules governing them.

- Discussions of results. This includes information on entering results, and how to prevent the completion of a batch step until acceptable results are recorded and approved. The process for selecting samples and tests for mass results entry is described. The procedures for compositing tests results and adding tests to

composited results are presented. The specification comparison feature determines how closely a set of results meets the requirements of the comparison specification. Procedures for changing quality disposition and managing expired lots are presented. Requirements and procedures for associating results to other sample are presented.

- Several preformatted reports and inquiries help manage quality testing, analysis, and reporting.

- Appendixes provide navigator paths, profile options, specification matching business rules, workflows, and e-signature and e-record information.

Depending on your system security profile, it is possible that you do not have access to all of the windows and functions described in this guide. If you do not see a menu option described, and you need to access it, then contact your system administrator.

About Quality Management

To maintain productivity and a high level of customer satisfaction, the inherent variability of materials and methods used in a process manufacturing environment must be controlled. Most process companies use quality inspection to determine the capabilities of their manufacturing procedures. By understanding process and material variability, process manufacturers optimize throughput without sacrificing product quality.

Understanding Quality Improvement

Quality improvement is a continuous process that controls component variability by monitoring the sources of material instability. Quality responsibilities in the enterprise assist in this process by:

- Monitoring process behavior, and assigning reasons for process failures.
- Understanding the source of a nonconforming material, and taking action to minimize, or virtually eliminate it.

The aim is to identify methods to turn unpredictable manufacturing events into well characterized manufacturing capabilities.

Process control begins with understanding process capability. Knowing how to improve the manufacturing process helps everyone in the enterprise. One of the aims of total quality management is to design quality into products. The overall aim of quality inspection is to ensure material conformance to specification in inventory, production, shipping, and receiving operations.

Designing Quality into Products

Consistent testing of products and materials reduces waste by detecting potential problems before they become major issues. A total quality approach designs the manufacturing process in parallel with the quality testing process. OPM Quality Management interfaces quality testing into all aspects of research, development, commercialization, production, purchasing, and shipping operations. This seamless interfacing across the supply chain assists in the consistent development and application of quality standards.

Communicating Quality Throughout the Enterprise   The most important part of quality management is the successful communication of quality requirements from receipt of incoming materials to the shipment of finished goods. OPM Quality Management provides notification and approval workflows to control quality throughout the enterprise.

Communicating Quality Consistently   Consistency is essential to uniform quality communications. By using common test methods, sampling plans, and decimal precision for reports, the enterprise benefits from a standardized approach to quality testing.

Agreeing to Quality Capabilities   The specification serves as a written agreement on the conformance of a material to a predefined level of acceptance. OPM Quality Management uses the specification and the specification validity rule to manage the inspection sampling. From the laboratory batch to the full production run, the specification validity rule controls the use of the specification in the enterprise. Workflows reduce the specification and validity rule approval process to a series of defined steps that are managed by the application.

Ensuring Proper Sample Collection and Processing   The coordination of sampling throughout the enterprise is often complex and error prone. OPM Quality Management controls the sampling process through workflow notifications to create and process samples. The application monitors business events that require sampling, and optionally updates inventory to reflect material sampled. Using this transaction event-based approach, each of the quality inspection points are coordinated. From material receipt, through batch step release, the sample is traced by source, priority, and disposition.

Ensuring Proper Result Reporting   From result entry to result evaluation, OPM Quality Management coordinates the appropriate capture of electronic signatures for electronic results records. The application composites results and compares specifications on analyzed samples for efficient quality grade assignment and customer specification matching.

Tasks and Responsibilities

Each role in the organization must collaborate throughout the enterprise to ensure effective quality management and information sharing.

The following is representative of the work breakdown structure for managing quality within the enterprise. It lists most of the key tasks and job titles responsible for those tasks:

- Set up quality system parameters.
  - Quality Manager
- Set up test methods.
  - Quality Manager
- Set up individual tests.
  - Quality Manager
- Create sampling plans for quality inspection.
  - Quality Manager
- Create certificate requirements.
  - Formulator
  - Quality Manager
- Create specifications.
  - Formulator
  - Process Engineer
  - Quality Manager
- View specifications throughout the enterprise.
  - Formulator
  - Process Engineer
  - Production Operator
  - Production Supervisor
  - Quality Manager
  - Quality Technician

- Inventory application

- Order Management application

- Create specification validity rules for inventory, work in process, customer, or supplier use.

    - Formulator

    - Process Engineer

    - Quality Manager

- Sample materials.

    - Formulator

    - Process Engineer

    - Quality Technician

    - Quality Manager

    - Production Supervisor

    - Production Operator

- Perform tests.

    - Quality Technician

    - Quality Manager

- Report results.

    - Quality Technician

    - Quality Manager

    - Formulator

    - Process Engineer

    - Production Supervisor

    - Production Operator

- Approve results.

    - Quality Manager

- Perform additional tests, if required.

    - Quality Technician

- - Quality Manager
  - Formulator
  - Process Engineer
  - Production Supervisor
  - Production Operator
- Publish certificates.
  - Quality Manager
- Run reports and inquiries.
  - Quality Technician
  - Quality Manager
  - Formulator
  - Process Engineer
  - Production Supervisor
  - Production Operator

Process Flow

The following provides a suggested process flow for setting up and running OPM Quality Management.

Set Up Other Applications

Set up each of the following applications:

- System Administration

    - Set up required profile options and setups as described in the *Oracle Process Manufacturing Implementation Guide*, *Oracle Approvals Management (OAM) Implementation Guide*, *Oracle Workflow User's Guide*, and this document. Required.

    - Set up responsibilities for Quality Manager , Quality Technician, Workflow Administrator Event Manager, Workflow User Web (New), AME General Business User, and Electronic Record and Electronic Signatures Web Administrator. Required.

- OPM System Administrator

    - Set up organizations including quality laboratories.

    - Configure document numbering for samples. Optional.

- OPM Inventory Control

    - Set up items for sampling and test kits, lots, and sublots, item attributes, unit of measure conversions, and item lot and sublot conversions. Required.

    - Set up warehouses and locations.

- OPM Product Development

    - Set up formulas, routings, operations, and recipes.

    - Set up quality laboratory equipment or instruments as plant resources.

    - Set up a sample as a formula byproduct. Required if controlling batch step completion based on results.

- OPM Process Execution

    - Set up batches.

    - Verify sample byproduct on batches for sampling WIP steps.

- Oracle Receivables

- ■ Set up customers.

- ■ Set up ship to locations.

- Oracle Order Management

  - ■ Set up sales orders.

- Oracle Purchasing

  - ■ Set up suppliers.

  - ■ Set up test providers as suppliers, supplier sites, and purchase orders.

Set Up OPM Quality Management

Set up OPM Quality Management in the Quality Manager responsibility:

- Define Action codes. Optional.

- Define Grades. Optional.

- Define Hold Reasons. Optional.

- Define Test Classes. Optional.

- Define Test Units. Required.

- Define Sampling Plans. Optional.

- Configure Quality System Parameters for a particular organization or globally. Optional.

- Enable the Specification Version Control profile option. Optional.

- Define Test Methods. Optional.

- Define Tests. Required.

- With Oracle E-Records enabled:

  - ■ Set up specification approval.

  - ■ Set up specification validity rule approval for Inventory, WIP, Customer, and Supplier types.

  - ■ Set up sample creation approval.

  - ■ Set up results entry approval.

  - ■ Set up results evaluation approval.

  - ■ Set up sample disposition approval.

- Set up sample group approval based on the last sample and composite results or both.

- Set up appropriate workflow notifications. Refer to the "Understanding OPM Quality Management Workflows" topic in "Appendix D" for additional information.

Set Up and Create Specifications

Set up and create specifications in the Quality Manager responsibility:

- Create and approve new item specifications. Required.

- Create and approve new item specification validity rules. Required.

Set Up and Create Item Samples

Set up and create samples in the Quality Manager or Quality Technician responsibilities:

- Define samples manually or automatically. Required.

- Associate a sample to a specification version. Optional.

Enter Test Results

Enter results in the Quality Manager or Quality Technician responsibility:

- Enter results against a sample. Required.

- Use mass entry of results option. Optional.

- Associate results to new item and lot. Optional.

- Add tests to the result set. Optional.

Evaluate Test Results

Results are evaluated in the Quality Manager responsibility:

- Review results. Optional.

- Change the sample disposition. Required.

- Change the sample group disposition. Required.

- Change lot status and grade. Optional.

Composite Test Results

Composite results in the Quality Manager responsibility:

- Find the sample group to composite results. Optional.

- Create or view composite results. Optional.

- View the samples that comprise the composite result set. Optional.

- Add a test to all samples in the sample group. Optional.

- Save the composite results. Optional.

Compare Specifications

Specifications comparison for results is performed in the Quality Manager responsibility:

- Retrieve sample results and find a specification for comparison. Optional.

- Add tests from the comparison specification to the results set. Optional.

- Change the comparison specification to the current specification. Optional.

Set Up, Run, and Evaluate a Stability Study

Refer to the "Stability Testing" topic for a complete discussion of how to set up, run, and evaluate a stability study.

Understanding the Interface to Other Applications

Quality Management interfaces with OPM Process Execution, OPM Inventory Control, and Oracle Purchasing applications to allow the following optional functionality:

Batch Updated by Sample Quantity

When sampling is performed on work in process material, the batch must account for the sample quantity drawn from it. This quantity is either consumed for destructive testing purposes, or it is retained in inventory for possible future testing. The application lets you trace this material by yielding the sample as a byproduct of the batch. In cases where the sample quantity drawn is negligible, the WIP sample quantity can be configured as part of the overall process loss, and does need to be accounted for in the batch.

Batch Step Release Notifies Sampler

Configure the validity rule for a WIP specification to notify appropriate individuals to draw the number of samples required by the sampling plan. The release of a batch step sends a summary notification of all the samples required for the batch. By notifying samplers at the beginning of a batch step, they can prepare for the sample drawing process. This also serves to constrain batch step completion based on the results of quality testing.

Batch Step Completion Controlled by Quality Testing Requirements

The validity rule for a WIP specification prevents a batch step from completing once a sample is taken and quality testing results are pending. Once testing is complete, the application allows the batch step to complete if quality results and the sample disposition are acceptable. Completion of the batch step is not permitted if a sample is rejected, or if adjustments must be made.

Inventory Adjusted for Sample Quantity

The sample quantity can be deducted from the on-hand balance of an item when a sample is drawn from inventory. This inventory adjustment option is configurable at the specification validity rule and sample levels.

Lot Status and Grade Updates Based on a Final Results Set

The application updates lot status and grade based on the final results for the item lot sampled from inventory or production. It ensures that each required sample and

the sample group has a final disposition that is acceptable or unacceptable before updating the lot status and grade of the material sampled.

Receipts Sampled Prior to Being Inventoried

Receiving inspection can be enforced through a supplier specification validity rule for items that require quality inspection. Create a sample against both the receipt and the receipt line without the need to specify a lot number until the material is inventoried.

Changing the Status of Expired Lots

You can access the Inventory Quantities - Mass window to change the status of expired lots.

Refer to the *OPM Inventory Management User's Guide* for a complete discussion of the Inventory Quantities - Mass window.

Understanding Navigation

The following information is a summary of more detailed discussions found in the *Oracle Applications User's Guide*.

Navigating the Application

In addition to the standard menu and tool palette, a hierarchical navigator provides a display of the objects in a treelike framework known as a workbench.

Node and Leaf

The top-level nodes in the navigator are expanded to display groups of individual database objects. Lower level nodes, and the objects they contain, are indented to indicate that they belong to these higher level nodes. The terminal node in a branch is called a leaf node.

Menu and Tools

Menu and tools let you access all globally available functions.

Data Organizer

The Data Organizer groups objects on separate tabs. Each has a unique icon and its own hierarchy. The Quality Management application uses Data Organizer tabs to group specifications and samples. Refer to the "Identifying Nodes and Tabs on the Navigator" topic for specific nodes and tabs that are used in OPM Quality Management.

Summary Views

Summary views provide the highest level of business information and only display information. When you select an unexpanded, higher level node on the Data Organizer, the summary view can also list the contents of the container in a multirecord block.

Detail Views

Detail views let you display and edit information.

Refer to the *Oracle Applications User's Guide* for more information on navigation.

▶ **To navigate the application from the workbench:**

The following is a typical flow through the Quality Management application:

1.   Log on to your assigned responsibility.

2. Select **Quality Workbench** from the **Navigator** menu.

3. Click the tab that contains the object type of interest.

   ■ Click **Specifications**, and select the **Show Active Specs** indicator to display only approved specifications and specification validity rules. Clear the indicator to show all specifications and specification validity rules.

   ■ Click **Samples**, and select the **Show Active Samples** indicator to display only pending or in-progress samples. Clear the indicator to show all samples, regardless of their disposition.

4. Select the appropriate **View By** field. This field presents records sorted and grouped by the selection you make.

5. Use one of the following methods to find the appropriate folder:

   ■ Expand or collapse entries in the hierarchical Data Organizer.

   ■ Use the Find feature to retrieve the appropriate object from the results. Save the objects in a Personal or Public folder for future reference in the Data Organizer.

6. Use one of the following methods to show the detailed view of a selected object:

   ■ Select the object in the Summary View and click the desired button.

   ■ Double-click the object in the Data Organizer until you reach the terminal or leaf object.

7. Perform actions on selected objects that you have permission to edit.

8. Navigate from detailed view to other related windows.

Identifying Nodes and Tabs on the Navigator

The navigator has these two tabs:

■ Specifications

■ Samples

Selecting the Specifications Tab

The following lists some of the typical elements displayed on the navigator when you display active specifications on the Quality Workbench in the View By Specification mode. The numbers reference each of the nodes and tabs depicted in the graphic that follows this discussion. Click nodes that are marked with a plus (+) sign to expand them.

- 1 is the Show Active Specs indicator. When you select Show Active Specs, the navigator only displays those specifications that are active. Active specifications have a status of Approved for Laboratory Use or Approved for General Use.

- 2 is the View By box. You can display the list by Specifications, Customer, Supplier, Item, Owner Organization, or Status.

- 3 is the Specifications tab. Click it to display all available quality specifications.

- 4 is the Samples tab. Click it to display available quality samples.

- 5 is the specification name. Click it to display the Specification Summary window. This window is discussed in the "Displaying the Specifications Summary" topic.

- 6 is the specification version, item, and status. Click it to display the Specifications window. This window is discussed in the "Entering a Specification" topic.

- 7 is the Tests node. Select it to display the Specifications window. This window is discussed in the "Entering a Specification" topic. Expand this node to view the list of tests on the specification.

- 8 is the Customer Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. Information displayed includes the Customer, Order Number, Effective Start Date, and Specification Validity Rule Status. This window is discussed in the "Displaying the Specification Validity Rules Summary" topic.

- 9 is the Inventory Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. This expanded node displays the list of inventory specification validity rules. This window is discussed in the "Displaying the Specification Validity Rules Summary" topic.

- 10 is the list of each of the inventory specification validity rules. The information displayed after each validity rule is comma-delimited, and corresponds to each row of information displayed on the Validity Rules Summary for Item Spec window. For example, Warehouse, Location, Effective Start Date, and Spec Validity Rule Status.

- 11 is the Supplier Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. Information displayed includes the Supplier, Purchase Order, and Specification Validity Rule Status. This window is discussed in the "Displaying the Specification Validity Rules Summary" topic.

- 12 is the WIP Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. This window is discussed in the "Displaying the Specification Validity Rules Summary" topic.

- 13 is the list of each of the WIP validity rules. The information displayed after each validity rule is comma-delimited, and corresponds to each row of information displayed on the Validity Rules Summary for Item Spec window. This information displayed includes the Batch, Recipe, Recipe Version, and Specification Validity Rule Status.

- 14 is the next active version of the specification and its status.

- 15 is the next active specification.

The following graphic illustrates the previously described nodes and tabs in the navigator window when the Specifications tab is selected:
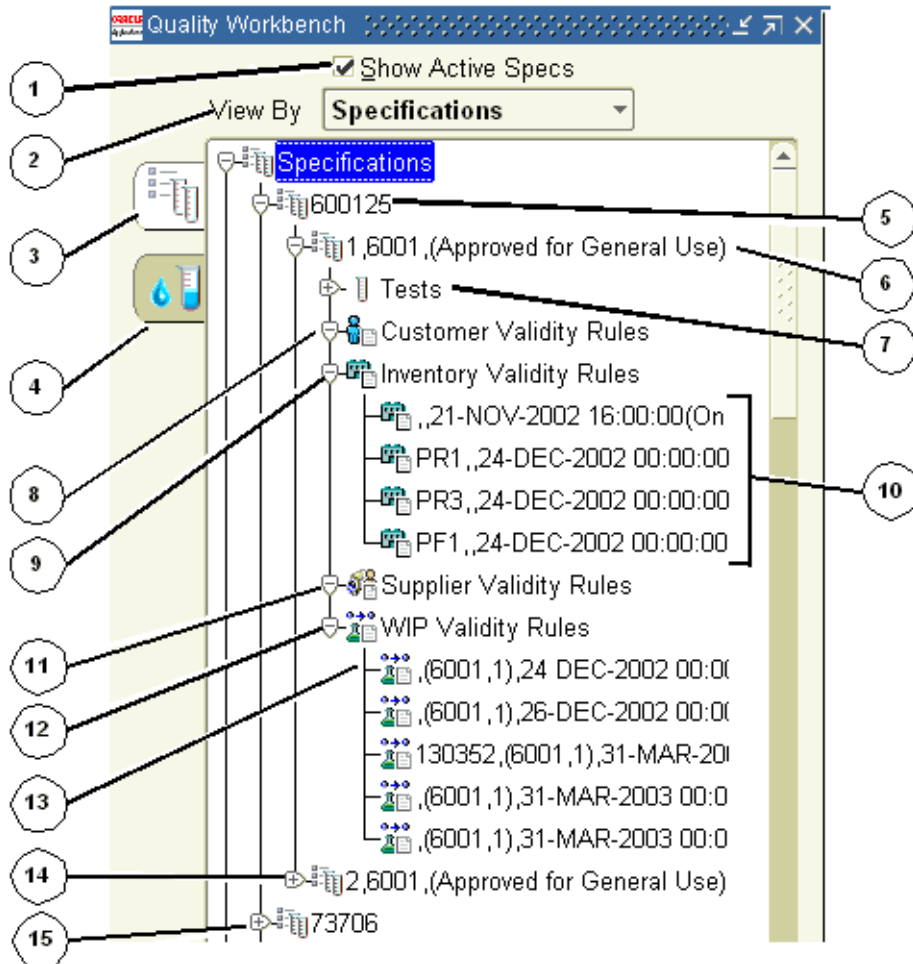
Selecting the Samples Tab

The following lists some of the typical elements displayed on the navigator when you display active samples on the Quality Workbench in the View By Organization mode. The numbers reference each of the nodes and tabs depicted in the graphic that follows this discussion.

- 1 is the Show Active Samples indicator. When you select Show Active Samples, the navigator only displays those samples that are active. Active samples have a disposition of Pending or In Progress.

- 2 is the View By box. You can display the list by Organization, Item, Disposition, Test, Test Class, Test Method, or Laboratory.

- 3 is the Specifications tab. Click it to display all available quality specifications.

- 4 is the Samples tab. Click it to display available quality samples.

- 5 is the Samples By Organization node. Expand it to display all the organizations that your responsibility can access.

- 6 is an Organization node. Expand it to display all samples in the organization. If you select Show Active Samples, then only the active samples are displayed.

- 7 is a Sample node. Select it to display the sample in the Item Samples window.

- 8 is the Results node. Select it to display the Results window for the sample. Expand it to display all tests assigned to the sample.

- 9 is the results set for the sample. Select it to display the Results window. You must be a valid user in the laboratory associated to a test in order to enter test results, or to add tests to a sample with a disposition of Pending or In Progress.

- 10 is the next Organization node.

Displaying the Samples Summary window: Display the Samples Summary window for an item by selecting View By Item, and then select the item. Refer to the "Displaying the Samples Summary from the Navigator" topic for a complete discussion of this feature.

Displaying the Item Samples window: Display the Item Samples window for each sample by expanding the node and selecting an individual sample.

The following graphic illustrates the previously described nodes and tabs in the Quality Management workbench window when the Samples tab is displayed:
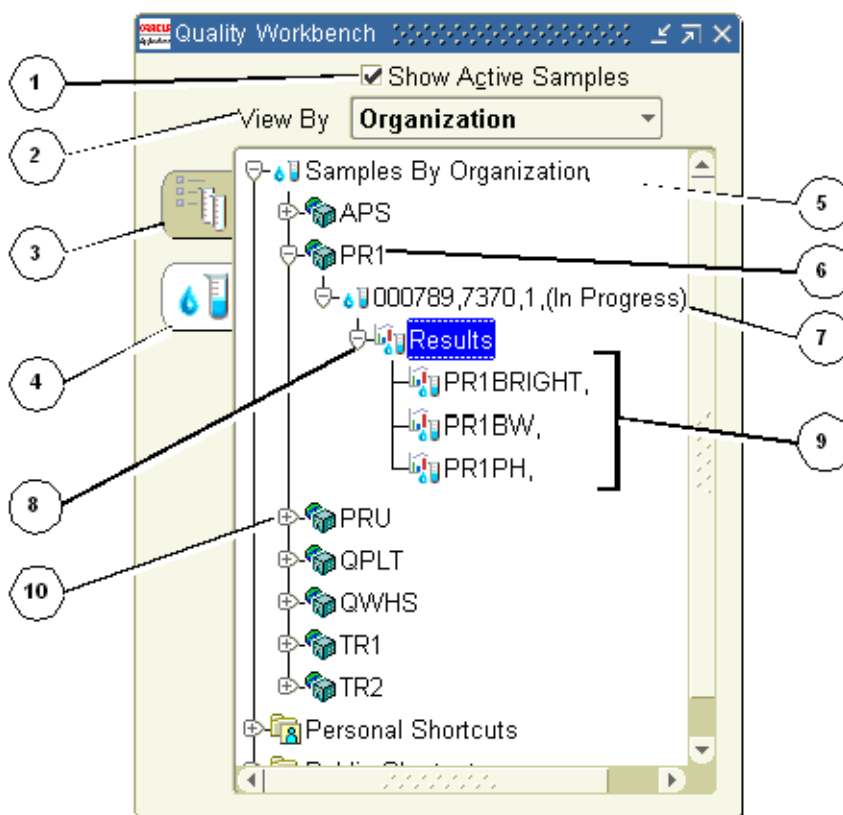
Standard Custom View

A standard custom view lets you query the database for:

- Specifications based on:
  - Specification, to view a list of specifications based on specification name displayed in ascending alphanumeric order
  - Customer, to view a list of specifications based on customer displayed in ascending alphanumeric order

- Supplier, to view a list of specifications based on supplier displayed in ascending alphanumeric order

- Item, to view a list of specifications based on item displayed in ascending alphanumeric order

- Owner Organization, to view a list of specifications based on owner organization displayed in ascending alphanumeric order

- Status, to view a list of specifications based on specification status

- Samples based on:

   - Item, to view a list of samples based on item displayed in ascending alphanumeric order

   - Disposition, to view a list of samples based on sample disposition displayed in ascending alphanumeric order

   - Test, to view a list of samples based on test displayed in ascending alphanumeric order

   - Test Class, to view a list of samples based on test class displayed in ascending alphanumeric order

   - Test Method, to view a list of samples based on test method displayed in ascending alphanumeric order

   - Laboratory, to view a list of samples based on laboratory displayed in ascending alphanumeric order

Once a view is generated, the criteria or output can be saved for future use in the Personal or Public Shortcuts. Click a node to display a summary window.

Using the Navigator Find Window

Use the Quality Workbench Find Samples or Find Specifications window to find one or a series of specifications and samples.

- To display the Find Samples window, select the Quality Workbench navigator, click the Samples tab, and choose Find from the View menu, or right-click then choose Find.

- To display the Find Specifications window, select the Quality Workbench navigator, click the Specifications tab, and choose Find from the View menu, or right-click then choose Find.

See: *Oracle Applications User's Guide*

▶ **To display the Find Samples window from the Quality Workbench:**

1. Navigate to the **Find Samples** window on the navigator.

2. Enter one or more search criteria on the **Standard**, **Source**, or **Advanced** tabs.

Standard

3. Enter **Sample** as the sample number which is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn.

4. Select sample **Disposition** as:

   - **Retain** when the sample is reserved and put in storage. Typically, results do not exist for a sample with this disposition.

   - **Pending** when the sample is saved, and results are expected, but not yet recorded.

   - **In Progress** when at least one result exists for the sample, but testing is not yet complete.

   - **Complete** when testing of all required tests and all additional tests is complete.

   - **Accept** when sample testing is complete, and results are in-specification.

   - **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.

- **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.

- **Cancel** when the sample is canceled.

5. Enter **Item** as the item sampled.

6. Select the sample **Source** as:

   - Customer

   - Inventory

   - Supplier

   - Stability Study

   - WIP

   When Source is selected, you can also enter these additional search criteria:

   - Customer Name

   - Operating Unit

   - Ship To

   - Order

   - Line

7. Enter **Lot** as the item lot number.

8. Enter **Sublot** as the item sublot number, if the item is sublot controlled.

9. Enter **Laboratory** as the laboratory where the sample is sent for analysis.

10. Enter **Date Drawn** as the date the sample was taken. This must be entered in the format DD-MMM-YYYY.

11. Select **Priority** as:

    - **Normal** to indicate that the sample has the usual processing requirements.

    - **Low** to indicate that the sample has minimal urgency for processing.

    - **High** to indicate that the sample has urgent processing requirements.

12. Enter **Spec** as the specification name and version associated to the sample entered.

Source

13. Enter any of these additional criteria when Source is selected as one of the search criteria:

   - Customer Name

   - Operating Unit

   - Ship To

   - Order

   - Line

Advanced

14. In an advanced search of samples, select **Item** as:

   - Sample

   - Date Drawn

   - Disposition

   - Organization

   - Laboratory

   This selection functions with the **Condition** field and the **Value** field to define a custom search. You can enter any number of individual criteria to narrow your search.

15. Select **Condition** as:

   - **Equals** to find targets equal to the specified Value entered.

   - **Greater than** to find targets greater than the specified Value entered.

   - **Less than** to find targets less than the specified Value entered.

   - **Greater than or equal to** to find targets greater than or equal to the specified Value entered.

   - **Less than or equal to** find targets less than or equal to the specified Value entered.

   - **Like** to find targets similar to the information specified using the wildcard %.

For example, if you specify the Item as Sample, select the Condition Like, and enter FORM%, then you find each target product that contains entries with the letters FORM.

16. Enter the **Value** for the appropriate condition selected.

17. Click **Find**. The window displays the results of the search.

18. Select the drill-down indicator next to the row you want to display the details of the search.

▶ **To display the Find Specifications window from the Quality Workbench:**

1. Navigate to the **Find Specifications** window on the navigator.

2. Enter one or more search criteria on the Standard, Validity Rule Type, or Advanced tabs.

Standard

3. Enter **Spec** as the name for the specification.

4. Enter **Version** as the version for the specification.

5. Select **Specification Status** for the specification you want to find as:

- **New** to indicate that the specification is new.

- **Request Approval for Laboratory Use** to indicate that an approval is requested for using the laboratory specification.

- **Revise for Laboratory Use** to indicate that a revision is requested for using the laboratory specification.

- **Approved for Laboratory Use** to indicate that the specification is approved for laboratory use.

- **Request Approval for General Use** to indicate that a request was made to approve the specification for general use.

- **Revise for General Use** to indicate that a request was made to revise the specification for general use.

- **Approved for General Use** to indicate that the specification is approved for general use.

- **On Hold** to indicate that the specification is on hold.

- **Frozen** to indicate the specification is frozen.

- **Obsolete/Archived** to indicate that the specification is no longer approved for use and is obsoleted, archived, or both.

6. Enter **Item** as the item code for the material being specified as it is listed on the Item Master.

7. Enter **Grade** as the grade for the item lot.

8. Enter **Owner Organization** as the owner organization of the specification.

9. Enter **Owner** as the owner of the specification.

10. Enter **Validity Rule Type** as:

   - Customer

   - Inventory

   - Supplier

   - Stability Study

   - WIP

Validity Rule Type

11. Enter any of these additional criteria when a Validity Rule Type is selected as one of the search criteria:

   - Organization

   - Status

   - Customer Name

   - Operating Unit

   - Ship To

   - Order

   - Line

Advanced

12. In an advanced search of specifications, select **Item** as:

   - Specification

   - Item

   - Status

- Owner Organization

- Owner

This selection functions with the **Condition** field and the **Value** field to define a custom search. You can enter any number of individual criteria to narrow your search.

13. Select **Condition** as:

- **Equals** to find targets equal to the specified Value entered.

- **Greater than** to find targets greater than the specified Value entered.

- **Less than** to find targets less than the specified Value entered.

- **Greater than or equal to** to find targets greater than or equal to the specified Value entered.

- **Less than or equal to** to find targets less than or equal to the specified Value entered.

- **Like** to find targets similar to the information specified using the wildcard %.

  For example, if you specify the Item as Sample, select the Condition Like, and enter FORM%, then you find each target product that contains entries with the letters FORM.

14. Enter the **Value** for the appropriate condition selected.

15. Click **Find**. The window displays the results of the search.

16. Select the drill-down indicator next to the row you want to display the details of the search.

2

Setting Up

This topic explains how to set up quality responsibilities, action codes, quality grades, quality hold reasons, test classes, test units, sampling plans, and quality system parameters.

The following topics are covered:

- Setting Up Quality Responsibilities
- Setting Up Action Codes
- Finding Action Codes
- Setting Up Grades
- Finding Grades
- Setting Up Hold Reasons
- Finding Hold Reasons
- Setting Up Test Classes
- Finding Test Classes
- Setting Up Test Groups
- Setting Up Test Units
- Finding Test Units
- Setting Up Sampling Plans
- Finding Sampling Plans
- Setting Up Quality System Parameters
- Delaying the Entry of Lot Numbers

Setting Up Quality Responsibilities

The application offers the following responsibilities:

- Quality Manager with unlimited access to the entire application

- Quality Technician with privileges to view specifications, access the Item Samples window, the Sample Groups window, the Entry, Internal, and External tabs on the Results window, and all reports and inquiries

Set up these responsibilities using the procedure described in "Creating Responsibilities" found in the *Oracle Process Manufacturing Implementation Guide.*

Setting Up System Administration

Following is the setup for System Administration:

Profile Options

Set up the following profile options in the System Administration responsibility:

- GMD: Exact Specification Match

- GMD: Include Optional Tests in Sample Disposition

- GMD: Specification Version Control

Stability Studies Document Type

Set up the STBL document type for stability studies.

See: *Oracle Process Manufacturing Implementation Guide*

Samples Document Type

Set up the SMPL document type for samples.

See: *Oracle Process Manufacturing Implementation Guide*

Setting Up OPM Inventory Control

If you plan to set up inventory quality attributes, then set up the following in the OPM Inventory Control application:

- Items and item attributes for every raw material, intermediate, and end item

- Unit of measure conversions for each item, between the primary inventory unit of measure and the unit of measure you use, if these are different

- Status and Grade control on the Item Master

- Expiration date, retest date, and retest interval

See: *Oracle Process Manufacturing Inventory Management User's Guide*

Setting Up Quality Attributes for Items   Once you enter actions, grades, and hold reason codes, use them to set default attributes for inventory items. Quality attributes include grade and lot status control.

Setting Up Lot Status   With lot status, OPM lets you identify the use of lot-controlled material in production, order processing, or shipping. Once it is determined that a sample does not meet quality specifications or has failed quality tests, you change the status of the sample lot for certain purposes in production or shipping.

The first step is to define each Lot Status and its associated permissions. After you perform quality tests, change the status of lots that do not meet quality specifications in order to prevent them from being sold or used for production.

Refer to "Assigning Lot Status" in *Oracle Process Manufacturing Inventory Management User's Guide* for a complete description of setting up lot status.

Setting Up Security Profiles

Depending on your security profile, some of the information on certain windows may not be available to you. Contact your Product Development Security Manager or Product Development Security Profile Manager if you require access to this information.

Setting Up Reason Code Access

When you select an inventory transaction reason code on the Quality System Parameters window or the Quality Change Disposition dialog box, you can only display those reason codes that you were granted permission to access. The reason code usage on these windows is secured using OPM standard reason code security. In order to see a reason code on Quality Systems Parameters window, your responsibility must have security enabled for STSI, GRDI, and ADJI document types. In order to view a reason code on the Change Disposition window, your responsibility must have security enabled for STSI and GRDI document types.

Setting Up Specification Matching for Use In Oracle Order Management

Order Management users define specifications, create samples, and record results for customers, specific customer ship-to locations, customer orders, or order lines. Defining a customer order specification requires entry of the operating unit and

order information. Customer quality data and Query Find functions display optional fields for customer ship-to location, operating unit, order number, order type, and order line number.

In order for specification matching to find results, a sample and set of results must exist for the order line item and at least one lot must be displayed on the Move Order Transaction window or the OPM Inventory Transact Process Move Orders window using the Manual Allocate option.

The Customer Test Results report displays customer number, operating unit, ship-to, order number, type, and line when this information is entered.

Setting Up Customer Specifications for Use in OPM Order Fulfillment

OPM Order Fulfillment users can continue to define specifications, create samples, and record results for customers or customer ship-to locations, and create a customer specification for an item that covers:

■ any order and ship-to location, by entering the customer number only.

■ a specific ship-to location and any order, by entering the customer number, operating unit, and ship-to location.

Using the Product Analysis Workbook to View Matching Specifications

You can view specifications that match existing inventory in the Product Analysis Workbook included in the Oracle Supply Chain Intelligence application.

The workbook shows the results of quality tests for an item by warehouse, location, lot, sublot, and test data type. Specification minimum, maximum, and target specifications are displayed. Numeric and text results are displayed.

Refer to "OPM Product Analysis Workbook" in the *Oracle Business Intelligence System Implementation Guide* for more information. Online help is available for users.

Setting Up Quality Tests

Set up test methods and tests using information provided in "Tests."

Setting Up Action Codes

The Actions window lets you set up action codes, view all existing action codes, and define an interval to implement the action. Action codes represent user actions to perform when quality testing yields out-of-specification exception cases, such as out-of-specification conditions, or experimental error results. You can associate an action to a result disposition when you evaluate the result. Action codes are assigned for experimental error at the test and specification levels. They are also assigned in individual specification tests for out-of-specification results. Action codes are displayed for items on appropriate quality reports.

Prerequisites

❑ Analyze all exception cases, out-of-specification conditions, and experimental error results.

❑ Develop a list of actions that need to be taken for appropriate response to quality testing results.

❑ Develop a list of action codes and descriptions.

▶ **To set up action codes:**

1. Navigate to the **Actions** window.

2. Enter a code to identify the **Action**. For example, enter REJ for reject. Required.

3. Enter a **Description** of the action to be taken. For example, this is the action to take when an item expires, fails a quality test, or falls within the experimental error results region. Required.

4. Enter the **Interval** for the action as one of the following:

   ▪ The number of days between the expiration date and the date that the action must be taken.

   ▪ The number of days after the result date of the failed test that the action must be taken.

   Required.

5. Save the window.

Finding Action Codes

The Find Actions dialog box lets you search for actions by action code, description, or marked for deletion.

Prerequisites

❑ Enter an action code.

▶ **To find an action code:**

1. Navigate to the Find Actions dialog box.

2. Enter any of the following to narrow your search:

   ■ **Action** code

   ■ **Description** of the action code

   ■ **Interval** as the number of days between the expiration date and the date that the action must be taken, or the number of days after the failed quality test date that the action must be taken

3. Select **Marked for Deletion** as:

   ■ **Yes** to find action codes that are marked for deletion.

   ■ **No** to find action codes that are not marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a action codes is marked for deletion.

4. Click **Find**. The **Actions** window displays the results of the search.

▶ **To create a new action code from the Find Actions dialog box:**

1. Click **New**. The **Actions** window displays.

2. Create a new action as described in "Setting Up Action Codes."

Setting Up Grades

The Grades window lets you set up grades and view all existing grades. Grade is a characteristic of an item lot and is usually a combination of inventory and quality attributes. Items must be lot and grade controlled in order to enter grades for them. The process of assigning a grade to a lot provides a standardized means of describing its marketability. Grades are often based on criteria such as color, physical size, weight, or appearance. If a lot grade changes on a location controlled item, then you need to assign the item to a new location manually.

Prerequisites

❏ Analyze quality grades to identify specific rating characteristics for lots.

❏ Develop a list of quality grades and descriptions.

▶ **To set up grades:**

1. Navigate to the **Grades** window.

2. Enter a code to identify the **Grade**. For example, A for grade A, or B for grade B. Required.

3. Enter a **Description** for the grade. For example, enter Grade A. Required.

4. Save the window.

Finding Grades

The Find Grades dialog box lets you search for grades by grade code, description, or marked for deletion.

Prerequisites

❏ Enter a grade.

▶ **To find a grade:**

1. Navigate to the Find Grades dialog box.

2. Enter any of the following to narrow your search:

   ■ **Grade** code

   ■ **Description** of the grade

3. Select **Marked for Deletion** as:

   ■ **Yes** to find grades that are marked for deletion.

   ■ **No** to find grades that are marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a grade is marked for deletion.

4. Click **Find**. The **Grades** window displays the results of the search.

▶ **To create a new grade from the Find Grades dialog box:**

1. Click **New**. The **Grades** window displays.

2. Create a new grade as described in "Setting Up Grades."

Setting Up Hold Reasons

The Hold Reasons window lets you set up hold reasons and view all existing hold reasons. Hold reason codes are used when you place an item or lot on hold if it expires or if it fails a quality test. The hold reason description is displayed for the item or lot to indicate that it must not be sold or used for production.

Prerequisites

❏ Analyze the reasons to place an item or lot on hold.

❏ Develop a list of hold reason codes and descriptions.

▌ **To set up hold reason codes:**

1. Navigate to the **Hold Reasons** window.

2. Enter a code to identify the quality **Hold Reason**. For example, enter BLW for Below Grade. Required.

3. Enter a **Description** for the hold reason code. Required.

4. Save the window.

Finding Hold Reasons

The Find Hold Reasons dialog box lets you search for hold reasons by hold reason code, description, or marked for deletion.

Prerequisites

❏ Enter a hold reason.

▶ **To find a hold reason:**

1. Navigate to the Find Hold Reasons dialog box.

2. Enter any of the following to narrow your search:

   ■ **Hold Reason** code

   ■ **Description** of the hold reason

3. Select **Marked for Deletion** as:

   ■ **Yes** to find hold reasons that are marked for deletion.

   ■ **No** to find hold reasons that are not marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a hold reason is marked for deletion.

4. Click **Find**. The **Hold Reasons** window displays the results of the search.

▶ **To create a new hold reason from the Find Hold Reasons dialog box:**

1. Click **New**. The **Hold Reasons** window displays.

2. Create a new hold reason as described in "Setting Up Hold Reasons."

Setting Up Test Classes

The Test Classes window lets you group specific tests into meaningful sets for purposes of evaluating them or managing them in workflows, or managing results. You set up basic classes for each test data type.

Here are some examples of test classes:

- CHEMICAL, a test class containing test measurements of pH, sugar content, or water content

- PROTEIN, a test class containing test measurements of total protein, albumin, and globulins.

- MICROBIO, a test class containing test measurements of bacterial, fungal, or viral components

- ENTERICS, a test class containing tests for enteropathogens

- PHYSICAL, a test class containing test measurements of specific gravity, hardness, or visual opacity

- DISSOLVE, a test class containing measurements for various materials to dissolve

Prerequisites

❏ Analyze all tests performed and group them into meaningful classes.

❏ Develop a list of test classes and descriptions.

▶ To set up test classes:

1. Navigate to the **Test Classes** window.

2. Enter a code for the test **Class**. Required.

3. Enter a **Description** of the test class. Required.

4. Save the window.

Finding Test Classes

The Find Test Classes dialog box lets you search for test classes by class, description, or marked for deletion.

Prerequisites

❏ Enter a test class.

▶ **To find a test class:**

1. Navigate to the Find Test Classes dialog box.

2. Enter any of the following to narrow your search:

   ■ **Class** code

   ■ **Description** of the class

3. Select **Marked for Deletion** as:

   ■ **Yes** to find test classes that are marked for deletion.

   ■ **No** to find test classes that are not marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a test class is marked for deletion.

4. Click **Find**. The **Test Classes** window displays the results of the search.

▶ **To create a new test class from the Find Test Classes dialog box:**

1. Click **New**. The **Test Classes** window displays.

2. Create a new test class as described in "Setting Up Test Classes."

Setting Up Test Groups

A test group organizes tests into a meaningful set for collaborative analysis. Test grouping facilitates the rapid creation of specifications and addition of tests during sample analysis. After tests are grouped and sequenced into a test class, you can add a test group to a specification or results record using the Test Group window. You can add individual tests or all tests in the group before the specification is approved or results have a final sample disposition. A test can belong to only one test class or test group.

Prerequisites

❏ Perform all required setup procedures.

❏ Enter tests.

❏ Optionally, enter specifications for test group assignment.

▶ **To define a test group:**

1. Navigate to the **Test Classes** window.

2. Enter a **Test Class**.

3. Enter a **Description** for the test class.

4. Select the **Group Enabled** indicator to treat the test class as a test group.

▶ **To sequence tests in a test group:**

1. Navigate to the **Tests** window.

2. Enter a test as described in "Entering Tests."

3. Select the desired test class with a previously defined **Group Enabled** indicator.

4. Enter **Ordering** as the sequence number for the test to appear in the list of tests in the test group. Tests are listed in ascending order. If you plan to add tests before 10, then sequence the list beginning at 10.

Setting Up Test Units

The Test Units window lets you set up quality test units and view all existing quality test units. You can set up standard or custom test units such as %T for percent optical transmittance, or A for spectral absorbance. Test units are used for recording results.

If you want to convert test units, then set up an expression test for the conversion. For example, to convert a Celsius temperature of 100 degrees into degrees Fahrenheit, first multiply the Celsius temperature reading by nine-fifths, or the decimal 1.8, to get 180. Then, add 32 to 180 to get 212 degrees Fahrenheit. The expression is:

"CELSIUS" test result

"FAHRENHEIT" expression is: (1.8*"CELSIUS")+32

Prerequisites

❏   Analyze all tests performed and identify their reporting units.

❏   Develop a list of units and a description for each one.

To set up test units:

1.   Navigate to the **Test Units** window.

2.   Enter a code for the test **Unit**. Required.

3.   Enter a **Description** of the test unit. Required.

4.   Save the window.

Finding Test Units

The Find Test Units dialog box lets you search for test units by unit, description, or marked for deletion.

Prerequisites

❑ Enter a test unit.

▶ **To find a test unit:**

1. Navigate to the Find Test Units dialog box.

2. Enter any of the following to narrow your search:

   ■ **Unit** code

   ■ **Description** of the unit

3. Select **Marked for Deletion** as:

   ■ **Yes** to find test units that are marked for deletion.

   ■ **No** to find test units that are not marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a test unit is marked for deletion.

4. Click **Find**. The **Test Units** window displays the results of the search.

▶ **To create a new test unit from the Find Test Units dialog box:**

1. Click **New**. The **Test Units** window displays.

2. Create a new test unit as described in "Setting Up Test Units."

Setting Up Sampling Plans

The Sampling Plan window lets you define how much and how often to sample. By entering the number, size, and frequency of samples to take, the sampling plan lets you prescribe sample groups. Used in conjunction with the Sample Creation Notification workflow, individuals responsible for sampling are notified when and where to sample materials that require quality testing. Sampling plans are an optional setup. They are associated to a specification validity rule on the Item Specification Validity Rule window.

Understanding Count, Frequency Type, and Frequency Period

The Count, Frequency Type, and Frequency Period, or Per fields, work together to define the number of repetitions for sampling.

For example, to indicate ten samples that each contain 5 milliliters every hour, you would enter:

Count = 10

Quantity = 5 mL

Per = 1 hour

The following are examples of each sampling plan type:

Time-based Sampling Rate   Time-based sampling is entered in hours, minutes, days, weeks, months, or years. To take one sample every five minutes, enter:

- Count = 1
- Per = 5 Minutes

Quantity-based Sampling Rate   Quantity-based sampling is entered in a valid inventory UOM. To take one sample every 1,000 kilograms produced, enter:

- Count = 1
- Per = 1000 kg

Fixed Number of Samples to Take   Fixed number sampling is entered for a batch, batch step, or receipt. To take three samples per receipt, enter:

- Count = 3
- Per = 1 Receipt

To take two samples of 10.0 grams for every five batches produced, the sampling plan is entered as:

- Count = 2
- Quantity = 10.000000000
- UOM = GRAM
- Frequency Type = Fixed Number
- Per = 5 Batch

Percentage of Samples to Take   Percentage-based sampling frequency applies to the amount of product produced, or the amount of item delivered. To sample 20% of a delivery, enter:

- Count = 1
- Per = 20 Percent Amount of Product Produced

Sampling Plan Definition is Optional

Defining a sampling plan is optional, however, if you want to set up a sampling plan, then set it up prior to creating specifications and samples in which you intend to use it. A sampling plan becomes effective for an item and optionally, for a grade when it is associated with a specification validity rule. The Specification Validity Rule window displays all applicable details of a sampling plan if one is selected for use. You can have required, reserved, or archived samples associated with a sampling plan. As long as one of these sample types is specified, the sampling plan is valid.

You can use flexfields and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites
❑   Set up inventory item units of measure for the material requiring sampling inspection.

▶ **To set up a sampling plan:**

1.   Navigate to the **Sampling Plan** window.

2.   Enter the **Name** of the sampling plan. Required.

3.   Enter a **Description** for the sampling plan. Required.

Required Samples

4. Enter the **Count** as the number of samples to take at each instance of the frequency entered. You do not have to enter this field. You can specify the sampling plan in terms of reserved or archived samples to be taken.

5. Enter **Quantity** and **UOM** as the sample size, or the amount of material needed to take a sample from the material requiring inspection. This is expressed in the primary inventory unit of measure. Required.

6. Enter the **Frequency Type** as previously described:

   ■ **Time Based** to indicate time-based sampling in hours, minutes, days, weeks, months, or years.

   ■ **Quantity Based** to indicate quantity-based sampling in a valid inventory UOM. Enter the sample UOM.

   ■ **Fixed Number** to indicate fixed number sampling for a batch, batch step, or receipt.

   ■ **Percent** to indicate sampling by percentage of product produced, or percentage of item delivered.

7. Enter **Per** as the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

8. Depending on the entry you make in the **Frequency Type** field, do one of the following:

   ■ For time based sampling, select **Hours**, **Minutes**, **Days**, **Weeks**, **Months**, or **Years**.

   ■ For quantity based sampling, enter a valid inventory **UOM**.

   ■ For fixed number sampling, select **Batch**, **Batch Step**, or **Receipt**.

   ■ For percent sampling, select **Percent**.

Reserved Samples

9. Enter **Count** as the number of samples to take at each instance of the frequency entered.

10. Enter the **Quantity** of sample for the reserved sample.

11. **UOM** displays the unit of measure for the sample size. This defaults from the default UOM for required samples.

Archived Samples

12. Enter **Count** as the number of samples to take at each instance of the frequency entered.

13. Enter the **Quantity** of sample for the archived sample.

14. **UOM** displays the unit of measure for the sample size. This defaults from the default UOM for required samples.

15. Save the window.

Finding Sampling Plans

The Find Sampling Plans dialog box lets you search for sampling plans by name, frequency type, or marked for deletion.

Prerequisites

❏   Enter a sampling plan.

▶ To find a sampling plan:

1.   Navigate to the Find Sampling Plans dialog box.

2.   Enter any of the following to narrow your search:

- **Name** of the sampling plan

- **Frequency Type** of the sampling plan as Time-Based, Quantity-Based, Fixed, or Percent

3.   Select **Marked for Deletion** as:

- **Yes** to find sampling plans that are marked for deletion.

- **No** to find sampling plans that are not marked for deletion.

- Leave this field blank if you do not want to limit your search based on whether a sampling plan is marked for deletion.

4.   Click **Find**. The **Sampling Plan** window displays the results of the search.

▶ To create a new sampling plan from the Find Sampling Plans dialog box:

1.   Click **New**. The **Sampling Plan** window displays.

2.   Create a new sampling plan as described in "Setting Up Sampling Plans."

Setting Up Quality System Parameters

The Quality System Parameters window lets you set up system defaults to enforce quality management business rules for a specific or global organization. This window serves as a default template that is typically defined at the time of implementation by a system administrator and may be updated later. The following lists the windows and options that are configurable on other OPM Quality Management windows:

- Specification Validity Rule window

    - Control Batch Step Status

    - Control Lot Attributes

    - In-Specification Status

    - Out-of-Specification Status

    - Update Inventory Quantity

- Item Samples window

    - Lot Optional

    - Update Inventory Quantity

When you select an inventory transaction reason code on this window, you can only display those reason codes that you were granted permission to access. In order to see a reason code on this window, your responsibility must have security enabled for STSI, GRDI, and ADJI document types.

Prerequisites

❏ Set up organizations.

❏ Set up quality action codes to assign them to retest and resample actions.

❏ Set up reason codes for the inventory transaction for samples.

❏ Set up lot statuses for in-specification and out-of-specification statuses.

▌ **To set up the quality system parameters:**

1. Navigate to the **Quality System Parameters** window.

2. Enter the desired default **Organization**. If you leave this field blank, then you define the defaults for the global organization.

3. Enter **Control Batch Step Status** as:

■ **No** to indicate that you do not want the test results to control the completion of batch steps.

■ **Yes** to indicate that you want the test results to control the completion of batch steps. The batch step quality status of whether sampling and results are required is reflected at the batch step level. Only in-specification results let a batch step to be completed.

Lot Attributes

4. Enter the **Control Lot Attributes** as follows:

■ Select **No** for **Control Lot Attributes** if you do not want the application to update lot attributes based on the test results of one or more samples in a sample group.

■ Select **Yes** for **Control Lot Attributes** if you want the application to update lot attributes based on the test result of one or more samples in a sample group.

■ Enter the default **In-Spec Status** to update the lot status when in-specification results are entered, the sample group disposition is Accept, and the Control Lot Attributes indicator is set to Yes.

■ Enter the default **Out-of-Spec Status** to update the lot status when out-of-specification results are entered, the sample group disposition is Reject, and the Control Lot Attributes indicator is set to Yes.

Samples

5. Select **Update Inventory Quantity** as:

■ **No** if you do not want to enforce an inventory transaction for drawing the sample quantity.

■ **Yes** if you do want to enforce an inventory transaction for drawing the sample quantity.

6. Enter an appropriate **Inventory Transaction Reason** code. This previously defined reason code is used for the sample inventory transaction when a sample record is created and the Update Inventory Quantity indicator is set to Yes.

7. Select **Lot Optional** as:

■ **No** if you do not want to require a lot to be entered on a sample for a lot-controlled item.

- **Yes** if you do want to require a lot to be entered on sample of a lot-controlled item. Defaults to Yes.

8. Select **Manual Spec Selection** as:

   - **Yes** to override the default specification and select an alternate on the Samples window.

   - **No** to select the default specification only. When you select No, you cannot change the default specification.

9. Select **Create Samples Automatically** as:

   - **Yes** to enable automatic sample creation on the Specification Validity Rules window for an Inventory, WIP, or Supplier sample type.

   - **No** to disable automatic sample creation.

10. Select **Delayed Lot Entry** as:

    - **Yes** to permit the assignment of a lot number after sample creation for a supplier, inventory, or WIP specification validity rule. The sample must have a final disposition of Accept, Accept with Variance, or Reject.

    - **No** to permit the assignment of a lot number at sample creation only for a supplier, inventory, or WIP specification validity rule.

    Refer to "Delaying the Entry of Lot Numbers" for additional information.

11. Enter a **Retest Action** for samples. This field associates a previously defined quality action code for the purposes of retesting and optionally for invoking the Testing Notification workflow. This retest action can be assigned as an out-of-specification action, experimental error action, or result evaluation action.

12. Enter a **Resample Action** for samples. This field associates a previously defined quality action code for the purposes of resampling and optionally for invoking the Sample Creation Notification workflow. This resample action can be assigned as an out-of-specification action, experimental error action, or result evaluation action.

13. Select one of the following for **Applications Programming Interface Decimal Precision**:

    - **Round** to round decimals for the data imported by the Applications Programming Interface.

    - **Truncate** to truncate decimals for the data imported by the Applications Programming Interface.

If a test or specification is defined with a decimal precision that is less than the default of nine places, and the numeric results are imported using an Applications Program Interface (API), then the numeric results are rounded as indicated by this entry.

14. Save the window.

Delaying the Entry of Lot Numbers

When you select the Delayed Lot Entry indicator on the Quality System Parameters window, it is displayed on the Validity Rules for Item Specifications window. If a WIP, Inventory, or Supplier sample is created with the Delayed Lot Entry indicator enabled, then you can create a sample without entering a lot number. Enter the lot number when you enter a final disposition for the sample group.

Setting Up on the Quality System Parameters Window

The Delayed Lot Entry indicator is available when the Lot Optional On Sample field is set to Yes. The field defaults to null.

Select Delayed Lot Entry as:

- **Yes** to permit the assignment of a lot number after sample creation for a supplier, inventory, or WIP specification validity rule. The sample must have a final disposition of Accept, Accept with Variance, or Reject.

- **No** to permit the assignment of a lot number at sample creation only for a supplier, inventory, or WIP specification validity rule.

Implementation Considerations

Following is a summary of implementation considerations:

- If you enter a lot when you create the sample record, then delayed lot entry is not permitted. The Lot Optional on Sample indicator must be selected on a valid item specification validity rule. Do not select the Update Inventory indicator.

- Enter a lot number for all the samples in a sample group, because all samples in the sample group are affected. If the lot number changes across samples, then create separate sample groups that correspond to each lot.

- The Lot field is not available on the Item Samples window after you save the sample. Enter the lot number when you change the sample group to a final disposition of Accept, Accept with Variance, or Reject. Changing to a final sample group disposition controls several updates to inventory lot attributes. Receiving or in-process inspection results also reflect the quality characteristics of the material inventoried. Therefore, you can enter the lot number simultaneously with updates to its lot attributes such as lot status, grade, hold date, and reason code and the recommended lot-specific unit of measure conversions.

- The lot entered must belong to the receipt or batch identified on the supplier or WIP sample record.

- The specification matching logic associated to the Get Spec button is based on the sample source information entered when you create a new sample. If a lot is not entered on a new sample record, then it is not included as specification matching criteria.

Process Flow for Delayed Lot Entry

1. Create a sample without entering a lot number. The Lot field is protected after you save the sample.

2. Enter and evaluate results.

3. Assign a final sample group disposition and enter the following:

   - Lot number, to update all sample records in the sample group

   - Lot update information, including requirements for status, grade, hold date, and the UOM conversion recommendation

Lot number and appropriate lot update information displays for all the samples in the sample group. If the sample group has a single sample, then update the sample to a final disposition to enter the lot number.

Quality Change Disposition Window

Lot and Sublot are required fields if:

- You access this window from the Composite Results window for a sample group or from the Item Samples window if the sample is the only sample in the sample group.

- The Source field is Supplier, Inventory, or WIP for the sample or sample group.

- The item is lot controlled. You can enter sublot if the item is sublot controlled and you entered a lot.

- There is no lot specified on the sample or sample group, and Lot Optional on Sample is selected.

- Delayed Lot Entry is selected for the supplier, inventory or WIP specification validity rule associated to the sample.

- The current disposition is changed to a final disposition of Accept, Accept with Variance, or Reject. An error message displays if the lot is entered and the sample disposition is not updated.

3

Tests

This topic explains the fundamentals of quality tests. It provides the processes to enter or find test methods, gives a concise explanation of test data types, and explains how to enter tests, customized customer display information, and experimental error.

The following topics are covered:

- Requirements
- Solutions
- Entering Test Methods
- Finding Test Methods
- Understanding Tests
- Entering Tests
- Entering Customer Display Information
- Entering Experimental Error
- Finding Tests

Requirements

Following are some requirements that customers have for tests in Quality Management. The answers are explained in detail in the "Solutions" topic.

Can a separate test be entered that calculates one or more tests performed on a sample?

Yes. Use the expression test data type to build a mathematical expression to reference the results of other numeric-based tests.

Can the actual method used to generate a test result be identified?

Yes. Test Methods let you describe how a test is performed, and help distinguish tests by their methods of execution.

Can test resources be monitored?

Yes. Associate instruments to test methods to identify testing resources that you can monitor in your planning application.

Is there flexibility in displaying decimals on-screen and in reports?

Yes. For numeric-based tests, the application saves and reports nine decimal places for each test result, specification target, minimum, maximum, and experimental error value. You can specify decimal precision for displaying and saving results in the application by using the Display Decimal Precision field. You can also use the Report Decimal Precision field to specify the desired decimal precision for reporting results on a Certificate of Analysis.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the quality process. The following represent some of the key performance solutions for tests.

Build Mathematical Expressions in a Test Format   Enter arithmetic operators such as +, -, *, /, (), exponents, constants, or any valid SQL operator to build an Expression test data type. Calculate the results of Expression test after you enter results for all tests referenced in it. In case of replicated tests, the latest result of the referenced test is used. An Expression test can be added to a result set on an as needed if all of the referenced tests already exist in the result set. Decimal precision and experimental error regions and actions can be defined for an Expression test.

Identify Test Methods Used to Generate Results   Enter test methods to describe how a test is performed. A test method can refer to a test protocol or standard operating procedure. The test method is associated to the test during test definition. It facilitates the execution of quality tests by providing requirements for the quantity of test material, specific instrumentation to be used for testing, number of replicates required, and the duration of the test.

Develop Quality Procedures for Laboratory Instrumentation   The quality laboratory is a miniature production plant. It contains resources or equipment that must be scheduled, calibrated, and evaluated for cost. You can now define an instrument for quality testing purposes. You can associate the instrument to a test method in order to support quality laboratory management and scheduling. You can perform a test in various ways using different laboratory equipment. OPM supports unique combinations of instrument and test method for a particular test. Define laboratory instruments used for quality testing as generic resources in the OPM Planning application. Instrument resources are assigned at the organization level in the Product Development application.

Define Decimal Precision for Displayed and Printed Values   Define decimal precision for Numeric Range, Numeric Range with Display, and Expression test data types. Test results are rounded based on the display precision specified at the test and specification levels. During test definition, define the reported decimal precision for specific customers.

The Display Decimal Precision is used for results evaluation, composite results, specification comparison, and specification matching functionality. The Report Decimal Precision is applied only for Certificate of Analysis functionality. If

defined, then the customer-specific Report Decimal Precision applies to the printing of results and specification targets and limits on quality certificates.

Entering Test Methods

The Test Methods window lets you enter and display all previously defined test methods. A test method is associated to a single test on the Tests window so that there is a one-to-one relationship between the test and the test method. This window lets you relate test-specific attributes to ensure the referential integrity of your overall testing process. For example, a test for chloride in material can be done by several methods. Attributes of a test method include:

- Quantity of material required

- Instrument to perform the test

- Number of replicates required

- Test kit produced internally or externally

- Duration of the test

- Decimal precision

In order to interpret a test result, you need to know not only the test, but the method that was used to run it. A test method is associated to a test on the Tests window. For quality laboratory management and scheduling purposes, you need to know which instruments are scheduled for testing, and test time duration on these resources.

Prerequisites

❏ List all test methods to be entered.

❏ Set up quality testing instruments as resources.

❏ Identify any instrument-test dependencies. For example, a standard is only run on a specific instrument to test calibration.

▶ To enter a test method:

1. Navigate to the **Test Methods** window.

2. Enter the test **Method** code. Required.

3. Enter a brief **Description** of the test method Required.

4. Enter the test **Qty** of material required for the test. If the test is passive, and does not require a physical sample quantity, then leave this field blank. For example, determining the color of a lot by visual methods may not require the removal of a physical sample.

5. Enter the test **UOM** for the test method. Required if you enter a test quantity.

6. Enter the **Instrument** used for the test method. This instrument is identified as a resource.

7. Enter the desired **Display Precision** for the test method. The stored decimal precision default is 9.

8. Enter the required number of test **Replicates**. Required.

9. Enter the **Test Kit** item.

10. Enter the test method **Duration** as the total time it takes to perform the test. If the test is a sent to an external laboratory, then enter the total test turnaround time in this field.

11. Save the window.

▶ **To duplicate a test method:**
   1. Query the test method to duplicate.

   2. Choose **New** from the **File** menu.

   3. Choose **Duplicate**, then choose **Record Above** from the **Edit** menu. The record in the row is is copied.

   4. Enter a new **Method**, and make any necessary changes to other fields.

   5. Save the window.

▶ **To mark a test method for purge:**
   1. Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.

   2. Save the window.

▶ **To edit text in a test method:**
   1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

   2. Make appropriate text changes.

   3. Save the window.

Finding Test Methods

The Find Test Methods dialog box lets you search for test methods by method, description, instrument, or marked for deletion.

Prerequisites

❏ Enter a test method.

▶ **To find a test method:**

1. Navigate to the Find Test Methods dialog box.

2. Enter any of the following to narrow your search:

   ■ **Method** code

   ■ **Description** of the method

   ■ **Instrument** used for the test method

3. Select **Marked for Deletion** as:

   ■ **Yes** if you want find test methods that are marked for deletion.

   ■ **No** if you do not want to find test methods that are marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a test method is marked for deletion.

4. Click **Find**. The **Test Methods** window displays the results of the search.

▶ **To create a new test method code from the Find Test Methods dialog box:**

1. Click **New**. The **Test Methods** window displays.

2. Create a new test method as described in the "Entering Test Method Codes" topic.

Understanding Tests

A test helps determine a quality characteristic or attribute of an item or lot. Test data type refers to the data type or format expected for the test result. Following are the test data types you can set up:

Non-Validated Test

Enter a test code and description. Test results for the Non-Validated test data type are free-form text. This entry does not require validation. Results for items or lots cannot fail this test data type.

Numeric Range Test

Enter a test code, description, test unit, and range of acceptable values for the test. If results for the item or lot fall outside this range, then the material fails this test. For example, a glucose test has a full functional test range of 20 to 300 g/dL. Results outside this test range cannot be saved.

List of Test Values Test

Enter a test code, description, unit, and list of valid values for this test data type. For example, Clear, Slightly Cloudy, and Turbid are valid list of test values. Test results must match an entry in the list.

Text Range Test

Enter a test code, description, unit, and ordered list of valid values for this test data type. Defining a test of this type builds a lookup table where a text value in the list maps to a sequence number. Values in this ordered list are defined in a text or alphanumeric format so that the specification minimum, target value, specification maximum, and results are recorded as text or alphanumeric formatted values.

The sequence number is a display-only field that represents the order of the values relative to each other and to a result. Enter the text range values in the order used for results evaluation. By selecting New Record and then Insert Record, you can insert new values between existing values in the list.

The following is an example of entering a sequenced set of values for a Text Range test data type:

- The test minimum is A2.

- The test maximum is D2.

- The specification minimum is A1.

- The specification maximum is D1.

Sequence	Value
1	A2
2	A1
3	D1
4	D2

A specification against a Text Range test data type refers to a subset of this list of values as acceptable results. When you enter results, the application validates the value entered by looking up the corresponding sequence number in order to evaluate whether the results are within the acceptable range of the test or the specification.

Numeric Range with Display Text

When you define a Numeric Range with Display Text test, the application builds a lookup table so that a numeric value in the list maps to a text equivalent. The application converts a numeric result into a text results for display and reporting purposes. You can define subranges within the numeric range that have individual display values assigned.

In the following example, a numeric result greater than or equal to zero and less than or equal to ten displays LOW. A result greater than or equal to 10.0001 and less than or equal to 20 displays MEDIUM.

Open-ended ranges are permitted. The maximum field in the last row of subranges is blank. You can also leave the minimum field on the first row of subranges blank to allow for values less than the maximum of the first subrange.

Range Minimum	Range Maximum	Displayed Text Result
0	10	LOW
10.0001	20	MEDIUM
20.0001	30	HIGH
30.0001	No Value Entered	DILUTE AND REPEAT

Subranges Cannot Overlap   Numbers used for a minimum or a maximum cannot be repeated for a specific test code. This allows for the less than or equal to

condition and the greater than or equal to condition observed at the ends of ranges. It also allows for holes in ranges. In the previous example, 10 is used for the maximum of the first subrange. It cannot, however, be used for the minimum of the next subrange. When 10 is entered in as the maximum, of a subrange, the next minimum has a default minimum of 10.001.

Display Text Can Be Repeated   Display text does not have to be unique for each subrange. This helps in situations where results below a certain number or above a certain number display RESULT OUTSIDE THE DETECTION LIMIT.

Enter Single Numbers or a Range of Numbers   You can enter a single number rather than a range of numbers as a result. Each number in the list is associated to display text. If the numeric result is within the minimum and maximum values, then the result is associated to the specified display text. The Results window displays both the numeric result and equivalent display text. To enter a single number, enter it as both a minimum and maximum value.

Expression Test

The Expression test data type lets you enter a mathematical expression to calculate test results. The application uses the results from other Numeric Range tests and constants, and applies a mathematical expression to calculate a result.

Use Valid Arithmetic Operators and Mathematical Functions   Valid arithmetic operators are: +, -, *, /, and any SQL operators such as SQRT("A") and ABS("B"). Define the decimal precision of an Expression test data type. You can change arithmetic operators, mathematical functions, and other tests used in the expression until the time that the Expression test is used in a specification. Once it is used in the specification, you cannot update it.

Business Rules Followed in Expression Test Data Types   The following summarizes the business rules for Expression test data types:

- You can define experimental error for an Expression test data type.

- Tests that are referenced in the Expression test must be either Numeric Range or Numeric Range with Display Text, and they should not be marked for deletion.

- Test codes that are referenced in an Expression test must be enclosed within double quotation marks. For example, FAHRENHEIT is a valid test code for entry in an Expression test, if the test for Fahrenheit is a defined test.

- Referenced tests must have lower test sequence numbers than the Expression test.

- Decimal precision defaults from the test method.

- Specification target, minimum, and maximum follow the same rules as for other numeric-based tests.

- The expression is calculated at result time when all referenced tests have a result entered in the result set. In cases of replicated or repeated tests that are referenced in the Expression test, the most recent result of the referenced test is used.

- Expression tests can only be added to a result set on an as needed basis if any and all of the referenced tests already exist in the result set.

- Expression tests are calculated regardless of whether the tests they reference pass or fail their individual specifications.

Entering Arithmetic Operators   To enter arithmetic operators, put quotation marks around the names of component Numeric Range tests used in the expression. Operands in the expression are enclosed within double quotation marks.

Tests A and B are two Numeric Range test codes:

- To add the two tests, enter "A"+"B"

- To subtract the two tests, enter "A"-"B"

- To multiply the two tests, enter "A"*"B"

- To divide the two tests, enter "A"/"B"

Tests C and D are two Numeric Range tests:

- To take the square root of test C, enter SQRT("C"). If you use the POWER function, then enter POWER("C",(1/2))

- To take the cube root of test D, enter POWER("D",(1/3))

Example of Entering an Expression Test   To enter an Expression test data type for calculation of Density, define the mathematical expression for Density, which is by definition, Density = Mass/Volume. Define tests for Mass and Volume. Define an Expression type test for Density. Enter "Mass"/"Volume" in the Expression field. Enter other appropriate fields for the Expression test. Save the window.

Entering Tests

The Tests window lets you define tests that become part of a specification, or that are added on an impromptu basis for sample analysis.

Refer to the "Understanding Test Data Types" topic for a complete understanding of all the test data types you can enter on this window.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*.

Prerequisites

❑ Enter test methods and test units.

❑ Enter test classes to group specific tests into meaningful sets.

❑ Enter instruments to track them as resources.

❑ Enter quality action codes to assign them to experimental error regions for tests.

❑ Enter customers in Oracle Receivables to define customer-specific test information for reporting purposes.

▶ To set up test data types:

1. Navigate to the **Tests** window.

2. Enter a **Test** code for the test. For example, CHLORIDE. Required.

3. Enter a **Description** for this test code. For example, Chloride in mEq/L. Required.

4. Enter the **Class** code for this test data type. A description of the test class displays in the unlabeled field.

5. Enter the test **Method**. For example, Ion-Specific Electrode. Test Method entry is described in the "Entering Test Methods" topic. Required.

6. Select one of the following as test **Data Type**:

    ■ **Non-Validated** if you do not want test results to cause the item or lot to be rejected. Enter a test code and description. Test results are simply recorded for future evaluation against the test value. Test results from this test data type do not cause an item or lot to be rejected. Non-validated results do not prevent a step from completing.

    ■ **Numeric Range** if you want an item or lot falling outside a specified range to be rejected. Enter a test code, description, and range of possible values.

- **List of Test Values** if you want an item or lot to match an entry in a specific list of values. Enter a test code, description, and a list of valid test values for the test.

- **Text Range** if you want an item or lot to match an entry in an ordered list, and a particular specification to restrict the acceptable entries to a subset of the list by specifying the limits of the subset. Enter a test code, description, and a list of valid values. The entries you make are sequenced automatically.

- **Numeric Range with Display Text** if you want subsets of a numeric range to display text values. Enter a test code, description, subranges, and corresponding text values. Make the range open-ended by not making an entry in the minimum of the first subrange or the maximum of the last subrange.

- **Expression** if you want to enter a mathematical expression for calculation of test results. Only those tests with numeric data types can be referenced. These are Numeric Range and Numeric Range with Display Text. For example, to calculate density, you must first define tests for mass and volume, since density equals mass divided by volume.

Required.

Depending on selection of test data type, the remaining fields on the window vary. For example, if you select Numeric Range, the Range fields are editable. If you select List of Specifications, then the Value and Description fields are editable.

7. Enter the test **Unit** code for the test. For example, enter mEq for milliequivalents. The description of the unit displays. Required for all test data types except Non-Validated.

8. Enter the test **Priority** as **Low**, **Normal**, or **High**. Test priority determines the order a test is displayed on a worklist. Test priority is defined initially at the Test level. It can be overridden at the Specification level. A System Administrator can add to the seeded list of values for test priority using the lookup functionality.

9. **Replicates** displays the number of test replicates for this test. It defaults from the value entered on the **Test Methods** window. Enter this field if you have not defined a test method for this test.

Values

10. Enter the fields as described for the test data type selected:

- For a Non-Validated test data type, you cannot enter data in this panel.

- For a Numeric Range test data type, enter the lower limit of the **Range** in the first field. Enter the upper limit of the range in the next field. You define the target value in the specification. For example, pH has a test range of 0 to 14, but an item could have a pH specification range of 4.2 to 6.7. The **Seq** field displays the sequence number of each value listed.

- For a List of Test Value test data type, enter each possible **Value** required for item or lot characteristic state. Define the target value in the specification. Enter one value and description per line. For example, the value list could include RED, BLUE, and CLEAR, but an item could have a value specification of RED. The **Seq** field displays the sequence number of each value listed.

- For a Text Range test data type, enter a **Value** and text **Description**. Enter values in the order you want. The text description represents the text to assign to each of the sequenced values. The **Seq** field displays the sequence number of each value listed.

- For a Numeric Range with Display Text test data type:

  Enter the minimum value for the interval in the **Min** field. Leave the first Min field blank for an open-ended test range. This field is automatically entered for each interval in the range after the first subrange. Required if it is not the first subrange.

  Enter the maximum value for the interval in the **Max** field. When you enter a maximum value and tab to the next field, the Min field automatically displays the next Min value. Leave the last Max field blank for an open-ended test range. Required if it is not the last subrange.

  Enter the text to **Display** when a test value is within the interval specified by the minimum and maximum values entered for the row.

  The **Seq** field displays the sequence number of each value listed.

- For Expression test data types:

  Enter the expression in the **Expression** field. Refer to the "Understanding Test Data Types" topic for guidance on entering an expression. To enter a test to reference in the expression, click **Test** and select the test code from the LOV. The test displays with double-quotation marks around it. Enter the appropriate arithmetic and mathematical operators outside the double quotation marks. Enter any SQL-compatible expression.

For example, to take the cube root of a test named EXAMPLE, click **Test**, select "EXAMPLE". Enter the following mathematical operators: POWER("EXAMPLE",(1/3))

11. Enter the **Display Decimal Precision** as the number of decimals stored and displayed for this test. The default value is entered on the **Test Methods** window. Required if the test entered is a Numeric Range, Numeric Range with Display Text, or an Expression type test.

12. Enter the **Report Decimal Precision** as the number of decimals to report on the Certificate of Analysis for this test. Values entered on the **Customer Display** window for a particular test override this information. The precision entered must be less than or equal to the value entered in the **Display Decimal Precision** field. Required if the test entered is a Numeric Range, Numeric Range with Display Text, or an Expression type test.

13. For Numeric Range, Numeric Range with Display Text, and Expression test data types, you have the option to click **Experimental Error** to display the **Experimental Error** window. This window lets you define an experimental error region that is calculated from either a percentage of the entire test range, or from a number representing the tolerance around the specification minimum or maximum. Values entered default to the test when it is added to a specification.

14. Click **Customer Display** to display the **Customer Display** window where you can enter an optional customized set of test-specific information that is used when you run a report on this test for specific customers.

15. Save the window.

◗ **To insert a new row in a List of Test Values, Text Range, or Numeric Range with Display Text test:**

You can only insert a new row for these test data types if the test is not already used in a specification and has results entered for it.

1. Position the cursor on the row directly above where you want to insert the row. For example, if you want to insert a row between the second and third entries in the list, position the cursor at the second entry.

2. Choose **New** from the **File** menu. A new blank row inserts directly below the row selected.

3. Enter new values.

4. Save the window.

▶ **To enter a new test method:**

1. Choose **Test Methods** from the **Actions** menu. The **Test Methods** window displays.

2. Enter the new test method as described in the "Entering Test Methods" topic.

▶ **To mark a test for purge:**

1. Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion. Once a test is marked for deletion, you cannot edit it.

2. Save the window.

▶ **To edit text in a test:**

1. Choose **Edit Text** from the **Actions** menu. The Select Text Paragraph dialog box displays.

2. Make appropriate text changes.

3. Save the dialog box.

▶ **To edit text in a List of Test Values, Text Range, or Numeric Range with Display Text test:**

1. Position the cursor on the record to edit in the **Values** tab.

2. Make appropriate text changes.

3. Save the window.

Entering Customer Display Information

The Customer Display dialog box lets you enter an optional customized set of test-specific information that is used when you run a report for specific customers. Display this dialog box from the Tests window where a specific test is entered or maintained. This information includes a test alias label that prints on customer-specific quality certificates, and the decimal precision that the customer wants to show for test results.

Prerequisites

❑ Enter the test to customize with customer-specific information.

▶ **To enter customer display information:**

1. Navigate to the Customer Display dialog box.

2. Enter a **Customer** previously defined in Oracle Receivables.

3. **Number** displays the customer account number that corresponds to the customer entered.

4. Enter a label or customer alias name for the test to **Display** on all reports generated. This field overrides the test name when it is displayed on a customer-specific quality certificate.

5. Enter **Report Precision** to use for the customer. This field allows you to enter the preference for decimal precision for numeric results printed on a quality certificate. Report precision defined here overrides the precision entered on the **Tests** window. You can only enter this field for Numeric Range, Numeric Range with Display Text, and Expression test data types for a customer-specific quality certificate.

6. Click **OK** to navigate back to the **Tests** window.

Entering Experimental Error

Experimental error accounts for inaccuracy and imprecision in test results by defining action zones around the specification limits or target. User actions such as RETEST are displayed as warnings when a test result falls inside the experimental error region.

You can define experimental error at the test level for Numeric Range, Numeric Range with Display Text, and Expression test data types. When a test is associated to a specification, the corresponding experimental error values default from the test. However, you can override these values at the specification level.

Understanding Experimental Error Regions

The experimental error region is calculated from either a percentage of the entire test range, or from a number representing the tolerance around the specification minimum or maximum. Experimental error regions must not overlap. If gaps are entered, then an error displays when the specification is validated.

Experimental error is defined for any combination of regions:

- Experimental error region below the specification minimum = Specification Minimum - Number or, Specification Minimum - (Percentage * Test Range)

- Experimental error region above the specification minimum = Specification Minimum + Number or, Specification Minimum + (Percentage * Test Range)

- Experimental error region below the specification maximum = Specification Maximum - Number or, Specification Maximum - (Percentage * Test Range)

- Experimental error region above the specification maximum = Specification Maximum + Number or, Specification Maximum + (Percentage * Test Range)

The experimental error regions below the Specification Minimum and above the Specification Maximum can overlap with the out-of-specification regions.

The following is a specific example of a Numeric Range test data type:

- Test data type is Numeric Range.

- Test range C is from 0 to 14.

- Test minimum at point A is 0.

- Test maximum at point B is 14.

- Test error type is number.

- Item specification range F is from 8 to 12.

- Specification minimum at point D is 8.

- Specification maximum at point E is 12.

- When a test error of plus or minus 1 is applied:

    - Specification minimum - test error at point G is 7.

    - Specification minimum + test error at point H is 9.

    - Specification maximum - test error at point I is 11.

    - Specification maximum + test error at point J is 13.

The following is an assessment of values:

- Values less than 7 and greater than 13 are outside the specification, as shown by ranges K1 and K2.

- Values ranging from:

    - 7 to 8 are outside the specification, but within the experimental error region, as shown by range L.

    - 12 to 13 are outside the specification, but within the experimental error region, as shown by range M.

    - 8 to 9 are within the specification, but also within the experimental error region, as shown by range N.

    - 11 to 12 are within the specification, but also within the experimental error region, as shown by range O.

    - 9 to 11 are within-specification, as shown by range P.

The following graphic depicts the previously described points, ranges, and values using the specific example of a Numeric Range test data type:
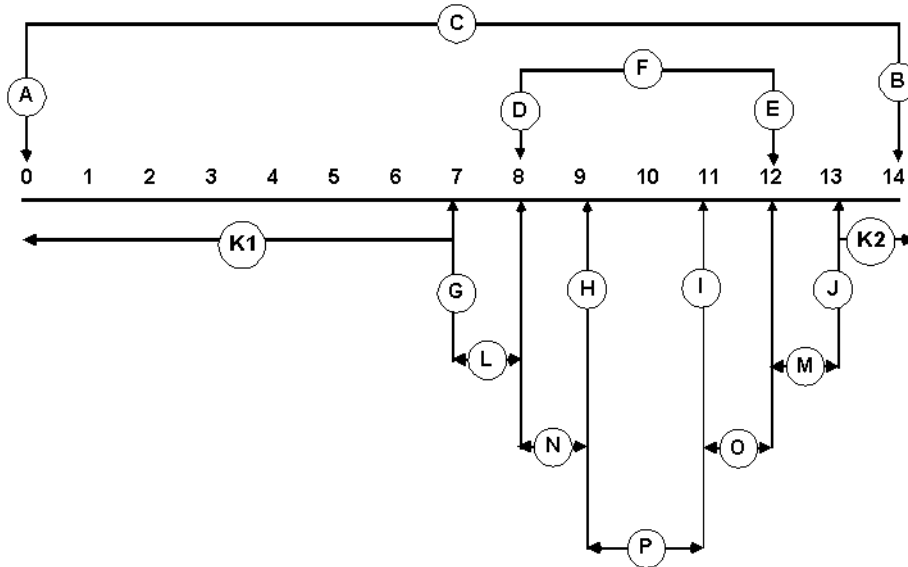
Assigning Action Codes

Associate an action code to each of the experimental error regions that you define. If no experimental error is defined for a test, then action codes cannot be assigned. Entering a result within the experimental error region displays a warning message with the associated out-of-specification action code. Appropriate action codes also display for results that are outside the specification limits.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Define action codes.

❏ Enter a test that requires entry of experimental error.

▶ To enter experimental error for a test:

1. Navigate to the **Experimental Error** window.

2. Select the **Error Type**:

   - **Percent** to indicate the specification value for calculating the experimental error regions is a percent.

   - **Number** to indicate the specification value for calculating experimental error regions is a number.

   Required.

3. Enter one or more of the following fields:

   - **Below Specification Min** to define the percentage or number to be used in calculating the experimental error region below the specification minimum. Enter the beginning of the action zone at the low end of the specification.

   - **Above Specification Min** to define the percentage or number to be used in calculating the experimental error region above the specification minimum. Enter the end of the zone of the action zone at the low end of the specification.

   - **Below Specification Max** to define the percentage or number to be used in calculating the experimental error region below the specification maximum. Enter the beginning of the action zone at the high end of the specification.

   - **Above Specification Max** to define the percentage or number to be used in calculating the experimental error region above the specification maximum. Enter the end of the action zone at the high end of the specification.

4. Enter the appropriate **Action** code to be associated with the experimental error region. The **Action Description** field displays the action associated with the code entered.

5. Optionally, press **Reset** to reset the values to those that were displayed when you originally displayed the window.

6. Click **OK** to return to the **Tests** window.

Example of Entering Experimental Error   A test has a range of 0 to 200. The test has an experimental error of plus or minus two percent of the specification minimum. Two percent is four points on either side of the specification minimum. If results are inside this action zone, then the individual performing the test must repeat it, and alert the individual requesting the test or owner of the sample. The action RTAO is defined to indicate Retest and Alert Owner.

In this case, select Percent as Error Type, enter 2 in the Below Specification Min field, and enter 2 in the Above Specification Min field. Enter RTAO in the Action

field to indicate that you want to retest the sample and alert the sample owner. After you click OK and save the window, the experimental error and action is applied to the database.

In the Specifications window, you can override the test numbers or add percentages for an action zone around the specification maximum. The specification minimum for this example is 90, the specification maximum is 170, and the test default experimental error is plus or minus two percent. Enter a result of 91. This is within the action zone which ranges from 86 to 94. The application displays a warning on the appropriate Results window with the action code and action code description.

Finding Tests

The Find Tests dialog box lets you find tests by class, method, data type, test unit, priority, or if they are marked for deletion.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*.

Prerequisites

❏ Enter a test.

▌ **To find a test:**

1. Navigate to the Find Tests dialog box.

2. Enter any of the following to narrow your search:

   ■ **Test** code

   ■ **Class** code for the test data type

   ■ **Method** for the test

   ■ **Data Type** for the test

   ■ **Unit** as test unit for the test

   ■ **Priority** for the test as High, Low, or Normal

3. Select **Marked for Deletion** as:

   ■ **Yes** if you want find tests that are marked for deletion.

   ■ **No** if you do not want to find tests that are marked for deletion.

   ■ Leave this field blank if you do not want to limit your search based on whether a test is marked for deletion.

4. Click **Find**. The **Test** window displays the results of the search.

▌ **To create a new test from the Find Tests dialog box:**

1. Click **New**. The **Tests** window displays.

2. Create a new test as described in the "Entering Tests" topic.

3. Save the window.

4

Specifications

This topic explains the basic concepts of quality specifications. You are shown how to enter and find specifications and their associated specification validity rules for both item and monitoring specifications. Specification summaries available from the Quality Workbench navigator are described.

The following topics are covered:

- Requirements
- Solutions
- Understanding Specifications
- Understanding the Status Approval Workflow
- Adding and Editing Status Codes
- Understanding Specification Version Control
- Entering a Specification
- Finding an Item Specification
- Entering an Item Specification Validity Rule
- Finding an Item Specification Validity Rule
- Displaying the Item Specification Validity Rules Summary
- Entering a Monitoring Specification Validity Rule
- Displaying the Monitoring Specification Validity Rules Summary
- Displaying Specification Summaries from the Navigator

Requirements

Following are some requirements that were addressed in defining and managing specifications in Quality Management. The answers are explained in detail in the "Solutions" topic.

Can several item specifications with the same set of tests, but different ranges be set up?

Yes. Define the specification for an item and grade to distinguish specifications with the same test requirements, but different limits or targets. Use base and overlay specification functionality to refine a series of specifications.

Is there a way to set up a test that needs to be performed several times on a sample?

Yes. Define the test replicate on the specification as the number of times the test needs to be run.

Does every test on a specification have to be used for evaluating results?

No. Mark a test as Optional to indicate that it is not required to meet a specification. Use the GMD: Include Optional Tests in Sample Disposition profile option to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample.

Can the tests required when a lot expires be identified?

Yes. A Lot Retest/Expiry indicator on the specification shows which tests need to be done when a lot expires.

Can results that are printed on the Certificates of Analysis be controlled?

Yes. Set up certificate formatting options on the item specifications. The specification validity rule applies these options to the certificate type specified.

Can specifications developed for internal versus external use be controlled?

Yes. Use specification validity rules to control item specifications developed for inventory, WIP, customer shipment, and supplier receipts. Configure the customer display on the Tests window and the report precision on individual specifications.

Can customer test results on certificates they receive be formatted?

Yes. Select the certificate type on the specification validity rule.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the quality process. The following represent some of the key performance solutions for specifications.

Enter the Item Grade on a Specification   The entry of grade to grade controlled item specifications facilitates the regrading of materials sampled and improves specification matching capabilities. Define several specifications for grade controlled items. Compare results to these different specifications and change lot attributes under the appropriate circumstances. Use the overlay specification functionality to refine a series of specifications for an item as related to a base specification.

Specify the Number of Test Replicates for a Test on a Specification   To simplify data entry, test replicates are specified to denote the number of times a test should be performed on an instrument against the same sample. For example, if a test should be repeated three times on a sample, the test can be defined on a single line of the specification record with a test replicate of three. The application adds result lines on the results record corresponding to the number of replicates specified on the applicable specification. For composite results and specification matching functionality, the result with the latest result date, acceptable value, and highest test replicate number is used.

Mark Tests as Optional   Mark a test as optional to indicate that it is not required to meet specification. Tests that are marked optional are not considered in specification matching. Results of these tests are not included in the evaluation or compositing of results. Optional tests are not considered when updating the sample disposition, or lot status and grade. They cannot be used to control batch step status based on quality results. Use the GMD: Include Optional Tests in Sample Disposition profile option to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample. For example, a new test is measured over time but does not factor into sample dispositions until its test limits are formalized based on the results collected. This configurable option is enforced globally wherever the test is used, and is independent of items or organizations. If an optional test result must be used, then its result evaluation obeys the existing business rules to change sample disposition. An out-of-specification result for an optional test only permits the sample disposition to change to Accept with Variance, Reject, or Cancel.

Indicate the Purpose of Retesting   The specification Lot Retest/Expiry indicator identifies which tests need to be performed when retesting an expired lot, or when

retesting is required. An indicator also appears on the sample record to identify the purpose of retest. Send an electronic notification to create a sample based on the dates for lot retesting or lot expiration scenarios. The corresponding results record lists only the tests marked by the specification Lot Retest/Expiry indicator.

Choose Quality Certificate Formatting Options on the Specification   Specify whether to print specification targets, limits, and results on a quality certificate when you define a specification. This gives you the flexibility to format the certificate for customers who receive these documents. The Specification Validity rule uses settings for these options.

Validity Rules and Status Control Specification Use   The item specification validity rule provides the specific information for how and when an item specification version applies to inventory, process execution, order management, and receiving operations. The item specification validity rule controls the:

- Intended use of the specification, including inventory, WIP, customer, or supplier

- Certificate of Analysis or Certificate of Conformance requirements at invoice, at shipment, or from supplier

- Associated sampling plan

- Inventory update for the sample quantity

- Batch step completion based on quality sampling and results

- Lot attributes update with default in-specification and out-of-specification lot statuses, with the exception of the WIP item specification validity rule.

Select the Certificate Type on the Item Specification Validity Rule   Select the Certificate of Conformance or Certificate of Analysis on the item specification validity rule. This gives you the flexibility to specify the type of quality certificate to send to customers who receive these documents.

Understanding Specifications

Specifications state the quality conformance requirements for materials, such as an item or a lot, or for environmental conditions, such as a resource or a warehouse location.

Item Specifications   Item specifications identify a target or ideal result for each quality test performed by listing test requirements that specify these characteristics or attributes. When you complete the initial quality setup, then combine tests and test methods to design specifications. The specifications entered are used to compare against actual test results from samples taken. For range-validated tests, define the minimum and maximum acceptable range values for the test as well as the out-of-specification action to be performed when a test fails.

Monitoring Specifications   Create a specification for a set of calibration tests on a resource or location. A resource can be an instrument in a quality laboratory, or a piece of equipment in a plant. View the scheduled tests for this specification in context with the sample load for an instrument. Monitoring specifications are used to list the acceptable conditions for each variant storage condition in a stability study. When you create a monitoring specification, the Item and Grade fields on the Specifications window cannot be entered.

Using Specification Versions and Status Approval

Specification name, version, and the approval processes provide the flexibility and control required to manage quality specifications. The combination of Spec and Version fields lets you define several specifications for the same item, lot, and sublot combination, batch work in process, individual customers, suppliers, resources, or warehouse locations. Status lets you determine the approval level of a specification. Use the Status Approval workflow to ensure that the appropriate internal or external individuals are notified when a quality specification version is created or modified. The combination of version control and status control lets you track changes to the specification record, and helps enforce consistency when evaluating results against specification requirements.

Creating a Base and Overlay Specification

Define new specifications either as a base specification, or as an overlay specification that references a base specification. The base specification contains the framework as a standard set of tests, or all possible tests that you can use to build overlays. Version and status control on the base specification affect the definition and usage of the dependent overlay specifications. You can only create an overlay specification from a base specification that has a status of Approved for Lab Use, or

Approved for General Use. Configure the overlay specification to exclude tests carried over from the base specification. You can also create several overlays to model various test frequencies. The overlay specification can include additional tests. For example, you can create an overlay specification for purposes of customer acceptance of the material or to fulfill regional regulatory requirements. Base and overlay specifications can be created for both item and monitoring specification types.

Setting Up Test Requirements

Set up test methods and tests prior to entering a specification. Refer to "Entering Test Methods" and "Entering Tests" for discussions of test requirements.

Understanding Test Sequence

Test sequence is a sequence number entered in the Seq field on a specification. Test sequence specifies the relative sort order of tests that display in a specification and results set. When a test is added to a specification, the application enters the test sequence number as a sequential integer multiple of ten. You can override the application-assigned sequence (Seq) by entering a different number. When you save changes, the application sorts the list of tests again in ascending order based on the test sequences on the specification. However, the test sequence cannot be changed on the Results window. When you add a new test to the set of results, it is added to the end of the set.

Marking Optional Tests

Mark a test as optional on a specification to indicate that it is not required criteria to determine the quality conformance or acceptability of an item. Tests that are marked optional are not considered in specification matching. Results of these tests are not included in the automated business rules of the application:

- Evaluating results

- Compositing results

- Finalizing sample disposition

- Finalizing sample group disposition

- Updating lot status and grade

Use the GMD: Include Optional Tests in Sample Disposition profile option to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample.

Setting the Lot Retest/Expiry indicator to Indicate the Purpose of Retesting

The Lot Retest/Expiry indicator identifies tests on the specification that need to be performed when retesting an expired lot, or when retesting is required at specified intervals. Set this indicator for each test on a specification. The Lot Retest/Expiry indicator is also included on the sample record to identify it for retesting purposes. When a notification is sent to create a sample based on lot retesting or lot expiration dates, the sample record is marked for lot retest. Results are expected for these tests when they are selected as Lot Retest/Expiry tests on the specification.

Recommending Lot-Specific Interclass UOM Conversions Based on Test Results

Use quality test results to update a quality attribute that varies from lot to lot in inventoried material. For example, when the active ingredient of a raw material varies across lots, despite the standard potency established for all lots of a particular item, you can adjust for this variability by storing a lot conversion factor between the primary and secondary units of measure for the material based on quality test results for the specific attribute. By accepting the sample group disposition, the conversion factor is recommended for update of the material attribute. When a result is entered for a sample from a supplier source where the lot is not yet received into inventory, the lot-specific interclass UOM conversion update must be done manually.

Understanding Experimental Error Used in Tests

Experimental error accounts for inaccuracy and imprecision in test results by defining an action zone around the specification limits or target as well as associated user actions such as retesting. Experimental error is defined initially at the test level for Numeric Range, Numeric Range with Display Text, and Expression test data types only. The Experimental Error region is calculated from either a percentage of the entire test range or from a number representing the tolerance around the specification minimum or maximum. Experimental error regions must not overlap or have gaps with respect to the specification limits or the target. If they do, then an error displays when the specification is validated. Associate an action code to each of the experimental error regions for a test. If no experimental error regions are defined for a test, then action codes cannot be assigned. Override the experimental error values and actions defaulting from the test definition at the specification level. When you enter a result that is within the experimental error region, the application displays a warning message with the associated experimental error region action code. If a result falls within an experimental error region that is also outside the specification limits, then the experimental error action

code takes precedence over any out-of-specification action that is predefined on the specification.

Refer to "Entering Experimental Error" for more information.

Indicating Certificate Formatting Options on the Specification

You can specify whether to print specification targets, limits, and results on a quality certificate when you enter a specification. If a generic or customer-specific test alias was previously specified during test definition, then the alias is used to generate the quality certificate. These formatting options are used when generating a quality certificate.

Specifying the Expiration of Tests on a Specification

You can specify the time window that a sample is viable for analysis. This information assists in planning laboratory tests and managing time-sensitive tests.

Using Item Specification Validity Rules

The Validity Rules for Item Spec window lets you define the validity rule type as inventory, WIP, customer, or supplier for item specifications, and resource or location for monitoring specifications. It also lets you assign date ranges within which the specification is effective. With the appropriate responsibility, you can override the system default values for the indicators that control the inventory update for the sample quantity, batch step status, and lot attributes update. The lot attributes indicator is not used for a WIP specification validity rule. When associating a specification version to a sample, the application uses a predefined hierarchy to select the specification validity rule that most closely meets the information identified with the sample.

Specifying Certificate Type on the Specification Validity Rule

A results set that has a sample group disposition of Accept or Accept with Variance must exist before you can print a Certificate of Analysis. Select the Certificate Type on the Specification Validity Rule to designate either Certificate of Conformance or Certificate of Analysis as the type of quality certificate to generate, and whether the certificate is required at invoice, at shipment, or from the supplier.

Creating a Monitoring Specification Validity Rule

Monitoring specification usage is controlled by the monitoring specification validity rule. Specify either of these attribute groups:

- Organization, Warehouse, or Location

- Organization, Resource, or Resource Instance

The monitoring specification is used primary for controlling the environmental conditions in a stability study, but it is not limited to this functionality. Create and use monitoring specifications for other resources or locations that you need to assess as part of your quality operations in the enterprise.

Matching Customer Specifications in Oracle Order Management

The following discussion presents the rules of the matching customer specifications in Oracle Order Management. The specification matching process only works with Oracle Order Management. In order for specification matching to function properly, set up a specification for the item to be matched. The specification must have an effective customer specification validity rule that coincides with the scheduled ship date. If a test has more than one replicate in the customer specification, then only the most recent replicate is considered in the matching process. Sample dispositions must be marked Accept or Accept with Variance. All tests not marked as optional in the specification must have a result, and they must be marked In-spec.

The specification matching procedure accepts and searches for any combination of lots and locations. Searches for location require that an active warehouse is available for the item. This allows the procedure to be used for non-lot controlled items.

The search for a matching customer specification delivers:

- Results that are in-specification
- Results that are out-of-specification
- No matching results

Accessing Specification Matching from Oracle Order Management   You can view the matching customer specifications in Oracle Order Management from the Sales Order Allocations window or from the OPM Inventory Transact Process Move Orders window using the Manual Allocate option.

The Quality Match field on the Available Inventory tab of these windows displays the level at which the specification matching results correspond to the customer specifications for the line item selected. If a result corresponds to the entry on the Quality Match field, then one of these values displays:

- Acceptable (Yes)
- Unacceptable (No)
- Not Applicable (Blank)

Click Review Spec to display the specification, specification version, and customer specification validity rule associated to the selected line item. Click Review Results to display results associated to the selected line item.

Refer to *Using Oracle Order Management with Process Inventory* for more information on these applications.

Refer to "OPM Product Analysis Workbook" in the *Oracle Business Intelligence System User's Guide* for more information on customer specification matching based on the OPM Order Fulfillment application.

Finding a Customer Specification

To find a customer specification, the specification matching operation uses the base customer hierarchy. In the specification matching process, it then considers local, global, and other plant specifications as outlined in Appendix C.

Refer to *Using Oracle Order Management with Process Inventory* for additional information.

Using Lot UOM Conversions Based on Quality Results

Use quality test results to propose a new lot-specific for an item lot. This is useful for items that have attributes that vary from lot to lot.

For example, the standard protein concentration of item ABC is:

1 milliliter (mL) = 0.10 Protein Concentration Unit (PCU)

Lot1 of item ABC is received, and the protein concentration determined by quality testing is:

1 mL = 0.13 PCU

The actual potency of the lot is 0.03 PCU greater than the standard protein concentration for the item. It is useful to create a precise lot UOM conversion for item ABC Lot1 so that 1 mL = 0.13 PCU. If several samples are taken for the same lot and the results are composited, then the average composite result becomes the conversion factor.

Lot UOM conversions from quality results are proposed when a sample group disposition changes to Accept, Accept with Variance, or Reject. The UOM Conversion tab on the Quality Change Disposition window displays lot UOM conversions that are derived from sample group results. You can accept the recommended conversions, or reject them. After an e-signature is processed for the sample disposition change, the OPM Quality UOM Conversion workflow sends a notification with the UOM conversion information to each of the defined workflow roles. In this notification, a link is created to the OPM Inventory Item Lot/Sublot Standard Conversion window that displays the proposed conversion. Update inventory transactions and inventory balances based on the recommended lot-specific UOM conversions. The lot UOM conversions are performed based on acceptance of the proposed conversions in OPM Quality Management. When this process is completed, you can close out the workflow notification.

Prerequisites

❑ Create inventory lots and sublots.

❑ Set up the OPM Quality UOM Conversion workflow.

▶ To set up for item lot UOM conversions:

1. Decide which item lot UOM conversions are dependent on quality results. You can only apply UOM conversions to items that are lot and sublot controlled.

From UOM = X * To UOM, where X is the result value, and the From UOM and To UOM are UOMs that are specified on specification test. The From UOM is the item primary UOM.

Example: In this example, mL is entered as ML in the application. A UOM conversion is desired for item ABC, lot LOT1 for protein concentration between the ML UOM and the Protein Concentration Unit (PCU) based on quality results. The From UOM is ML and the To UOM is PCU. The base UOM for volume is L and 1L = 1000 ML.

2. Create the tests to generate lot UOM conversion recommendations based on quality results.

Example: Create a numeric test, Protein Concentration%, with a test unit of %, since the concentration is recorded as a percentage. Create an expression test called Protein Concentration Expression with a test unit of PCU_TEST. The expression for this is (Protein Concentration %) /100. This expression is created to obtain the 1ML = X PCU conversion where X is the result value.

3. Create the desired specification.

Add tests to the specification and select the Calculate UOM Conversion next to the conversion tests. Specify the From UOM and To UOM for the conversion for the test. The From UOM displays the primary UOM for the item. Specify the To UOM for the conversion. The To UOM cannot belong to the same UOM class as the From UOM. Two test lines that belong to a single specification can reference the To UOMs that belong to the same UOM Class.

Example: Add the tests Protein Concentration % and Protein Concentration Expression to specification Spec1 for item ABC and lot LOT1. Select the Calculate UOM Conversion indicator for test Protein Concentration Expression, and enter the From UOM as ML and a To UOM as PCU.

4. Save and approve the specification.

5. Create and approve a specification validity rule that applies to the desired lot.

▶ **To convert units of measure based on quality results:**

1. Record samples and results for all tests saved on the item specification created in the previous setup task.

Example: Create the sample PR1 00093. There is one sample in the sample group for item ABC, lot LOT1 using the specification Spec1. Enter the results for the sample PR1 00093 as follows:

Test	Test Unit	Result	Auto UOM Conv Indicator	From UOM	To UOM
Protein Concentration %	%	10	N/A	N/A	N/A
Protein Concentration Expression	PCU_TEST	10/100 = 0.1	Selected	ML	PCU

2. Navigate to the **Quality Change Disposition** window.

3. Change the sample group disposition to **Accept**, **Accept with Variance**, or **Reject**.

4. Select the **UOM Conversion** tab. The application enters all data displayed on this tab:

   ▪ If at least one test on the specification has the Calculate UOM indicator selected

   ▪ If the **Change Disposition To** field displays **Accept**, **Accept with Variance**, or **Reject**

   ▪ If the sample group source is **Inventory** or **Supplier**

   Data appears on this tab even when test results are out-of-specification.

   If a lot and sublot UOM conversion already exists for the lot, then the current conversion between the UOM class of the base UOM and the UOM class of the To UOM is displayed below the new proposed conversion.

5. Select the **Recommend** indicator next to the desired UOM conversions. If this indicator is not selected, then the proposed conversion is not used in inventory.

6. Click **OK** to change the disposition of the sample group.

7. Provide an e-signature for the disposition change if one is required.

8. Receive the OPM Quality UOM Conversion workflow notification.

9. Click the **UOM Conversion** link to the **OPM Inventory Control Item Lot/Sublot Standard Conversion** window, and save to create the conversions.

10. Close the workflow notification.

Understanding the Status Approval Workflow

When the OPM Quality Spec Status Change Approval workflow and the OPM Quality Spec Validity Rule Status Change Approval workflow are activated in Quality Management, new versions of specifications and their specification validity rules require a series of approvals that result in reassigning their statuses through a predefined approval process. Laboratory approval is optional.

Stability study statuses are preseeded. Refer to "OPM Quality Stability Study Change Status Workflow" in Appendix D for additional information.

Setting Up the Status Approval Workflows

Set up the workflows in the OPM System Administration application. Contact a system administrator if you are not sure that this is set up.

Enabling the Status Approval Workflow

Enable workflows by setting them up in the System Administration application. Once workflows are set up and operating, each workflow is activated by changing the Status of a specification from New to any of the other available status.

Adding and Editing Status Codes to the Status Approval Workflow

If you modify or delete any of the predefined status codes that are supplied with this application, then the workflows do not run as described in this documentation. Add or edit status codes as described in "Adding and Editing Status Codes."

Running the Status Approval Workflow

When an item specification, or item validity rule is created, workflows run as follows:

1. Upon creation, by default, the **Status** for a specification or validity rule is assigned as **New**.

2. If you choose **Change Status** from the **Actions** menu and then select **Approved for Laboratory Use**, then the workflow changes Status to **Request Approval for Laboratory Use**. Once approved, Status changes to **Approved for Laboratory Use**.

3. If you choose **Change Status** from the **Actions** menu and then select **Approved for General Use,** then the workflow changes Status to **Request Approval for General Use**. Once approved, Status changes to **Approved for General Use**.

4. You have the option to assign the Status as **Obsolete** or **Archived**.

5. An **Approved for Laboratory Use** status can be assigned these statuses:

   ■ On Hold

   ■ Obsolete or Archived

6. An **Approved for General Use** status can be assigned these statuses:

   ■ On Hold

   ■ Frozen

   ■ Obsolete or Archived

7. A **Pending Approval for Laboratory** status or a **Pending Approval for General Use** status can be assigned these statuses:

   ■ Obsolete

   ■ Archived

8. Specification validity rules that:

   ■ Fail the approval of **Pending Approval for Laboratory Use** Status are assigned **Revise for Laboratory Use**.

   ■ Fail the approval of **Request Approval for General Use** Status are assigned the **Revise for General Use**.

The following depicts the previously described workflows for versions of specifications and specification validity rules:
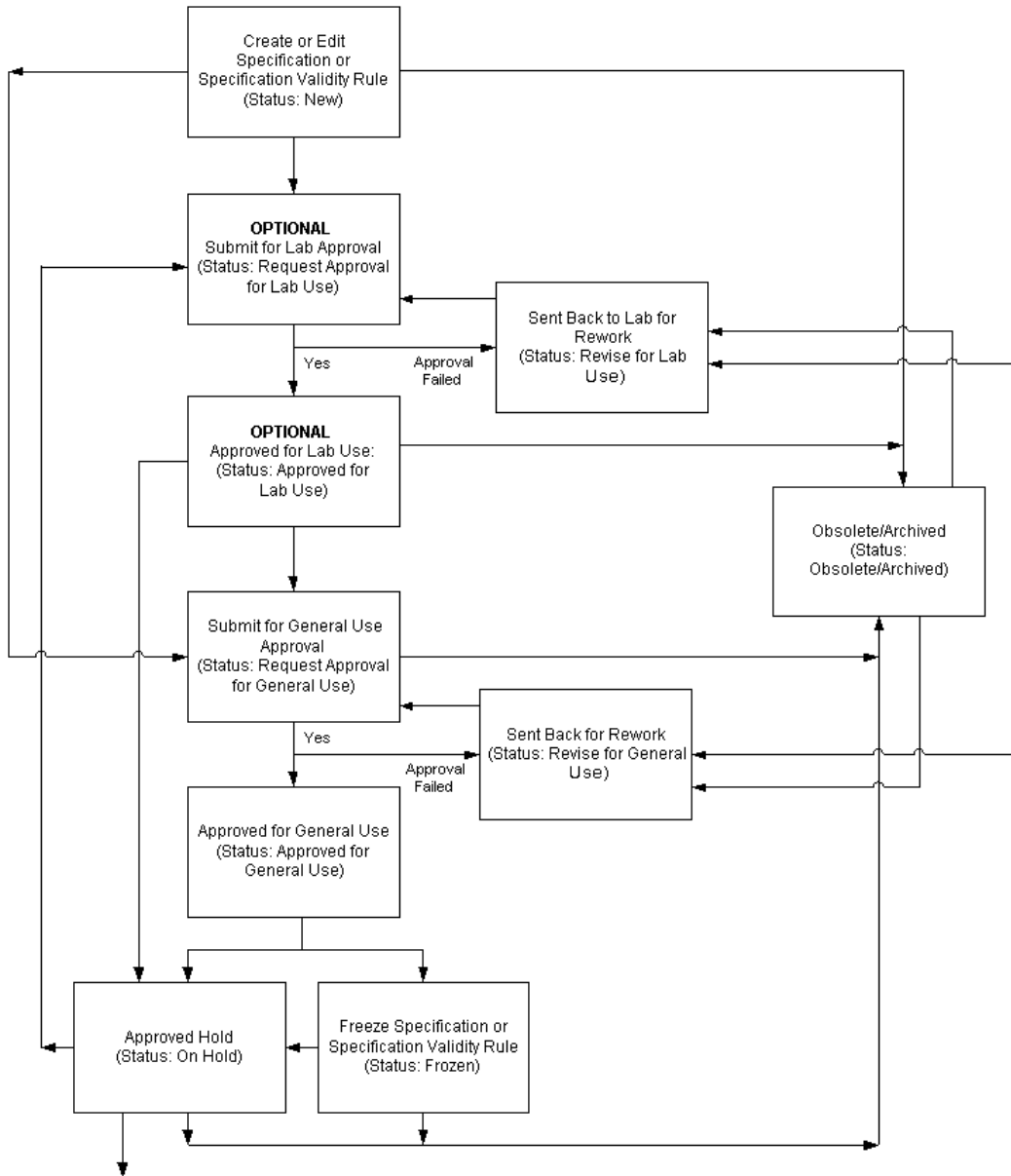
Disabling the Status Approval Workflow

The System Administrator must disable the workflows. If the workflow is disabled, then you can change the status of a specification or a validity rule manually. However, the status change does not initiate a workflow.

See Also

Oracle Process Manufacturing System Administration User's Guide

Adding and Editing Status Codes

You can add to or edit the predefined status codes. Modification or deletion of the predefined status codes that are supplied with the application may result in the workflows not working properly.

Stability studies have a preseeded status approval workflow. Refer to the "OPM Quality Stability Study Change Status Workflow" topic in Appendix D for additional information on these customized status codes.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Read the "Understanding the Status Approval Workflow" topic.

▶ To add a new status code:

1. Navigate to the **Status Codes** window.

2. Choose **New** from the **File** menu. A new row displays.

3. Enter a new **Status Code**. The number you enter is sorted into ascending order with the other status codes when you save and reopen the Status Codes window.

    Codes entered between any two predefined codes, such as 101 to 199, or 201 to 299 are included in the workflow associated with the predefined status code with the same first digit. For example, if you enter the code 110, it becomes part of the workflow associated to code 100. If you enter a code number 699, then it becomes part of the workflow associated to code 600. Predefined status codes are shown in a table at the end of this task. Required.

4. Enter a **Description** for the status code. Required.

5. Enter the information to display on the Status field in the **Meaning** field. Required.

6. **Enable Version** determines whether the status code entered is set up for version control. Any modification made to a specification or a specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here, and the value entered for the specification version control profile option.

■ Select Enable Version if you want the status code to enable version control when a modification is made to a specification or specification validity rule The specification version control profile option must be set to Yes or Optional.

■ Clear Enable Version if you want the status code to bypass version control when a modification is made to a specification or specification validity rule.

7. Save the window.

8. Click **Details** to enter Status Details as described in the "Entering Status Details" topic.

The following are the required predefined status codes:

Code	Meaning	Description	Version Enabled
100	New	Can make changes at any time, assuming security access is granted.	Yes
200	Request Approval for Laboratory Use	Submitted for approval of use in the laboratory.	No
300	Revise for Laboratory Use	Approval has failed and rework is required.	No
400	Approved for Laboratory Use	Can be used in laboratory.	Yes
500	Request Approval for General Use	Submitted for final approval.	No
600	Revise for General Use	Approval has failed and rework is required.	Yes
700	Approved for General Use	Can be used for production batches and cost rollups.	Yes
800	On Hold	Cannot be used until status is changed.	No
900	Frozen	Prevents further changes to specification, specification validity rule, and any dependent data. Both specification and specification validity rule can still be used.	No
1000	Obsolete/Archived	Can no longer be used unless status is changed.	No

◗ **To edit an existing status code:**

1. Navigate to the **Status Codes** window.

2. Edit the following fields as required:

   ■ **Description** to change the explanation of the status code.

   ■ **Meaning** to change the information displayed on the Status field in the application.

3. **Enable Version** determines whether the status code entered is set up for version control. Any modification made to a specification or a specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here, and the value entered for the specification version control profile option.

   ■ Select Enable Version if you want the status code to enable version control when a modification is made to a specification or specification validity rule. The specification version control profile option must be set to Yes or Optional.

   ■ Clear Enable Version if you want the status code to bypass version control when a modification is made to a specification or specification validity rule.

4. Click **Details**. The **Status Details** window displays.

5. Edit the following fields as required:

   ■ **Target Status** to change the code that appears as the destination status on the **Change Status** window. Required.

   ■ **Rework Status** to change the destination for the listed status code when it is not accepted and must be reworked.

   ■ **Pending Status** to change the destination of the listed status code when it enters the approval workflow, and is pending approval.

6. Edit the **Workflow Indicator** by selecting:

   ■ **Enable or Disable Workflow** to indicate that the fields listed in the row enable or disable the workflow.

   ■ **Workflow Approval** to indicate that the fields listed in the row require workflow approval.

   ■ **No Workflow Approval** to indicate that the fields listed in the row do not require workflow approval.

   Required.

7. Click **OK**.

8. Save the window.

Entering Status Details

The Status Details window lets you enter a target status for a new status code. You can enter rework status, pending status, and indicate how you want workflow to manage the status entered.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

▶ **To enter status details:**

1. Navigate to the **Status Details** window.

2. Enter a **Target Status** for the new status code. This is the code that appears as the destination status on the **Change Status** window. You can enter several destinations for each status code. They must be entered on separate lines. Required.

3. Optionally, enter a **Rework Status**. This code defines the destination for the listed status code when it is not accepted and must be reworked.

4. Optionally, enter a **Pending Status**. This code defines a destination of the listed status code when it enters the approval workflow and is pending approval.

5. Select one of the following as **Workflow Indicator**:

   ■ **Enable or Disable Workflow** to indicate that the fields listed in the row enable or disable the workflow.

   ■ **Workflow Approval** to indicate that the fields listed in the row require workflow approval.

   ■ **No Workflow Approval** to indicate that the fields listed in the row do not require workflow approval.

   Required.

6. Click **OK**.

7. Save the window.

Finding a Status Code

The Find Status Codes dialog box lets you find a status code by code number, description, version enabled, or mark for purge status.

◗ **To find a status code:**

1. Navigate to the Find Status Codes dialog box.

2. Enter one or more of the following fields to narrow your search:

   ■ **Status Code** to find a specific code number.

   ■ **Description** to find a specific status code description.

   ■ **Version Enabled** determines whether the status code entered is set up for version control. Any modification made to a specification or specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here, and the value entered for the specification version control profile option.

     Select Version Enabled to find the status codes that enable version control when a modification is made to a specification or specification validity rule.

     Clear Version Enabled to find the status codes that bypass version control when a modification is made to a specification or specification validity rule.

   ■ **Mark For Deletion** lets you find status codes with the status:

     Yes indicating the status code has been marked for purge

     No indicating that the status code has been undeleted.

3. Click **Find** to display the results of your query.

4. Click the down arrow to display all status codes that were found.

5. Click **New** to enter a new status code. The **Status Codes** window displays.

Understanding Specification Version Control

Some businesses require version control to generate an audit trail. By enforcing version changes you define rules for modifying quality specifications. Version control lets you determine if an existing version can be modified, or if a new version must be created. Quality Management lets you:

- Force the creation of new versions so that transaction sources stay intact.

- Deliver a combination of forced version creation and no version control.

- Provide no version control.

These decisions are made at the organization level with proper assignment of User Responsibilities. Status must be Approved for General Use for version control to be active. All other statuses do not require that a new version be created each time a change is made.

Version control does not validate the fields on a specification header. These fields cannot be changed once a specification is saved. A new specification must be created in order to change these fields, whether or not version control is used. Version control does not take the Status field into account when determining whether a new version should be created. This is also true for Mark for Purge and Undelete functions.

Specification Version Control Profile Option

The GMD: Specification Version Control profile option is set to one of the following values:

- Y means Yes, indicating that version control is activated and any change made requires a new version.

- N means No, indicating that version control is not activated and any change can be made to the existing version.

- O means Optional, indicating that version control is optional. You are asked if you want to create a new version if any change is made to the existing version.

You can set version control to any appropriate level of activation. It is a good idea to set version control profile options initially to O. You are notified each time you attempt to save changes. The setting of these options is based on your individual business requirements.

Refer to the *Oracle Process Manufacturing Implementation Guide* for specific details on setting this profile option.

Setting Up Version Control at the Organization and Responsibility Level

Your user must be associated with valid organizations in order to create transactions and perform certain functions in Quality Management. If new responsibilities are implemented as described in the following example, then you can achieve version control by association to an organization through a link to a specific responsibility within the organization.

Here is an example of how to set up specification version control:

Users are defined as:

    ABC for Quality Manager ABC

    JKL for Quality Manager JKL

    XYZ for Quality Manager XYZ

Organizations are:

    OA for Oracle Applications

    OPM for Oracle Process Manufacturing Company, consisting of:

        PLT1 for Plant1

        PLT2 for Plant2

        PLT3 for Plant3

Responsibilities are:

    Quality Manager for PLT1

    Quality Manager for PLT2

    Quality Manager for PLT3

User-Organization Associations are:

    ABC for PLT1

    JKL for PLT1

    XYZ for PLT1

User-Responsibility Associations are:

    ABC for Quality Manager PLT1

    JKL for Quality Manager PLT2

XYZ for Quality Manager PLT3

Profile Settings are:

GMD: Specification Version Control is set to Y for the PLT1 Quality Manager responsibility

At logon, user ABC is presented with a list of responsibilities for Quality Manager PLT1. Menus and windows associated with the Quality Manager responsibility are accessible to User ABC, and they are configurable. Specific windows and functions are enabled or disabled within menus and responsibilities. Since the user organization association for User ABC is limited to PLT1, and the Specification Version Control profile option is enabled for this responsibility, any modifications made to a specification during the session for User ABC requires a new version of a specification for PLT1.

If User ABC changes to a responsibility where Version Control is set to N, then modifications to a specification in that session do not require the creation of a new specification version.

If User ABC changes to a responsibility where Version Control was set to O, then modifications to a specification in that session notify User ABC that Version Control is optional. Prior to saving a change, User ABC is asked whether or not to change the existing specification version.

Entering a Specification

The Specifications window lets you enter or edit a quality specification. The window associates tests, targets, actions for results, and certificate formatting options with Specification Validity Rules to create usable, valid quality specifications. You can enter an item specification or a monitoring type specification.

Entering a Base Specification

The creation of a base specification provides a template to help you maintain a set of common tests and targets that you can propagate into overlay specifications. This process lets you customize individual test and target requirements on the overlay without compromising the integrity of the base specification. You cannot create overlay specifications with the same name.

Entering an Overlay Specification

The creation of an overlay specification lets you add new tests and targets to a base specification. You can override the test line data on the base specification. You can also exclude certain tests included in the base specification that do not apply to your customized evaluation needs. Refer to the "To create an overlay specification" task for the procedure to create an overlay specification.

Entering a Monitoring Specification

A monitoring specification defines the details of the storage condition for each one of the variants in the stability study. The monitoring specification provides the test requirements needed to evaluate the acceptability of environmental conditions for each variant storage condition in a stability study. You an also use the monitoring specification to define and monitor environmental conditions outside the stability study. Refer to the "Entering Monitoring Samples" topic for additional information on taking samples for the monitoring specification. Select the Spec Type as Monitoring to create a monitoring specification and follow the procedure to enter a specification.

Workflow Procedures

Refer to "Appendix D" for additional information on workflow procedures.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Define tests, test methods, and sampling plan.

❏ Optionally, set up required profile options.

❏ Optionally, set up the Quality System Parameters window.

▶ **To enter a base specification:**

1. Navigate to the **Specifications** window.

2. Enter **Spec** as the name for the specification. Required.

3. Enter a **Version** for the specification. Required.

4. After entering all relevant information and saving the specification with the default **Status** of **New**, return to this window if you need to change specification status by selecting **Change Status** from the **Actions** menu. Depending on whether the status approval workflows are enabled, a different set of statuses is available.

   Select a **Status** for the specification you are entering from one of the following:

   ■ **Approved for Laboratory Use** to indicate that the specification is approved for laboratory use.

   ■ **Approved for General Use** to indicate that the specification is approved for use in work in process.

   ■ **Obsolete/Archived** to indicate that the specification is no longer approved for use and is obsoleted, archived, or both.

   If the status approval workflows are enabled when you select:

   ■ **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the specification, then its Status changes to Approved for Laboratory Use.

- Approval for General Use, then Status changes to **Request Approval for General Use** until all approvers have accepted the specification, then its Status changes to Approved for General Use.

5. Enter a brief **Description** of the specification. Required.

6. Select **Spec Type** as:

   - **Item** if you are entering a specification for an inventory item.

   - **Monitoring** if you are entering a specification to monitor an environmental condition.

7. Do not select the **Overlay** indicator. This ensures you enter a base specification. Refer to the "To create an overlay specification" task for the procedure to create an overlay specification.

8. Enter the **Item** code for the material being specified as it is listed on the Item Master. The item description displays. Required if the Spec Type is Item. You cannot enter an item for a Monitoring type specification.

9. Enter a **Grade**. If the item is lot controlled and grade controlled, then the grade on this specification is used to update the grade of a lot. You cannot enter a grade for a Monitoring type specification.

10. The **Owner Organization** displays your default organization. Required.

11. Enter the **Owner** of this specification. You can change this entry to anyone who has access to the Owner Organization. Required.

Targets

12. Enter **Seq** as the sequence of the test in the specification. This field is populated with an integer number beginning with 10. Each test added increases the number displayed in this field by 10. Required.

13. Enter the **Class** code for this test. This field defaults from the test entered. You cannot enter a class for a Monitoring type specification.

14. Enter a predefined **Test** code for this specification. The list of tests available for entry is filtered if a test class was entered. Required.

15. Enter the test **Method**. This field defaults from the **Tests** window.

16. **From Base** is display only. It is cleared when the test in the row is not from the base specification.

17. The **Exclude** indicator is selected when the test listed in the row is eliminated from an overlay specification. If you are entering an overlay specification, then

you can select the indicator to exclude a test, or clear the indicator to include a test from the overlay specification.

18. The **Modify** indicator is selected to amend data on the test line. The base data is protected from modification until the indicator is selected. If the Modify indicator is cleared, then data on the test line reverts to its original base state, and is protected from updates. You can only select this indicator when the test listed in the row is derived from the base specification.

19. Enter the specification **Target** value for the test code. Depending on the test data type, the specification target may or may not be validated. For example:

   ■ For Non-Validated test data types, the specification target is not validated. Any entry is accepted in this field, including a blank.

   ■ For Numeric Range, Numeric Range with Display Text, or Text Range test data types, enter a value within the specification limits as defined in the Minimum and Maximum fields. Tighten the specification limits for a test by entering new values in the Minimum and Maximum fields to replace the default values of the test range.

   ■ For List of Test Values test data types, enter a valid value from the list of values available for the test.

   ■ For Expression test data types, enter a value within the calculated expression test specification limits.

20. Enter the specification **Minimum** value that is acceptable to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Tests** window.

21. Enter the specification **Maximum** value that is acceptable to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, or Text Range, or Expression. This field defaults from the **Tests** window.

22. **Unit** displays the default quality unit of measure for the test entered. This field defaults from the **Tests** window.

23. Enter the **Quantity** of material required to perform the test. This field defaults from the **Tests** window.

24. **UOM** displays the unit of measure for the test quantity. This field defaults from the **Test Method** window.

25. Enter **Replicate** as the number of times that the test is repeated for the same sample. This field defaults from the **Test Methods** window.

26. Enter the test **Priority** as **Low**, **Normal**, or **High**. Test priority identifies the relative priority of a test, and can be used to sort tests listed in a specification. Test priority is defined initially at the test level. You can override it here at the specification level.

27. Select **Optional** if the test is not required for the specification. You can indicate that a Result Set is complete even if an optional test is incomplete. Use the GMD: Include Optional Tests in Sample Disposition profile option to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample.

28. Select **Lot Retest/Expiry** to indicate whether this test is required for lot retesting or expiration testing.

Actions

29. The following fields display the values entered on the **Targets** tab:

    - **Seq** displays the sequence of the test in the specification. This field is populated with a number beginning with 10. Each test added increases the number displayed in this field by 10. Required.

    - **Class** code displays the class for this test data type. This field defaults from the **Tests** window.

    - **Test** displays the test code for this specification. Required.

30. Enter the **Out of Spec Action** as the action to take if the result of the test falls outside the specification range. This action is shown in a message window on the **Results** window.

31. **Description** displays a brief explanation of the action entered.

32. Depending on how you implement action codes, enter one of the following in the **Interval** field:

    - Enter the number of days between the expiration date and the date that the action must be taken.

    - Enter the number of days after the failed quality test date that the action must be taken.

33. **Error Type** displays the type of numerical or percentage Experimental Error associated with a numeric-based test. This defaults from the **Tests** window.

34. **Calculate UOM Conversion** functions with the **From UOM** and **To UOM** fields to convert the item primary UOM to a desired To UOM:

   - Select Calculate UOM to use the test result as an item lot and sublot conversion in the OPM Inventory Control application.

   - Clear Calculate UOM if you do not want the result value for this test to be used as an item lot and sublot conversion in the OPM Inventory Control application.

35. The **From UOM** field displays the specification item in its primary UOM.

36. Enter the **To UOM** as the desired item lot and sublot conversion UOM. The UOM class of the To UOM must differ from that used on other test lines that belong to the specification. The unit of measure conversion is stored in the OPM Inventory Control application once a sample group for the test has a final disposition of Accept, Accept with Variance, or Reject. Required if the Calculate UOM Conversion indicator is selected.

   Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for an example of the OPM Quality Management UOM conversion process.

37. The following fields are entered on a test-specific basis on the **Experimental Error** window.

   - **Below Minimum** displays the percentage or number to be used in calculating the experimental error region below the specification minimum. This is the beginning of the action zone at the low end of the specification.

   - **Below Minimum Action** displays the Action code associated with the Below Minimum experimental error region.

   - **Above Minimum** displays the percentage or number to be used in calculating the experimental error region above the specification minimum. This is the end of the action zone at the low end of the specification

   - **Above Minimum Action** displays Action code associated with the Above Minimum experimental error region.

   - **Below Maximum** displays the percentage or number to be used in calculating the experimental error region below the specification maximum. This is the beginning of the action zone at the high end of the specification.

   - **Below Maximum Action** displays the Action code associated with the Below Maximum experimental error region.

- **Above Maximum** displays the percentage or number to be used in calculating the experimental error region above the specification maximum. This is the end of the action zone at the high end of the specification.

- **Above Maximum** displays the Action code associated with the Above Maximum experimental error region.

Formatting

38. The following fields display the values entered on the **Targets** tab:

   - **Seq** displays the sequence of the test in the specification. This field is populated with a number beginning with 10. Each test added increases the number displayed in this field by 10. Required.

   - **Class** code displays the class for this test data type. This field defaults from the **Tests** window.

   - **Test** displays the test code for this specification. Required.

39. **Alias** displays an alternate name for the test. This field defaults from the **Tests** window.

40. Select **Print Spec** to print the specification target, minimum, and maximum values for this test on quality certificates. Clear this box if you do not want to print these values on quality certificates.

41. Select **Print Result** to print the result of this test on quality certificates. Clear this box if you do not want to print results on quality certificates.

42. Enter **Stored Precision** as the number of decimals to store and display for the specification target, minimum, maximum, and test result. This value defaults from the value entered on the **Tests** window. Required.

43. Enter **Report Precision** as the number of decimals to print on quality certificates for the specification target, minimum, maximum, and test result. This value defaults from the value entered on the **Tests** window. Required.

Planning

44. The following fields display the values entered on the **Targets** tab:

   - **Seq** displays the sequence of the test in the specification. This field is populated with a number beginning with 10. Each test added increases the number displayed in this field by 10. Required.

   - **Class** code displays the class for this test data type. This field defaults from the **Tests** window.

- **Test** displays the test code for this specification. Required.

45. The following fields function as a single entry for the test expiration time:

    - Enter **Test Expiration Days** as the number of days allowable for the test to be run after the sample is drawn.

    - Enter **Test Expiration Hours** as the number of hours allowable for the test to be run after the sample is drawn.

    - Enter **Test Expiration Minutes** as the number of minutes allowable for the test to be run after the sample is drawn.

    - Enter **Test Expiration Seconds** as the number of seconds allowable for the test to be run after the sample is drawn.

    For example, if a test expiration is 1 day, 6 hours, and 30 minutes after the sample is drawn, you enter:

    - 1 in the **Test Expiration Days** field

    - 6 in the **Test Expiration Hours** field

    - 30 in the **Test Expiration Minutes** field

46. Save the window.

◗ **To enter validity rules for the specification:**

1. Click **Validity Rule.** The **Validity Rules** window displays.

2. Enter appropriate information on the window. Refer to the "Entering Specification Validity Rules" topic for additional information.

3. Save the window.

◗ **To duplicate the specification:**

1. Choose **Duplicate**, then choose **Record Above** from the **Edit** menu. All fields are copied.

2. Enter a new **Name**, **Version**, and changes to other fields.

3. Save the window.

◗ **To mark a specification for purge:**

Choose Mark for Purge from the Actions menu. The record is marked for deletion.

▶ **To edit text in the specification:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To display test details:**

1. Select the desired test.

2. Choose **Tests** from the **Actions** menu. The **Tests** window displays for the selected test.

3. Close the window.

▶ **To create an overlay specification:**

1. Enter the required specification header information for an item specification or a monitoring specification.

2. Select the **Overlay** indicator.

3. Select the **Base Spec** and **Version** with a status of Approved for Lab Use or Approved for General Use to generate the overlay specification. The tests region of the window displays all data copied from the selected base specification. The From Base indicator is cleared if a test line was not derived from the base specification.

4. Select the **Exclude** indicator to exclude a test from the overlay specification.

5. Select the **Modify** indicator to modify other applicable fields in the row. If you select this field, then depending on the test type, enter each of the fields in the row to modify.

6. Select the next **Seq** to add a test to the overlay specification. Enter all necessary test information.

7. Save the window.

8. Create a specification validity rule. Refer to the "Entering Specification Validity Rules" topic for additional information.

▶ **To create a monitoring specification:**

1. Enter the required specification header information for a monitoring specification.

2. Select **Spec Type** as **Monitoring**.

3. Enter all necessary test information for the monitoring specification as discussed in the "To enter a specification" task.

4. Save the window.

5. Create a monitoring specification validity rule. Refer to the "Entering a Monitoring Specification Validity Rule" topic for additional information.

▶ **To assign a test group to a specification:**

1. Navigate to the **Specifications** window.

2. Query the desired specification to assign a test group.

3. Choose **Add Test Group** from the **Actions** menu. The **Test Group** window displays. You can add tests to a specification that has a status of New, Revise For General Use, or Revise For Lab Use. If the flexfield for specification tests is mandatory, you cannot use this option.

4. Query the desired **Test Group** as the test class that is also group enabled. The window displays all tests included in that test group.

   ■ **Ordering** is the sequence of the test in the group as entered on the Tests window.

   ■ **Test** is the name of the test entered.

   ■ **Description** is the description of the test code.

   ■ **Data Type** is the test data type as described in "Understanding Tests."

   ■ **Qty** is the amount of material required for the test. This defaults from the test quantity specified for the test method.

   ■ **UOM** is the unit of measure for the test quantity defined in the test method.

5. Select or clear **Include** to indicate the tests in the group to be copied to the specification. The Include indicator is disabled for tests that were previously added to the specification. To include an additional test replicate on the specification, increase the replicate by one.

6. Click **OK**. Selected tests are added to the specification.

7. Save your work.

Finding an Item Specification

The Find Specifications dialog box lets you find a specification based on its code, version, item or monitoring specification type, status, item, grade, or owner organization. You can also find item specifications that are overlays to a base specification, and identify base specifications by version.

Prerequisites

❏ Enter an item specification or a monitoring specification.

▶ **To find a specification:**

1. Navigate to the Find Specifications dialog box.

2. Enter any of the following to narrow your search:

    ■ **Spec** code entered for the specification

    ■ **Version** number of the specification

    ■ **Spec Type** as Item or Monitoring

3. Select **Overlay** to find overlay specifications of a specific base specification, and leave the Base Spec field blank to find all overlay specifications. Clear Overlay to exclude overlay specifications from the search.

4. Enter any of the following to narrow your search:

    ■ **Base Spec** to find a specific base specification

    ■ **Base Spec Version** to find a specific base specification version

    ■ **Status** of the specification

    ■ **Item** code for the material being specified as it is listed on the Item Master

    ■ **Grade** assigned to the item listed in the specification

    ■ **Owner Organization** entered for the specification

    ■ **Owner** of the specification

5. Select **Marked for Deletion** as:

    ■ **Yes** if you want find specifications that are marked for deletion.

    ■ **No** to exclude specifications that are marked for deletion.

    ■ Leave this field blank to limit your search based on whether a specification is marked for deletion.

6. Click **Find**. The **Specifications** window displays the results of the search.

◗ **To create a new specification from the Find Specifications dialog box:**

1. Click **New**. The **Specifications** window displays.

2. Create a new specification as described in the "Entering a Specification" topic.

3. Save your work.

Entering an Item Specification Validity Rule

The Validity Rules for Item Spec window lets you define the usage of the specification validity rule at the inventory, work in process, customer, and supplier levels.

Define specification validity rules for each item in your inventory, for each customer or supplier that you sell to or buy from, or for each recipe or work in process batch that you produce. You also have the option to define a specification validity rule for an item grade.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

Refer to "Solutions" for additional information.

Refer to "Appendix C" for the hierarchies of validity rules.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏   Enter and save a specification.

❏   Optionally, enter a sampling plan.

▶ **To enter an item specification validity rule:**

1.   Navigate to the **Validity Rules Summary for Item Spec** window.

2.   Click **New**. The **Validity Rules for Item Spec** window displays.

3.   **Item** displays the item code for which you are creating the specification validity rule.

4.   **Grade** displays the grade associated to the item on the specification, if the item is grade controlled.

5.   **Spec Status** displays the status of the specification used in the validity rule. Specification status is discussed in "Entering a Specification."

6.   Click one of the following tabs to create a validity rule for the item and optional grade entered:

- **Inventory** to create a specification validity rule for inventoried item. Proceed to step 7.

- **WIP** to create a specification validity rule for work in process. Proceed to step 20.

- **Customer** to create a specification validity rule for a customer. Proceed to step 31.

- **Supplier** to create a specification validity rule for a supplier. Proceed to step 45.

Inventory

7. **Organization** displays the default organization for the validity rule.

8. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by selecting **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

   Select a **Status** for the specification you are entering from one of the following:

   - **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.

   - **Approved for General Use** to indicate that the validity rule is approved for use in work in process.

   - **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

   If status approval workflows are enabled, when you select:

   - **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the validity rule, then its Status changes to Approved for Laboratory Use.

   - **Approval for General Use,** then Status changes to **Request Approval for General Use** until all approvers have accepted the validity rule, then its Status changes to Approved for General Use.

9. If the **Lot** field is dimmed, then the item is not lot controlled. If the item is lot controlled, then this field is editable. To enter a validity rule for a specific item, enter the lot code in this field. Otherwise, leave the field blank to indicate all lots. Lot control is set up on the **Items** window.

10. **Sublot** displays the sublot for the item if it is sublot controlled. This field is editable only if the item you entered is lot and sublot-controlled, otherwise it is blank. To enter a validity rule for a specific item-lot-sublot combination, enter the sublot code in this field. The inventory item and lot control is set up on the Items window.

11. Enter a **Warehouse** code to create the validity rule for an item in a particular warehouse. Otherwise, leave the field blank to indicate the validity rule is applicable to all warehouses.

12. Enter a **Location** to make this validity rule for a specific location if the item and warehouse have location control. Otherwise, leave this field blank to indicate the validity rule is applicable to all locations. Locations are created in the OPM Inventory Control application.

13. Select **Lot Optional on Sample** if you do want to require a lot to be entered on sample of a lot-controlled item. Clear this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Quality System Parameters window.

14. If **Lot Optional On Sample** is selected, then **Delayed Lot Entry** is available. This defaults from the selection on the Quality System Parameters window. You can update the indicator until the item specification validity rule status is changed to approved, frozen, or obsoleted/archived. When Delayed Lot Entry is selected, then samples created must have lot entered after sample creation. If the lot number is entered during sample creation, then the lot is used to choose a sample group and it cannot be changed.

15. To define **Effective Dates** for this validity rule:

    ▪ Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.

    ▪ The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until you need to stop this validity rule from being effective.

16. Select **Certificate Type** as:

    ▪ **Certificate of Analysis** to generate a certificate of analysis when this validity rule is selected.

    ▪ **Certificate of Conformance** to generate a certificate of conformance when this validity rule is selected.

    When you select the certificate type, you can choose one or more of the following to indicate at which stage the certificate is generated or required.

- Select **At Invoice** to generate it at invoice time.

- Select **At Shipment** to generate it when the item is shipped.

- Select **From Supplier** if the certificate is required when the item is received from a supplier.

17. **Control** indicates what to affect with this validity rule. Select a sampling plan. Select any of the following:

    - **Create Samples Automatically** to enable automatic sample creation. This defaults from the Quality System Parameters window. Clear this selection to disable automatic sample creation using this validity rule.

    - **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the system parameters for the organization specified.

    - **Control Lot Attributes** to control lot status, grade, and hold date based on the final disposition of the sample group. This indicator defaults from the system parameters for the organization specified. The In-Spec Lot Status and Out-of-Spec Lot Status can be specified.

18. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

    - **Count** displays the number of samples to take at each instance of the sampling frequency entered.

    - **Quantity** and **UOM** indicate the sample size, or the amount of material and its inventory unit of measure.

    - **Per** indicates the sampling frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

19. Save the window.

WIP

20. **Organization** displays the default organization for the validity rule.

21. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by selecting **Change Status** from the **Actions** menu.

Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.

- **Approved for General Use** to indicate that the validity rule is approved for use in work in process.

- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the validity rule, then its Status changes to Approved for Laboratory Use.

- **Approval for General Use,** then Status changes to **Request Approval for General Use** until all approvers have accepted the validity rule, then its Status changes to Approved for General Use.

22. Enter the **Batch** number for which this validity rule is applicable. If you enter a valid batch number, then the following fields are displayed with batch-specific information:

    - **Recipe** indicates the recipe used in the batch.

    - **Formula** indicates the formula and **Version** used in the batch.

    - **Formula Line** indicates the line in the formula that is controlled by this validity rule. The formula line type displays.

    - **Routing** indicates the routing that is tied to the recipe used in the batch.

    - **Operation** indicates the operation that is controlled by this validity rule and its **Version**.

    If no batch number is entered, then you can enter a recipe, formula and version, formula line, routing, or operation and version.

23. Enter **Step** and **Charge** on a new WIP specification validity rule, so that a sample from a WIP source with the specified step or charge can get the specification for this validity rule.

24. To define **Effective Dates** for this validity rule:

- Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.

- The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until you need to stop this validity rule from being effective.

25. Select **Certificate Type** as:

   - **Certificate of Analysis** to generate a certificate of analysis when this validity rule is selected.

   - **Certificate of Conformance** to generate a certificate of conformance when this validity rule is selected.

   When you select the certificate type, you can choose one or more of the following to indicate at which stage the certificate is generated or required.

   - Select **At Invoice** to generate it at invoice time.

   - Select **At Shipment** to generate it when the item is shipped.

   - Select **From Supplier** if the certificate is required when the item is received from a supplier.

26. Select **Lot Optional on Sample** to require a lot to be entered for a sample of a lot-controlled item. Clear this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Quality System Parameters window.

27. If **Lot Optional On Sample** is selected, then **Delayed Lot Entry** is available. This defaults from the selection on the Quality System Parameters window. You can update the indicator until the item specification validity rule status is changed to approved, frozen, or obsoleted/archived. When Delayed Lot Entry is selected, then samples created must have lot entered after sample creation. If the lot number is entered during sample creation, then the lot is used to choose a sample group and it cannot be changed.

28. **Control** indicates what to affect with this validity rule. Select any of the following:

   - **Create Samples Automatically** to enable automatic sample creation. This defaults from the Quality System Parameters window. Clear this selection to disable automatic sample creation using this validity rule.

   - **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the system parameters for the organization specified.

■ **Control Batch Step Status** to control the batch step status for the selected validity rule.

29. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

■ **Count** displays the number of samples to take at each instance of the frequency entered.

■ **Quantity** and **UOM** indicate the sample size, or the amount of material.

■ **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

30. Save the window.

Customer

31. **Organization** displays the default organization for the validity rule.

32. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by selecting **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

■ **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.

■ **Approved for General Use** to indicate that the validity rule is approved for use in work in process.

■ **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

■ **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the validity rule, then its Status changes to Approved for Laboratory Use.

> - **Approval for General Use,** then Status changes to **Request Approval for General Use** until all approvers have accepted the validity rule, then its Status changes to Approved for General Use.

33. Enter the **Customer** number for which the specification validity rule is applicable. Required.

34. Enter the **Operating Unit** as an OPM-related operating unit. Operating units are mapped to OPM companies in fiscal policy.

35. **Ship-To** displays locations for the specified customer and operating unit. You can enter this field if it does not default from the customer entered.

36. Enter the **Order** number from existing orders in the Oracle Order Management application for the operating unit specified. This field is not available for use in the OPM Order Fulfillment application.

37. **Type** displays the sales order type code from those that are set up for the operating unit in the Oracle Order Management application. This field only displays when an order is specified. This field is not available for use in the OPM Order Fulfillment application.

38. **Line** displays the sales order lines associated to the entry made in the Order field. This field is not available for use in the OPM Order Fulfillment application.

39. Select **Lot Optional on Sample** if you do want to require a lot to be entered on sample of a lot-controlled item. Clear this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Quality System Parameters window.

40. To define **Effective Dates** for this validity rule:

    - Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.

    - The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until you need to stop this validity rule from being effective.

41. Select **Certificate Type** as:

    - **Certificate of Analysis** if you want a certificate of analysis when this validity rule is selected.

    - **Certificate of Conformance** if you want a certificate of conformance when this validity rule is selected.

When you select the certificate type, choose one or more of the following to indicate at which stage the certificate is generated or required.

- Select **At Invoice** to generate it at invoice time.

- Select **At Shipment** to generate it when the item is shipped.

42. **Control** indicates what to affect with this validity rule. Select **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the system parameters for the organization specified.

43. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

- **Count** displays the number of samples to take at each instance of the frequency entered.

- **Quantity** and **UOM** indicate the sample size, or the amount of material.

- **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

44. Save the window.

Supplier

45. **Organization** displays the default organization for the validity rule.

46. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by selecting **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.

- **Approved for General Use** to indicate that the validity rule is approved for use in work in process.

- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the validity rule, then its Status changes to Approved for Laboratory Use.

- **Approval for General Use,** then Status changes to **Request Approval for General Use** until all approvers have accepted the validity rule, then its Status changes to Approved for General Use.

47. Enter the **Supplier** code for whom this validity rule is effective. Required.

48. **Name** displays the name of the supplier.

49. **Site** displays the supplier site number for which this validity rule is effective.

50. **PO** displays the purchase order number for which this validity rule is effective.

51. **PO Line** displays the purchase order line number for which this validity rule is effective. You can edit this field.

52. Select **Lot Optional on Sample** if you do want to require a lot to be entered on sample of a lot-controlled item. Clear this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Quality System Parameters window.

53. If **Lot Optional On Sample** is selected, then **Delayed Lot Entry** is available. This defaults from the selection on the Quality System Parameters window. You can update the indicator until the item specification validity rule status is changed to approved, frozen, or obsoleted/archived. When Delayed Lot Entry is selected, then samples created must have lot entered after sample creation. If the lot number is entered during sample creation, then the lot is used to choose a sample group and it cannot be changed.

54. **Control** indicates what to affect with this validity rule. Select a sampling plan. Select any of the following:

- **Create Samples Automatically** to enable automatic sample creation. This defaults from the Quality System Parameters window. Clear this selection to disable automatic sample creation using this validity rule.

- **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the system parameters for the organization specified.

- **Control Lot Attributes** to control lot status, grade, and hold date based on the final disposition of the sample group. This indicator defaults from the system parameters for the organization specified. The In-Spec Lot Status and Out-of-Spec Lot Status can be specified.

55. Select **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the system parameters for the organization specified.

56. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

- **Count** displays the number of samples to take at each instance of the frequency entered.

- **Quantity** and **UOM** indicate the sample size, or the amount of material.

- **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

57. Save the window.

Finding an Item Specification Validity Rule

The Find Validity Rules dialog box lets you find a specification validity rule based on its specification, version, status, item, grade, or ownership.

Prerequisites

❑ Enter and save a specification validity rule.

▶ **To find a specification validity rule:**

1. Navigate to the Find Validity Rules dialog box.

2. Enter any of the following to narrow your search:

   ■ **Spec** code entered for the specification validity rule

   ■ **Version** number of the specification validity rule

   ■ **Spec Type** as **Item**, for an item specification, or **Monitoring**, for a monitoring specification.

   ■ **Status** of the specification associated to the specification validity rule

   ■ **Item** code for the material

   ■ **Grade** associated to the validity rule

   ■ **Owner Organization** of the specification validity rule

   ■ **Owner** of the specification validity rule

3. Select **Marked for Deletion** as:

   ■ **Yes** if you want find specification validity rules that are marked for deletion.

   ■ **No** to exclude specification validity rules that are marked for deletion.

   ■ Leave this field blank to limit your search based on whether a specification validity rule is marked for deletion.

4. Click **Find**. The **Validity Rules** window displays the results of your search.

Displaying the Item Specification Validity Rules Summary

The Validity Rules Summary for Item Spec window displays a complete list of item specification validity rules for an item and its optional grade combination.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

◗ **To display a summary of item specification validity rules:**

1. Navigate to the **Validity Rules Summary for Item Spec** window.

2. **Item** displays the item code for the item specification.

3. **Grade** displays the default grade for the item, if the item is grade controlled.

4. **Spec Status** displays the status of the item specification validity rule.

5. The following fields are display only:

   - **Organization** is the default organization for the specification validity rule.

   - **Specification Type** is the type of specification that is associated to the validity rule. Options are:

     Inventory for inventoried items

     WIP for work in process materials

     Customer for customer items

     Supplier for vendor items

   - **Deleted** displays **Yes** if the specification validity rule is marked for deletion, or it displays **No** if it is not marked for deletion.

   - **Spec Validity Rule Status** is the status of the specification validity rule.

   - **Start Date** is the effective start date and time for the selected validity rule.

   - **End Date** is the effective end date and time for the selected validity rule. If this field is blank, then the validity rule is still in effect.

   - **Lot** is the lot associated associated to the selected validity rule, if the item is lot controlled. This field applies to specification validity rules for the inventory specification type.

   - **Sublot** is the sublot associated to the selected validity rule, if the item is sublot controlled. This field applies to specification validity rules for the inventory specification type.

- **Whse** is the warehouse code for an item in a specific warehouse associated to the selected validity rule. If the field is blank, then the validity rule applies to all warehouses. This field applies to specification validity rules for the inventory specification type.

- **Location** is the location of the item associated to the selected validity rule if the item or warehouse has location control. If the field is blank, then the validity rule applies to all locations. This field applies to specification validity rules for the inventory specification type.

- **Update Inventory Quantity** indicates whether the selected validity rule is set to decrease inventory by the sample amounts taken for testing.

- **Control Lot Attributes** indicates whether the selected validity rule controls lot status based on the disposition of the sample. This field applies to specification validity rules for the WIP specification type.

- **In-Spec Lot Status** is the default lot status for results that are within specification limits for the selected validity rule.

- **Out-of-Spec Lot Status** is the lot status for results that are outside of specification limits for the selected validity rule.

- **Control Batch Step Status** indicates whether the validity rule controls the batch step status for the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Lot Optional On Sample** indicates whether entry of a lot number is required when a sample is taken. If this field is selected, then entry of the lot number entry at sampling is optional. If this field is not selected, then a lot number must be entered when a sample is taken.

- **Certificate Type** indicates whether the validity rule prints a Certificate of Analysis or a Certificate of Conformance for the selected validity rule.

- **Certificate Type at Invoice** indicates whether the certificate type selected is generated at invoice time for the selected validity rule.

- **Certificate Type at Shipment** indicates whether the certificate type selected is generated when the item is shipped for the selected validity rule.

- **Certificate Type from Supplier** indicates whether the certificate type selected is generated when the item is received from a supplier for the selected validity rule.

- **Batch** is the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Recipe** is the recipe used in the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Recipe Version** is the recipe version used in the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Formula** is the formula used in the batch and the **Formula Version** for the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Routing** is the routing and **Routing Version** tied to the recipe used in the batch for the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Step** is the batch step and **Charge** associated to the routing for the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Operation** is the operation and **Operation Version** controlled by the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Order** is the purchase order number for the selected validity rule. This field applies to specification validity rules for the supplier specification type.

- **Order Line** is the purchase order line number for the selected validity rule. This field applies to specification validity rules for the supplier specification type.

- **Ship-To** is the location for the specified customer and operating unit for the selected specification validity rule. This field applies to specification validity rules for the supplier specification type.

- **PO** is the purchase order number, and purchase order type for the selected specification validity rule. This field applies to specification validity rules for the supplier specification type.

- **PO Line** is the purchase order line number for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.

- **Supplier** is the supplier for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.

■ **Site** is the supplier site for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.

6. Click the drill-down indicator next to a validity rule to display the **Specification Validity Rules** window.

7. Close the window.

▶ **To enter a new validity rule:**

Click **New VR** to display the **Specification Validity Rules** window where you can enter a new validity rule.

▶ **To edit an existing validity rule:**

1. Select the validity rule to edit.

2. Click **Edit** to display the **Validity Rules** window where you can edit an existing validity rule.

3. Save the window.

▶ **To display the E-Record Generic Query:**

1. Choose **E-Record Details** from the **Actions** menu. The **E-Record Generic Query** displays if this option is available in your application.

2. Refer to "Appendix C" for information on e-records.

Close the window.

Entering a Monitoring Specification Validity Rule

The Validity Rules for Monitoring Spec window lets you enter a new validity rule for a monitoring specification.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Enter and save a monitoring specification.

❑ Optionally, enter a sampling plan.

▶ **To enter a monitoring specification validity rule:**

1. Navigate to the **Validity Rules Summary for Monitoring Spec** window.

2. Click **New**. The **Validity Rules for Monitoring Spec** window displays.

3. **Spec** displays the monitoring specification name.

4. **Spec Status** displays the approval status of the monitoring specification.

5. Select **Rule Type** as:

   ■ **Resource** to create a validity rule for a resource such as a refrigerator, environmental chamber. If you select this field, then enter information in the Resource region.

   ■ **Location** to create a validity rule for a location such as a warehouse and warehouse location. If you select this field, then enter information in the Location region.

6. **Validity Rule Status** indicates the status of the monitoring specification validity rule. You can change the status of the validity rule after you enter and save all the following information.

7. Enter the following information in the Resource region for a resource validity rule:

   ■ **Name** as the name of the generic resource for the validity rule.

- ■ **Resource Org** as the resource organization where the validity rule is defined.

- ■ **Instance** as the specific instance of the resource in the resource organization where the validity rule is defined.

8. Enter the following information in the Location region for a location validity rule:

   - ■ **Organization** as the organization associated to the location validity rule.

   - ■ **Warehouse** as the warehouse where the specification validity rule applies.

   - ■ **Location** as the location in the warehouse where the specification validity rule applies if the warehouse is location controlled.

9. In the Effective Dates region, enter:

   - ■ **From** as the start date for the monitoring specification validity rule. Required.

   - ■ **To** as the end date for the monitoring specification validity rule. Leave this field blank if there is no end date for the monitoring specification validity rule.

10. In the Sampling Plan region, enter:

    - ■ **Name** as the name of the sampling plan.

    - ■ **Count** as the number of samples to take at each instance of the frequency entered. Required.

    - ■ **Qty** as and **UOM** as the sample size, or the amount of material needed to take a sample from the material requiring inspection. This is expressed in the primary inventory unit of measure. Required.

    - ■ **Per** as the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

11. Save the window.

12. Choose **Change Status** from the **Actions** menu to change the status of the validity rule entered to Approved for General Use.

13. Save the window.

▶ **To change the status of a monitoring specification validity rule:**

1. Query the desired monitoring specification validity rule.

2. Choose **Change Status** from the **Actions** menu.

3. Save the window.

▶ **To mark a monitoring specification validity rule for purge:**

Choose Mark for Purge from the Actions menu. The record is marked for deletion.

▶ **To edit text in the monitoring specification validity rule:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To display the E-Record Generic Query:**

1. Choose **E-Record Details** from the **Actions** menu. The **E-Record Generic Query** displays if this option is available in your application.

2. Refer to "Appendix E" for information on e-records.

3. Close the window.

Displaying the Monitoring Specification Validity Rules Summary

The Validity Rules Summary for Monitoring Spec window displays all the monitoring specifications entered. Fields on this window are display only. If you need to enter a new monitoring specification, then click New and refer to the "Entering a Monitoring Specification Validity Rule" for more information.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Enter and save a monitoring specification validity rule.

◗ **To display a list of monitoring specification validity rules:**

1. Navigate to the **Validity Rules Summary for Monitoring Spec** window.

2. The following fields are display only:

   ■ **Specification** displays the monitoring specification name.

   ■ **Spec Status** displays the approval status of the monitoring specification.

   ■ **Organization** displays the organization associated to the validity rule type displayed.

   ■ **Deleted** displays **Yes** if the monitoring specification validity rule is marked for deletion, or **No** if it is not marked for deletion.

   ■ **Spec Validity Rule Status** displays the current status of the monitoring specification validity rule.

   ■ **Start Date** displays the effective start date for the monitoring specification validity rule.

   ■ **End Date** displays the end date for the monitoring specification validity rule, if one was entered.

3. If the rule type entered is for a resource monitoring specification, then:

   ■ **Resource** displays the generic resource for the monitoring specification validity rule.

   ■ **Instance** displays the specific resource for the monitoring specification validity rule.

4. If the rule type entered is for a location monitoring specification, then:

■ **Whse** displays the warehouse where the specification validity rule applies.

■ **Location** displays the location in the warehouse where the specification validity rule applies if the warehouse is location controlled.

5. **Sampling Plan** displays the current monitoring specification sampling plan, if one is entered.

6. Close the window.

Displaying Specification Summaries from the Navigator

The Specification Summary window lets you view a list of specifications by individual specification, customer, supplier, item, owner organization, or status.

This window displays item specifications, including base and overlay specifications. It does not display monitoring specifications.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Enter and save specifications.

❏ Enter and save specification validity rules.

▶ **To display the Specification Summary window:**

1. Navigate to the **Quality Workbench**.

2. Select **Show Active Specs** to display only those specifications that are active, where specification statuses are either Approved for Lab Use, or Approved for General Use. Clear this indicator to display all specifications.

3. Select **View By**:

    ■ **Specifications** to display an alphanumeric sort of specifications. Expand the Specifications node. Select the desired specification node to display the **Specification Summary** window. Drill down to tests, customer validity rules, and inventory validity rules.

    ■ **Customer** to sort specifications by customer. Expand the desired customer node. Select each unexpanded specification node to display the **Specification By Item** window. Drill down to individual specifications, Tests, and Customer Validity Rules.

    ■ **Supplier** to sort specifications by supplier. Expand the Specifications By Supplier node. Expand the desired supplier node. Select each unexpanded specification node to display the **Specification By Item** window. Drill down to individual specifications, Tests, and Supplier Validity Rules.

    ■ **Item** to sort specifications by item. Select the unexpanded item to display the **Specifications by Item** window. Expand the item node to display the **Specification Summary** window for the item. Drill down to individual tests, customer validity rules, and inventory validity rules.

- **Owner Organization** to sort the specifications by owner organization. Select the unexpanded Specifications By Status node to display the **Specifications By Status** window. Drill down to individual specifications, tests, customer validity rules, and inventory validity rules.

- **Status** to display the **Specifications By Status** window.

4. The following fields are display only on the **Specification By Customer, Supplier, Item, Owner Organization**, or **Status**, and **Specification Summary** windows:

- **Specification** displays the name for the specification.

- **Version** displays the specification version.

- **Description** displays a brief description of the specification.

- **Item** displays the code for the material being specified as it is listed on the Item Master.

- **Grade** displays the grade defined by the specification.

- **Status** displays the status defined by the specification.

5. Click **Specification** to display the **Specifications** window.

5

Samples

This topic includes procedures for entering and finding item samples and monitoring samples. Procedures for displaying sample groups and displaying sample summaries on the navigator are also provided.

The following topics are covered:

- Requirements
- Solutions
- Understanding Sampling
- Entering Item Samples
- Entering Monitoring Samples
- Finding Samples
- Displaying Sample Groups
- Displaying Sample Summaries from the Navigator
- Displaying the Samples Summary Window

Requirements

Following are some requirements that customers have for samples in Quality Management. The answers are explained in detail in the "Solutions" topic.

Can the application help me plan sample collection?

Yes. Use the optional sampling plan to set up the sampling process in your facility. A Sample Creation Notification workflow helps manage the sample collection process. You can set up automatic sample creation so that the application creates planned sample records with the default sample group information such as batch, item, and optional lot and sublot.

Can I reserve a sample in case of sample breakage, leakage in transit to a testing facility, or future quality audits?

Yes. If you experience sample breakage, leakage, or spoiling during transit to a testing facility, then retain a reserve sample until testing is complete. For quality audits, retain an archive sample for future testing.

Can I track the lifecycle of a sample?

Yes. Record dates for when the sample is drawn and when it expires. If the sample is pulled from storage, then you can specify the date and time it was retrieved, when the quality laboratory received it, and when analysis is due.

Can I indicate which samples are designated for lot retesting purposes?

Yes. Select the Lot Retest/Expiry indicator for a sample when retesting an expired lot. Samples are marked appropriately to trace them in the storage warehouse if you need to retest the same material periodically.

Can I track sample quantities after testing is completed?

Yes. You can track the quantity of sample remaining based on the actual test quantities recorded. You can also track the physical storage warehouse and location of a sample taken for quality testing purposes using the Sample Storage Summary inquiry.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the quality process. The following represent some of the key performance solutions for samples.

Use a Sampling Plan to Schedule Sample Collection   Define both the sampling frequency and sample quantity with the optional sample plan that is set up prior to creating specifications and taking samples. Use the sampling plan with the Sample Creation Notification workflow. Use automatic sample creation when a lot or sublot is yielded to simplify data entry of production sampling in high volume production environments, or at various points in the supply chain.

Reserve a Physical Sample without Testing   Sometimes samples break or leak in transit to the testing facility. If you need the insurance of a replacement sample, then take an extra sample and mark it as Retain or Reserve. You can select reserve sample material during testing of the original sample. Create a Retain As Archive sample. If future testing is required, then change the disposition of this sample to Pending and send it for testing.

Enter Sample Dates to Track the Complete Sample Lifecycle   Manage samples from the moment they are drawn and stored to when they are retrieved for testing. You can enter additional dates for when analysis is required and when the sample expires. This helps you manage lab activities and ensures proper sample disposal.

Set a Lot Retest/Expiry Indicator to Indicate the Purpose of Retesting   The Lot Retest indicator is included on the Sample record to identify the purpose of retest as a lot retest or expiration test. A notification is sent to create a sample based on lot retesting or lot expiration requirements.

Track Sample Quantities and Storage Locations   Track remaining sample quantities on the Samples Summary window based on the actual test quantities recorded. Use the Sample Storage Summary inquiry to track the physical storage warehouse and location for all your samples.

Understanding Sampling

Acceptance sampling supports quality inspection of materials during various points in the supply chain. This includes sample collection at events such as receiving, batch creation, batch step release, production yield, and lot expiration. Sampling inspection also occurs for material received from suppliers, for work in process material, for inventory, for specific customers, and for shipments. Samples are also created as part of a stability study for a particular item. Samples are sent to a quality laboratory organization for testing. You can take multiple samples from the same source, and their collective disposition can be used to control and update other processes in the supply chain. Samples can be taken to monitor environmental conditions of locations or resources used for material storage.

Refer to "Setting Up Sampling Plans" for a discussion of the sampling plan.

Defining a Sample Numbering Scheme

You can set up a manual or automatic document numbering scheme for samples. When automatic sample numbering is enabled and the Sample record is saved, a sample number is generated as a noneditable sequential number prefixed by the organization code, which can represent the plant where a production sample is taken.

Defining and Applying Sampling Plan

Sampling methodologies are definable and maintainable using a sampling plan. The sampling plan lets you define the number of required, reserved, and archived samples. It also lets you specify the sample quantity and sampling frequency. Set up the optional sampling plan prior to creating specifications and samples. It becomes effective for an item, and optionally for a grade, when it is associated with a Specification Validity Rule. When a specification is associated to a sample, some data from the sampling plan defaults into the sample record:

- Sample quantity
- Number of samples required

Refer to "Setting Up Sampling Plans" for more information.

Creating an Item Sample

The sampling process can be performed whether the Sample Creation Notification workflow is enabled or disabled. Following are the conditions:

Sample Creation Notification Workflow is Activated   You receive a notification to take samples when the Specification Validity Rule in effect requires sampling for an event. The notification window displays details of the applicable sampling plan, if one is defined.

If a batch creation triggered a sample notification, then the batch number defaults as the sample source information. Optionally, enter the batch step where the sample was taken if this information is not entered by default, then save the sample.

Once testing is complete, results are entered against the sample. Enter or update additional sample details such as sample expiration date and time and the storage warehouse and storage location on the sample record.

When a batch is terminated, the sample creation workflow notifications that are open are canceled. Manage any samples that are created against the batch.

Sample Creation Notification Workflow is Not Activated   Determine the material to sample. This includes items that require retesting and items that require evaluation of their expiration dating. Refer to "Reports and Inquiries" for reports to run that assist in this process. When the Sample Creation Notification workflow is not enabled, create a sample directly using the Item Samples window.

Recording Sample Expiration Date

Record the sample expiration date and time to indicate sample shelf life. The sample expiration date and time defaults to the corresponding lot expiration date. This date is stored for informational purposes, and used as a reminder to complete required testing, and properly dispose of the sample.

Grouping Samples

Samples that originate from the same source or business event can be grouped together as a sample group so that the composite of their results can be reported or used to control inventory, production, receiving, shipping, and allocation processes.

If samples are not created using the workflow, then they can still be grouped by the Get Spec function that associates the same specification and version to these samples. Refer to "Appendix C" for the hierarchies used. The specification validity rule for this specification and version identifies the sampling plan where the required sample count is number of samples required in the sample group. When a new sample and sample group are created and a sampling plan is not specified in the specification validity rule, then the number of samples required in the sample group (and reflected in the sample record) is one.

By default, when you click Get Spec or save the sample record the application groups samples associated to the same specification and version until the sample group has a final disposition. For example, if the sampling plan requires three samples, then the first sample record has a sample instance of one of the three samples required. Each time a sample is added to a sample group, the total samples required increases by one, and each new instance is numbered appropriately in the series. When you use the Get Spec function, you can also create a new sample group instead of adding the new sample to an existing sample group.

The Get Spec function retrieves item specifications for item samples and monitoring specifications for monitoring samples. You can continue to add samples to a sample group while the sample group disposition is Pending, In Progress, or Complete. Samples with a disposition of Complete revert to In Progress when you add a test.

Understanding Retained, Archive, and Reserve Samples

Following is a discussion that describes the differences among retained, archive, and reserve samples:

Retained Sample   A Sample Disposition of Retain identifies that a sample is stored for possible future testing. Retained samples can be used as a control group for subsequent samples that have been tested against the same sample source. Samples drawn from the same source can be separated into aliquots, or fractional samples. These samples can be used for standard quality testing, archived into storage for investigative or forensic testing, or reserved as a backup for possible future testing. A retained sample is classified by its use or type.

Retained samples can be submitted for analysis later according to the specification assigned to the sample group. You can change the sample disposition of a standard testing sample from Retain to Pending to indicate that analysis is expected, and initiate the optional OPM Quality Test notification workflow if it is enabled. For example, a stability sample is created and put into storage. Later, it is pulled for time point testing according to an item specification. Samples with a disposition of Retain are not available for entry of results until the sample disposition is changed to Pending. You cannot change the disposition of a tested sample to a disposition of Retain.

The samples for archive and reserve use do not contribute to the total number of samples required in a sample group based on a sampling plan. Therefore, it is important to distinguish these samples for traceability purposes. A standard testing sample is created based on the sampling plan definition.

Archive Samples   The archive sample can be used to research a market complaint. This sample is stored immediately in sample archives without any default specification assignment or initial testing. When analyzed, you can select the specification or add tests manually to an archive sample. The archive sample can progress through the existing sample dispositions (Pending, In Progress, Complete, Accept, Accept with Variance, Reject, or Cancel), but it remains in an archived state without any of the subsequent updates to inventory and production based on the specification validity rule.

- Requirements for setting up archive samples:

  - Set up document numbering for samples (SMPL) in the creation organization where samples are taken. Required.

  - Define a sampling plan. Optional.

  - Create and approve item specifications and specification validity rules. Optional.

- To use archive samples:

  1. Create an item sample retained as an archive sample. Optionally, associate it to a specification with a sampling plan.

  2. Query the archive sample, change the sample disposition to Pending, and optionally, schedule tests from the associated specification upon request for investigation.

  3. Perform tests, enter results, and change sample disposition when the analysis is complete.

Reserve Samples   This type of retained sample is set aside as additional inventory from the same sample source. A reserve sample can be used as a backup supply of additional testing material when one or more tests need to be repeated due to instrumentation problems or reagent failure. Its quantity is consumed when the original sample for standard quality testing is insufficient to complete all required testing. A reserve sample remains in the Retain sample disposition and can only be changed to a disposition of Cancel. This supports the recording of results that are performed against a reserve sample, but reported against the original sample for standard quality testing.

- Requirements for setting up reserve samples:

  - Set up document numbering for samples (SMPL) in the creation organization where samples are taken. Required.

  - Define a sampling plan. Optional.

- Create and approve item specifications and specification validity rules. Optional.

- To use reserve samples:

    1. Create item samples in the same sample group as a required sample, and retain an additional sample as the reserve sample. Optionally, associate these samples to a specification with a sampling plan.

    2. Enter results against the required sample. When the remaining sample quantity of the required sample is insufficient for continuing analysis, select the reserve sample for the test where an additional testing quantity is needed, and enter results.

    3. Change the sample disposition of the required sample when analysis is complete.

Understanding Automatic Sample Creation

Automatic sample creation simplifies data entry and integrity when sampling in high volume production environments, or at various points in the supply chain. When you set up automatic sample creation, the application creates planned sample records with the default sample group information such as batch, item, and optional lot and sublot. This is based on a business event in the application. Existing business events that can trigger the sample creation workflow include lot expiration and retest, inventory adjustment, batch or batch step creation, batch step release, and receiving material into inventory or a receiving location. Automatic sample numbering and the sampling plan information such as sample count, sample quantity, and UOM, provide the information to create several sample records simultaneously, and associate these samples to a sample group. The application can create required, archive, and reserve sample record types. When samples are taken physically, you can update the planned sample records with details that include the actual sample quantity taken, date drawn, and sample expiration date.

Responsibilities: Workflow Administrator Event Manager, AME Application Administrator, Quality Manager

- Setting up for automatic sample creation:

    - Select the Quality System Parameter for Create Samples Automatically.

    - Set up automatic document numbering for samples (SMPL) in the creation organization. Required.

    - Enable the business event that triggers automatic sample creation. Required.

- Set up the quality workflow for notification of planned samples created by the system. Optional.

- Define a sampling plan. Required.

- To use automatic sample creation:

  1. Create an item specification with a specification validity rule that has Automatic Sample Creation enabled and a sampling plan associated.

  2. Trigger the business event (for example, create inventory, create a batch, release a batch step, receive into a receiving location or inventory).

  3. Perform one of the following:

     - Open the workflow notification

     - Query the sample group through the Quality Workbench, Samples Summary, or Sample Groups window to view the planned samples created by the application.

  4. Take physical samples by changing the sample disposition from Planned to Pending or Retain. Enter the actual sample quantity and date drawn.

Determining Sample Disposition Manually

Assign a control sample disposition manually, by responsibility, when the Sample Creation Notification workflow is not enabled. To assign a new disposition, select Change Disposition from the Actions menu on the Samples window. The following summarizes sample disposition change possibilities:

- Change from Planned to:

  - Pending

  - Retain

  - Cancel

- Change from Pending to:

  - Cancel

  - Retain prior to the sample being saved.

- Change from Retain to:

  - Pending in anticipation of sample analysis.

  - Cancel to terminate analysis.

- Change from In Progress to:
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Complete to:
  - Accept if results are recorded and acceptable, and sample results are within the limits of the specification.
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Accept to:
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Accept with Variance to:
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Reject to:
  - Cancel to terminate additional analysis.

Changing Disposition and Compositing Results for a Sample Group

An item sample group contains one or more samples that share the same organization, item, and source, and optionally, the same lot and sublot. Tie the sample group to a specification and specification validity rule at the Item Samples window for the first sample created. This must be done before assigning a sample group disposition or creating composite results.

Using the Sample Storage Summary Inquiry

The Sample Storage Summary inquiry lets you find item samples based on their storage warehouse and storage location. The Item Inquiry window in the OPM Inventory Control application is used to find the sample storage location based on the item and lot number.

Accounting for Sample Quantity Drawn from a Batch

This feature reflects the sample quantity taken from a batch by modeling the sample as a batch byproduct. An inventory transaction for this sample byproduct is created automatically based on the reason code defined on the Quality System Parameters window.

Responsibilities   Formulator, Process Engineer, Production Supervisor, Quality Manager

Prerequisites

- Configure the Quality System Parameter for Inventory Transaction Reason.

- Set up an item for the material to be sampled from the batch.

To update the batch with the sample quantity:

1. Create a formula by entering the item to be sampled as a byproduct formula line.

   - Set the byproduct quantity equal to the quantity you plan to take as a sample.

   - Set the Yield Type to Manual, and the Byproduct Type to Sample.

2. Change the status of the formula to Approved for General Use.

3. Create a recipe that contains the formula.

4. Create a recipe validity rule for the recipe and the plant in which you will run the batch.

5. Change the status of the recipe and the status of the recipe validity rule to Approved for General Use.

6. Create and approve a specification for the item.

7. Create and approve a WIP specification validity rule, specifying the recipe, formula, and formula line at which the sample byproduct is yielded. Make sure the Update Inventory Quantity indicator is selected

8. Create a batch from the recipe. If the Sample Creation Notification workflow is enabled, the system prompts for the creation of the WIP sample when the batch is created.

9. Release the batch.

10. Create a sample for the item in the batch. An inventory transaction is created for the byproduct line in the batch. If the Sample Creation Notification workflow is not enabled, then you can use the Get Spec function to tie the sample record to the applicable WIP specification validity rule for the sample byproduct line in the batch.

Terminating Batches

When a batch is terminated, the sample creation workflow notifications that are open are canceled. Manage any samples that are created against the batch.

Creating Stability Study Samples

Stability study sample records are created by the application when the planned stability study is approved. These samples are based on the:

■ Number of samples per time point

■ Number of retained samples for a variant

■ Sample quantity and UOM defined for a variant

These system-generated item samples are automatically associated to a stability study as identified by the sample source fields. You cannot create stability samples manually through the Samples window.

Creating a Monitoring Sample

You create a monitoring sample on the Monitoring Samples window. Monitoring samples are taken to check the acceptability of environmental conditions for each variant storage condition in a stability study. You take these samples for tests defined in a monitoring type specification. Refer to "Understanding Specifications" for additional information.

Entering Item Samples

The Item Samples window lets you create samples from the following sources:

- Inventory
- WIP
- Supplier
- Customer

Refer to the "Understanding Sampling" topic for an explanation of sampling.

Note: You cannot create stability study samples from this window, however you can query a sample with the Stability Study source from this window. Refer to the "Stability Studies" topic for additional information. You cannot create monitoring sample from this window. Refer to the "Entering Monitoring Samples" topic for additional information.

Using the Item Samples Window with Sample Creation Notification Workflow Activated

A sample group is created by a transaction event such as a receiving transaction, or an inventory transaction. If the Item Samples window is accessed from the Sample Creation Notification workflow, then the Item Samples window displays the following information:

- Organization
- Specification and version
- Source data, depending on where the sample is created
- Item and optional grade
- Date drawn
- Default for Update Inventory Quantity box, based on the Specification Validity Rule
- Priority as Normal
- Disposition as Pending

If a sampling plan is associated to the specification validity rule in effect, then Retain As, Sample Quantity, UOM, and Samples Required fields also default in the Item Samples window. Enter the following information:

- Sample, unless automatic sample numbering is enabled

- Sample Description

- Lot and sublot, unless defaults are available from the sample group

- Quality Laboratory

- External ID

- Storage Expiration date and time

- Storage Warehouse

- Storage Location

Change updateable fields and save your work.

Using the Item Samples Window with Sample Creation Notification Workflow Inactivated

When you enter a Specification, the Update Inventory Quantity box is set to the entry on the Specification Validity Rule. The Item Samples window displays the following information:

- Disposition is Pending

- Source defaults to Inventory

- Update Inventory Quantity box is cleared

- Sample Priority defaults to Normal

Enter the following minimum required information:

- Sample, unless automatic sample numbering is enabled

- Sample Description defaults from the item entered

- Retain As an Archive, Reserve, or required sample

- Source

- Lot and Sublot, for lot and sublot controlled items unless marked Optional on the Quality System Parameters window

- Quantity

- UOM

- Date Drawn, which defaults to the current date and time

Change updateable fields and save your work.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, attachments, and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*.

Prerequisites

❑ Set up a quality lab organization where sample testing is performed. Optionally, set up the GMD: Default Lab Organization profile option.

❑ Set up Quality System Parameters for required indicators and configurations including Update Inventory Quantity, Lot Optional for Sample, manual specification selection, and the document numbering for automatic or manual sample numbering.

❑ Enter tests, and optionally create a specification for sampling.

❑ Optionally, enter a sampling plan.

❑ Optionally, set up and activate the Sample Creation Notification workflow.

▶ To enter an inventory sample:

1. Navigate to the **Item Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.

3. Enter the **Disposition** as the sample status:

- **Planned** when the sample is scheduled for testing.

- **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

- **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

- **Cancel** when the sample is canceled.

  Required.

  Refer to the "Understanding Sampling" topic for an explanation of how to change sample disposition.

4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.

5. Enter **Retain As** to indicate whether the sample type is an Archive, Reserve, or required sample.

6. Enter the **Item** sampled. A description of the item entered displays. Required.

7. Enter the sample item **Lot** code. This field is editable if the item entered is lot controlled. Lot is not required if marked as optional for samples on the Quality System Parameters window.

8. Select the sample **Source** as **Inventory**.

9. Enter the sample item **Sublot** code. This field is editable if the item you specified is lot and sublot controlled. Sublot is not required if Lot is marked as optional for samples on the Quality System Parameters window.

10. Enter the **Warehouse** where the item sampled is located.

11. Enter the **Location** if the warehouse and item are location controlled. Required if the item and warehouse are location controlled.

12. **Lot Retest** is selected if the sample is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is running.

Note: If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. If any sample source fields (Lot, Sublot, Warehouse, or Location) are changed, then the Spec, Version, and Grade fields are cleared. You can also save a sample without having a specification associated to it.

---

13. Click **Get Spec** to associate a specification for this sample.

14. The Specification Association dialog box displays.

15. Select one of the following:

- **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

- **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

16. Click **OK** to continue.

17. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

18. **Version** displays the version of the specification selected.

19. **Grade** displays the grade associated to the item specification.

Identity

20. Enter the sample **Quantity** and its inventory **UOM**. The UOM must be either the item primary UOM, or another UOM with a valid conversion. This value defaults from the quantity entered on any associated sampling plan. Required.

21. **Remaining Quantity** displays the balance of sample remaining after the actual test quantities are deducted at the time of result entry.

22. Enter **Date Drawn** as the date and time the sample was taken. This field defaults to the current system date and time. Required.

23. **Date Retrieved** displays the date and time the sample was pulled from storage for testing by the quality laboratory.

24. Enter **Date Received** as the date and time the sample was received for testing by the quality laboratory.

25. Enter **Date Required** as the date and time when the sample analysis must be completed.

26. Enter a **Priority** for the sample as:

    - **Normal** to indicate that the sample has the usual processing requirements.

    - **Low** to indicate that the sample has minimal urgency for processing.

    - **High** to indicate that the sample has urgent processing requirements.

27. **Update Inventory Quantity** is selected if it is also selected on the associated Specification Validity Rule. You can change this default. When Update Inventory Quantity is selected, an inventory transaction deducts the sample quantity from the item onhand inventory balance when you save the sample.

28. **Sample Instance** displays the sample iteration with respect to the total number of samples in the sample group based on the samples taken.

29. **Samples Taken** displays the total number of samples already taken for the sample group. The position of this sample is indicated.

30. **Samples Required** displays the total number of samples required in the sample group based on the sampling plan requirement.

Storage

31. Enter the **Quality Laboratory** as the organization where the sample is tested. This defaults from the GMD: Default Lab Organization profile option. You can change this default to another lab organization. The Quality Laboratory defaults for every test assigned to the sample when you enter results.

32. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system. This field is for informational purposes only.

33. Enter **Expiration** date and time for the sample. This defaults to the lot expiration date if a lot is entered.

34. Enter **Storage Warehouse** as the warehouse where remaining sample quantity is stored. You can query item samples by storage warehouse and location using the Sample Storage Summary inquiry.

35. Enter a **Storage Location** for the sample. If the sample storage location is:

   ■ Validated, then a valid location must be entered for the specified storage warehouse. The LOV displays valid locations for the Storage Warehouse entered.

   ■ Nonvalidated, then you do not have to specify a valid location for the specified storage warehouse. Enter a storage location in this field, however there is no LOV.

   This field is protected from entry if the storage warehouse is not location controlled. Required if a Storage Warehouse is entered.

Approvers

> **Note:** If you intend to set up workflow and Oracle E-Records events against samples, then do not enter Sampler, Sample Approver, or Inventory Approver. Refer to "Appendix E" for additional information.

36. Enter the **Sampler** as a code for the individual who withdrew the sample. The name of the individual appears in the field next to this code. This field defaults to the current user.

37. **Sample Approver** displays the individual who is responsible to approve the sample. You cannot update this field.

38. **Inventory Approver** displays the individual who can approve the item to be released to production. You cannot update this field.

Composite Results

39. If the sample belongs to a sample group with composited results, then the Composite Results tab is enabled. The following fields are display only:

   ■ **Specification** indicates the specification name used for the composite results.

   ■ **Version** indicates the specification version used for the composite results.

   ■ **Grade** indicates the grade defined by the specification displayed.

■ **Validity Rule Use** indicates the type of validity rule in use to composite the results.

■ **Date Composited** indicates the date and time the composite results were saved.

■ **Disposition** indicates the disposition of the sample based on the composite results.

40. Click **View** to display the **Composite Results** window for this sample. This option may not be available to your responsibility.

Spec Disposition

41. If the specification associated to the sample was replaced through specification comparison, then the history of sample dispositions against each specification is displayed. The following fields are display only:

■ **Specification** indicates the specification name associated to the sample.

■ **Version** indicates the specification version.

■ **Grade** indicates the grade assigned to the specification displayed.

■ **Disposition** indicates the disposition of the sample with respect to the specification displayed.

■ **Disposition Date** indicates when the sample was assigned the disposition.

■ **Validity Rule Use** indicates the type of specification validity rule used.

■ **Control Lot Attributes** indicates if a lot status, and optionally a grade is dependent on the specification displayed.

Comments

42. Enter **Comments** for the sample.

43. Save the window.

▶ To enter a WIP sample:

1. Navigate to the **Item Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample number until the record is saved, at which point a sample number is assigned.

Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.

3. Enter the **Disposition** as the sample status:

   ■ **Planned** when the sample is scheduled for testing.

   ■ **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

   ■ **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

   ■ **Cancel** when the sample is canceled.

   Required.

   Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.

5. Enter **Retain As** to indicate whether the sample type is an Archive, Reserve, or required sample.

6. Enter the **Item** sampled. A description of the item entered displays. Required.

7. Enter the sample item **Lot** code. This field is editable if the item entered is lot controlled. Lot is not required if marked as optional for samples on the Quality System Parameters window.

8. Select the sample **Source** as **WIP**.

9. Enter the sample item **Sublot** code. This field is editable if the item you specified is lot and sublot controlled. Sublot is not required if Lot is marked as optional for samples on the Quality System Parameters window.

10. Enter **Batch** as the batch number for the WIP sample.

    If the sample is created through the Sample Creation Notification workflow, then the following is required for the sample source:

    ■ Batch number

    ■ Routing number and version

    ■ Recipe number and version

    ■ Operation number

- Formula number and version

If the sample is created manually, then one of the following is required for the sample source:

- Batch number

- Recipe number and version

11. **Recipe** displays the recipe used in the batch and its Version if a laboratory batch is entered. The recipe defaults from the batch number if the batch number is entered.

12. **Routing** displays the routing used in the batch and its **Version**. If a batch is entered, then routing and routing version default from the batch. If a valid recipe is entered, then the routing associated to the recipe displays. You cannot change these fields.

13. **Step** displays the routing step, if it is applicable. You can also enter the batch step for the batch entered. You can edit this field.

14. **Charge** displays the charge controlled by the listed specification. You can edit this field.

15. **Operation** and **Version** display the operation and version associated to the routing and step displayed. These fields are blank if no routing and step are entered.

16. **Formula** and **Version** display the formula and version associated to the specification displayed. These fields do not display if a recipe and routing are entered.

17. Enter **Formula Line** as the line sequence for the item listed in the formula.

18. **Type** defaults from the formula line entered, and indicates the type of consumption or yield that is applicable to the formula line.

Note: If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. You can also save a sample without having a specification associated to it.

---

19. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.

20. Select one of the following:

- **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

- **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

21. Click **OK** to continue.

22. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

23. **Version** displays the version of the specification selected.

24. **Grade** displays the grade associated to the item specification.

Note: The Identity, Storage, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

---

25. Save the window.

◗ **To enter a supplier sample:**

1. Navigate to the **Item Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample

number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.

3. Enter the **Disposition** as the sample status:

    ■   **Planned** when the sample is scheduled for testing.

    ■   **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

    ■   **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

    ■   **Cancel** when the sample is canceled.

    Required.

    Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.

5. Enter **Retain As** to indicate whether the sample type is an Archive, Reserve, or required sample.

6. Enter the **Item** sampled. A description of the item entered displays. Required.

7. Enter the sample item **Lot** code. This field is editable if the item entered is lot controlled. If you did not select Lot Optional on Samples on the Quality System Parameters or Specification Validity Rules windows, then this field is mandatory for a lot controlled item.

8. Select the sample **Source** as **Supplier**.

9. Enter the sample item **Sublot** code. This field is editable if the item you specified is lot and sublot controlled. Sublot is not required if Lot is marked as optional for samples on the Quality System Parameters window.

10. Enter the **Supplier** number. Required.

11. **Supplier Site** displays the applicable supplier site code.

12. Enter the sample **Supplier Lot** code. This field is editable if the item entered is lot controlled.

13. Enter the **PO Number** as the purchase order number and **Line** as the line on the purchase order.

14. Enter the **Receipt** number and receipt **Line** number.

15. Enter the **Receiving Warehouse** for the material.

16. Receiving **Location** for the material.

Note: If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. If any sample source fields (Lot, Sublot, Warehouse, or Location) are changed, then the Spec, Version, and Grade fields are cleared. You can also save a sample without having a specification associated to it.

---

17. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.

18. Select one of the following:

- **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

- **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

19. Click **OK** to continue.

20. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

21. **Version** displays the version of the specification selected.

22. **Grade** displays the grade associated to the item specification.

Note: The Identity, Storage, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

---

23. Save the window.

▶ **To enter a customer sample:**

1. Navigate to the **Item Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.

3. Enter the **Disposition** as the sample status:

   ■ **Planned** when the sample is scheduled for testing.

   ■ **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

   ■ **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

   ■ **Cancel** when the sample is canceled.

   Required.

   Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.

5. Enter **Retain As** to indicate whether the sample type is an Archive, Reserve, or required sample.

6. Enter the **Item** sampled. A description of the item entered displays. Required.

7. Enter the sample item **Lot** code. This field is editable if the item entered is lot controlled. Lot is not required if marked as optional for samples on the Quality System Parameters window.

8. Select the sample **Source** as **Customer**.

9. Enter the sample item **Sublot** code. This field is editable if the item you specified is lot and sublot controlled. Sublot is not required if Lot is marked as optional for samples on the Quality System Parameters window.

10. Enter the **Customer** name. Required.

11. Enter the **Operating Unit**. The operating unit must have an OPM fiscal policy to indicate that it is used for Process Manufacturing.

12. Enter one or both of the following fields only if you enter an operating unit:

    ■ **Ship-To** to indicate the ship-to location for the specified customer and operating unit.

    ■ **Order** to indicate the order number. If you enter an order number, then **Type** displays the sales order type code from those set up for the operating unit in the Oracle Order Management application. This field displays if an order is specified.

    If you did not enter an operating unit, then leave both of these fields blank.

13. Enter the **Line** associated to the order.

Note: If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. You can also save a sample without having a specification associated to it.

---

14. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.

15. Select one of the following:

    ■ **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

    ■ **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable

specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

16. Click **OK** to continue.

17. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

18. **Version** displays the version of the specification selected.

19. **Grade** displays the grade associated to the item specification.

Note: The Identity, Storage, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

---

20. Save the window.

▶ **To view a stability study sample:**

You cannot enter a stability study sample on the Item Samples window. However, you can display information about it.

1. Navigate to the **Variants** window.

2. Query the stability **Study** with the desired sample.

3. Select the variant **Num** that has the sample to view.

4. Click **Time Points**. The **Variant Time Point** window displays.

5. Select the **Time Interval** that has the sample to view.

6. Click **Samples**. The **Samples Summary** window displays.

7. Select the sample to view.

8. Click **View Sample**.

9. The **Item Samples** window displays the desired variant time point sample.

10. The following fields are display only:

   - **Sample** is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then New appears as the sample number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Required.

   - **Disposition** displays the sample status or disposition as:

     – **Planned** when the sample is scheduled for testing.

     – **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

     – **In Progress** when at least one result exists for the sample, but testing is not yet complete.

     – **Complete** when testing of all required tests and all additional tests is complete.

     – **Accept** when sample testing is complete, and results are in-specification.

     – **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.

     – **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.

     – **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

     – **Cancel** when the sample is canceled.

   - **Description** displays a description of the time point sample for the sample.

   - **Retain As** indicates whether the sample type is an Archive, Reserve, or required sample.

   - **Item** displays the item sampled and its description.

- **Lot** is the item lot.

- **Source** is **Stability Study**.

- **Study** is the organization and study number.

- **Sublot** is the item sublot.

- **Variant** displays the variant sampled.

- **Time Point** displays the variant time point sampled.

- **Scheduled** displays the date and time the sample is scheduled for testing.

> **Note:** The Identity, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

Storage

- **Quality Laboratory** displays the organization where the variant time point sample is tested.

- **External ID** displays an alternate or cross-reference code for the variant time point sample if the sample is recorded on another test database. You can enter this field if the sample is processed under an ID that is different from the one displayed on this window.

- **Expiration** displays the variant time point sample expiration date and time.

- **Storage Warehouse** displays the storage warehouse for the variant time point sample.

- **Storage Location** displays the for the variant time point sample.

- **Resource** displays the storage resource specified on the storage condition plan for the variant time point sample.

- **Instance** displays the specific resource instance identified for the storage condition specified in the monitoring specification for the variant time point sample.

11. Close the window.

▶ **To mark a sample for deletion:**

Choose Mark for Purge from the Actions menu. The sample is marked for deletion.

▶ **To edit text:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To change sample or sample group disposition:**

1. Choose **Change Disposition** from the **Actions** menu.

2. Enter the new sample disposition.

3. If the current sample completes testing for the entire sample group, then you can enter these additional fields if the **Control Lot Attributes** indicator is selected on the specification validity rule:

   ▪ Enter **Change Lot Status To** as the new or revised lot status.

   ▪ Enter **Change Grade To** as the new or revised grade.

   ▪ Enter **Reason Code** as a valid reason code for the change.

4. Enter **Hold Date** as the new or revised lot hold release date.

5. Select the recommended test results to store the lot-specific UOM conversion factors if **Calculate UOM Conversion** is selected on tests from the associated specification. Refer to "Using Lot UOM Conversions Based on Quality Results" for additional information.

6. Save the window.

▶ **Using a retained sample for testing:**

1. Query the sample with the disposition **Retain**.

2. Change the sample disposition to **Pending**. Retain As Reserve samples cannot be changed to a sample disposition of Pending. They are used when testing against a required sample.

3. Navigate to the **Results** window to enter results for the sample when they become available.

▶ **To display the Results window:**

You can choose Results from the Actions menu, or click Results to display the Results window.

◗ **Managing samples for terminated batches:**

When a batch is terminated, the sample creation workflow notifications that are open are canceled. Manage any samples that are created against the batch.

Entering Monitoring Samples

The Monitoring Samples window lets you create a sample against a location or resource using the monitoring specification that is associated to it. The monitoring sample provides the information needed to evaluate the acceptability of environmental conditions for each variant storage condition in a stability study. You take these samples for tests defined in a monitoring specification. A monitoring sample is defined for:

- Organization, warehouse, location to monitor a specific storage location that needs to maintain a defined quality environment. For example, define FREEZER as a location in warehouse WH1 to sample its temperature and humidity.

- Organization, resource, resource instance to monitor a specific storage resource that needs to maintain a defined quality environment. For example, define the resource CHAMBER, and the resource instance SERIALNUM-1000 to identify the specific environmental chamber used in a stability study.

Prerequisites

❏ Enter tests, and create a specification for sampling.

❏ Set up document numbering for the organization in which you take samples.

❏ Optionally, enter a sampling plan.

❏ Optionally, set up and activate the Sample Creation Notification workflow.

❏ Monitoring samples cannot have a disposition of Retained.

▌ To enter a location monitoring sample:

1. Navigate to the **Monitoring Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples used in a stability study. Required.

3. Enter the **Disposition** as the sample status or disposition as:

   - **Planned** when the sample is scheduled for testing.

> - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
>
> - **Cancel** when the sample is canceled.
>
> Required.
>
> Refer to the "Understanding Sampling" topic for an explanation of how to change sample disposition.

4. Enter a **Description** for the monitoring sample.

5. Select the sample **Source** as **Location**. Required.

6. Enter the **Warehouse** for the monitoring sample.

7. Enter the **Location** in the warehouse for the monitoring sample.

8. Click **Get Spec** to retrieve the specification for this sample. The Specification Association dialog box displays.

9. Select one of the following:

   - **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

   - **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

10. Click **OK** to continue.

11. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

12. Version displays the version of the specification selected.

Identity

13. Enter **Date Drawn** as the date and time the sample was taken. This field defaults to the current date and time.

14. Enter **Date Received** as the date and time the sample was received for testing.

15. Enter **Date Required** as the date and time when the sample is required to be taken.

Storage

16. Enter the **Quality Laboratory** as the organization where the sample is tested.

17. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system. This field is for informational purposes only.

18. Save the window.

▌ **To enter a resource monitoring sample:**

1. Navigate to the **Monitoring Samples** window.

2. Enter the **Sample**. The sample number is a combination of the four-letter Organization code and a number. The organization is a laboratory or plant organization where the sample is drawn. If automatic sample numbering is selected, and the sample is a new record, then **New** appears as the sample number until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples used in a stability study. Required.

3. Enter the **Disposition** as the sample status:

- **Planned** when the sample is scheduled for testing.

- **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

- **Cancel** when the sample is canceled.

Required.

Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the monitoring sample.

5. Select the sample **Source** as **Resource**. Required.

6. Enter the **Resource** for the monitoring sample.

7. Enter the resource **Instance** for the monitoring sample.

    Refer to the "Defining Plant Resource Parameters" topic in the *OPM Capacity Planning User's Guide* for detailed information on entering resource information linked to the resource instance that identifies it.

8. Click **Get Spec** to retrieve the specification for this sample. The Specification Association dialog box displays.

9. Select one of the following:

    ■   **Use Default** displays the specification, version, and grade having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix C.

    ■   **Use Alternate** to select a specification that is different from the default specification for the sample. You can select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

Note: The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Clear Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

---

10. Click **OK** to continue.

11. **Specification** displays the effective default specification that best matches the sample source information, or the alternate you selected.

12. **Version** displays the version of the specification selected.

Identity

13. Enter **Date Drawn** as the date and time the sample was taken. Defaults to the current date and time.

14. Enter **Date Received** as the date and time the sample was received for testing.

15. Enter **Date Required** as the date and time when the sample is required to be taken.

Storage

16. Enter the **Quality Laboratory** as the organization where the sample is tested.

17. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system. This field is for informational purposes only.

18. Save the window.

▶ **To mark a sample for deletion:**

Choose Mark for Purge from the Actions menu. The sample is marked for deletion.

▶ **To edit text:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To change sample or sample group disposition:**

1. Choose **Change Disposition** from the **Actions** menu.

2. Enter the new sample disposition.

3. Save the window.

▶ **To display the Results window:**

You can choose Results from the Actions menu, or click Results to display the Results window.

Finding Samples

The Find Samples dialog box lets you find a sample by item, disposition, priority, source, date and time drawn, specification, grade, quality laboratory, storage warehouse and location, or external ID.

Prerequisites

❏ Enter and save a sample.

▶ To find an item sample:

1. Navigate to the Find Samples dialog box.

2. Enter any of the following to narrow your search:

   - **Sample** code as the combination of the four-letter organization code and sample document number.

   - **Item** code as the item associated to the sample.

   - **Lot** as the sample lot, if the item is lot controlled.

   - **Sublot** as the sample sublot, if the item is sublot controlled.

   - **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, Retain, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.

   - **Retain As** to indicate whether the item sample was retained as an Archive or Reserve sample.

   - **Priority** of the sample as Normal, Low, or High. If you leave this field blank, then it does not include sample priority in the search.

3. Select one of the following as sample **Source**:

   - **Customer** to indicate that the sample source is for a customer sample. Enter Customer, Operating Unit, Ship-To, Order, and Line.

   - **Inventory** to indicate that the sample source is for an inventory sample. Enter Warehouse and Location.

   - **Supplier** to indicate that the sample source is for a supplier sample. Enter Supplier, Supplier Site, Supplier Lot, Purchase Order number and Line, and Receipt and Line.

   - **Stability Study** to indicate that the sample source is for a stability study sample.

■ **WIP** to indicate that the sample source is for a work in process sample. Enter Batch, Recipe and its Version, Routing and its Version, Step, Charge, Operation and its Version, and Formula and its Version.

The fields listed in this step for each source type are described in the "Entering Samples" topic.

4. To narrow the search to a specific time interval that samples were drawn:

   ■ Enter the **Date Drawn From** field as the starting date and time for the search.

   ■ Enter the **To** field as the ending date and time for the search.

5. Enter the **Specification**, its **Version**, and an optional **Grade** for the search.

6. Enter the **Quality Laboratory** for sample processing.

7. Enter the **Storage Warehouse** for the sample.

8. Enter the **Storage Location** for the sample.

9. Enter the **External ID** for the sample.

10. Select **Marked for Deletion** as:

    ■ **Yes** to find samples that are marked for deletion.

    ■ **No** to find samples that are not marked for deletion.

    ■ Leave this field blank if you do not want to limit your search based on whether a sample is marked for deletion.

11. Click **Find**. The **Item Samples** window displays the results of the search.

▌ **To find a monitoring sample:**

1. Navigate to the Find Samples dialog box.

2. Enter any of the following to narrow your search:

   ■ **Sample** code as the combination of the four-letter organization code and sample document number.

   ■ **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, Retain, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.

   ■ **Priority** of the sample as Normal, Low, or High. If you leave this field blank, then it does not include sample priority in the search.

3. Select one of the following as sample **Source**:

   ■ **Location** to indicate that the sample source is for a location sample. Enter the **Warehouse** and **Location**.

   ■ **Resource** to indicate that the sample source is for a resource sample. Enter the **Resource** and **Resource Instance**.

   The fields listed in this step for each source type are described in the "Entering Samples" topic.

4. To narrow the search to a specific time interval that samples were drawn:

   ■ Enter the **Date Drawn From** field as the starting date and time for the search.

   ■ Enter the **To** field as the ending date and time for the search.

5. Enter the **Specification** and its **Version**.

6. Enter the **Quality Laboratory** for sample processing.

7. Enter the **Storage Warehouse** for the sample.

8. Enter the **Storage Location** for the sample.

9. Enter the **External ID** for the sample.

10. Select **Marked for Deletion** as:

    ■ **Yes** to find samples that are marked for deletion.

    ■ **No** to find samples that are not marked for deletion.

    ■ Leave this field blank if you do not want to limit your search based on whether a sample is marked for deletion.

11. Click **Find**. The **Item Samples** window displays the results of the search.

▶ **To enter a new sample from the Find Samples dialog box:**

1. Click **New**. The **Item Samples** window displays.

2. Create a new sample as described in the "Entering Samples" topic.

Displaying Sample Groups

The Sample Groups window lists all existing sample groups that share common sampling information. The query function lets you filter the sample groups of interest. For a selected sample group, you can view or add samples in the sample group. You can create or view composite results for a sample group.

Prerequisites

❏ Create samples.

❏ Complete testing and enter results for the samples.

◗ **To display sample groups:**

1. Navigate to the **Sample Groups** window. The Find Sample Groups dialog box displays.

2. Enter any of the following to narrow your search:

   ■ Sample

   ■ Item

   ■ Lot

   ■ Sublot

   ■ Source

3. Click **Find**. The following fields are display only on the **Sample Groups** window:

   ■ **Source** indicates whether the sample source is Customer, Inventory, Location, Resource, Supplier, Stability Study, or WIP.

   ■ **Creation Date** indicates the date and time of sample group creation.

   ■ **Item** indicates the item sampled and its **Description**.

   ■ **Lot** indicates the lot number sampled, if the item is lot controlled.

   ■ **Sublot** indicates the sublot number of the sample, if the item is sublot controlled.

   ■ **Disposition** indicates the sample group disposition as Planned, Retain, Pending, In Progress, Complete, Accept, Accept with Variance, or Reject.

   ■ **Samples Required** indicates the total number of samples required in the sample group based on the sampling plan requirement.

- **Samples Taken** indicates the total number of samples taken for the sample group based on the sampling plan requirement.

- **Lot Retest** indicates selected if the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.

- **Archived Taken** indicates the total number of archived samples taken.

- **Reserved Taken** indicates the total number of reserved samples taken.

4. The following fields are display only for a customer sample source:

   - **Customer** indicates the name of the customer.

   - **Order** indicates the order number.

   - **Line** indicates the order line number.

   - **Operating Unit** indicates the operating unit.

   - **Ship To Site** indicates the ship to site.

5. The following fields are display only for an inventory sample source:

   - **Warehouse** is the inventory warehouse code.

   - **Location** is the inventory location code.

6. The following fields are display only for a location monitoring sample source:

   - **Warehouse** indicates the warehouse for the monitoring sample.

   - **Location** indicates the location in the warehouse for the monitoring sample.

7. The following fields are display only for a resource monitoring sample source:

   - **Resource** indicates the resource for the monitoring sample.

   - **Resource Instance** indicates the specific instance for the monitoring sample.

8. The following fields are display only for a supplier sample source:

   - **Supplier** is the supplier code.

   - **Supplier Site** indicates the supplier site number.

   - **PO** indicates the purchase order number.

   - **PO Line** indicates the purchase order line.

   - **Supplier Lot** indicates the supplier lot number.

   - **Receipt** is the receipt number.

- **Receipt Line** is the receipt line number.

9. The following fields are display only for a stability study sample source:

- **Study** indicates the stability study name.

- **Variant** indicates the variant for the sample group.

- **Time Point** indicates the time point tested for the sample group.

- **Schedule Date** indicates the scheduled date and time for drawing the sample group based on the stability study scheduled start date.

10. The following fields are display only for a WIP sample source:

- **Batch** indicates the batch document number.

- **Recipe** indicates the recipe used in the batch and its **Version**.

- **Formula** indicates the formula used in the batch recipe and its **Version**.

- **Routing** indicates the routing that is associated to the recipe used in the batch and its **Version**.

- **Operation** indicates the operation in the routing and its **Version**.

- **Line** indicates the formula line that is used in the batch recipe.

- **Step** indicates the step number in the batch.

- **Charge** indicates the charge number in the step.

11. Close the window.

▶ **To add a sample in a sample group:**

1. Select the **Sample Group** to add a sample.

2. Click **Add Sample**. The **Item Samples** or the **Monitoring Samples** window displays, depending on the sample source.

3. Refer to the "Entering Samples" topic for more information on creating a sample.

4. Save the window.

▶ **To view a sample in a sample group:**

1. Select the **Sample Group** that has the sample.

2. Click **View Samples**. The **Samples Summary** window displays.

3. Scroll through the samples to view the sample details.

4. Close the window.

▶ **To create or view a composite results set:**

1. Select the **Sample Group** to composite, or that has existing composite results to view.

2. Click **Composite Results**. The **Composite Results** window displays.

3. Refer to the "Compositing Test Results" topic for information on compositing a results set.

4. Save the window.

▶ **To find a sample group:**

1. Choose **Find** from the **View** menu.

2. Enter any of the following to narrow your search:

   ■ Sample

   ■ Item

   ■ Lot

   ■ Sublot

   ■ Source

   Refer to the "Finding Samples" topic for a discussion of these fields.

3. Click **Find**.

▶ **To select samples for mass entry from the Sample Groups window:**

1. Select the sample group that has the samples you want to process.

2. Click **Mass Results**. The **Mass Results Entry Test Selection** window displays. The **Test** and **Description** display for each test.

3. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.

4. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

5. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the sample group.

6. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

Displaying Sample Summaries from the Navigator

The Samples By... windows let you display summaries of item samples sorted by organization, item, disposition, test, test class, test method, and laboratory.

You can use flexfields and folders with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Enter and save samples.

▶ **To display the Samples By... windows:**

1. Navigate to the **Quality Workbench**.

2. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending or In Progress. Clear this indicator to display item samples with all sample dispositions.

3. Select **View By Organization**, **Item**, **Disposition**, **Test**, **Test Class**, **Test Method**, or **Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.

4. Expand the node, and select the desired **Samples By...** window.

5. Drill down to item samples and results.

6. The following fields are display only on the **Samples By...** windows:

   ■ **Organization** displays the four-letter organization code for the sample.

   ■ **Sample** displays the sample number. This is a combination of the four-letter organization code and a number.

   ■ **Item** displays the code for the material being specified as it is listed on the Item Master.

   ■ **Date Drawn** displays the date and time the sample was taken.

   ■ **Disposition** displays the sample disposition as:

   Pending when the sample is saved, and results are expected, but not yet recorded.

   In Progress when at least one result exists for the sample, but testing is not yet complete.

Complete when testing of all required tests and all additional tests is complete.

Accept when sample testing is complete, and results are in-specification.

Accept With Variance when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.

Reject when sample testing is complete, and results are not acceptable, or out-of-specification.

Retain when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.

Cancel when the sample is canceled.

- **Source** displays **Customer**, **Inventory**, **Monitoring**, **Supplier**, **Stability Study**, or **WIP** to indicate the sample source.

- **Lot** displays the sample lot.

- **Sublot** displays the sample sublot, if the item is sublot controlled.

- **Specification** displays the item specification.

- **Specification Version** displays the item specification version.

- **Grade** displays the grade associated to the item specification.

- **Sample UOM** displays the inventory unit of measure for the sample.

- **Sample Quantity** displays the sample quantity taken.

- **Laboratory Organization** displays the quality laboratory that analyzes the sample.

- **External ID** displays an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database.

- **Source Comment** displays the origin of the material sampled in addition to the sample source.

- **Expiration Date** displays the sample expiration date and time.

- **Storage Warehouse** displays the warehouse where the sample is stored.

- **Storage Location** displays the validated or nonvalidated storage location for the sample.

- **Sampler** displays the code for the individual that withdrew the sample.

- **Sample Instance** displays the sample iteration with respect to the total number of samples in the sample group based on the applicable sampling plan.

- **Samples Required** displays the total number of samples required in the sample group based on the sampling plan requirement.

- **Samples Taken** displays the total number of samples already taken for the sample group. The position of this sample is indicated.

- **Lot Retest** indicates whether the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.

7. Click **View Sample** to display the **Item Samples** window for the selected sample.

8. Click **Create Sample** to display the **Item Samples** window where you can create a new sample.

9. Click **Results** to display the **Results** window.

▶ **To select samples for mass entry from the Samples By... windows:**

1. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending or In Progress. Clear this indicator to display item samples with all sample dispositions.

2. Select **View By Organization**, **Item**, **Disposition**, **Test**, **Test Class**, **Test Method**, or **Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.

3. Expand the **Samples By...** node, and select the desired sample or sample group. The appropriate **Samples By...** window displays.

4. Click **Mass Results Entry** next to all samples that you want to select for entry of mass results. You cannot enter mass results for archive or reserve sample types.

5. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. The **Test** and **Description** display for each test.

6. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.

7. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

8. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the sample group.

9. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

Displaying the Samples Summary Window

The Samples Summary window displays a summary of samples by organization.

You can use flexfields and folders with this window.

Prerequisites
❑ Enter and save samples.

◗ **To display summaries of sample information:**

1. Navigate to the **Samples Summar**y window.

2. The following information is display only:

   ■ Organization

   ■ Sample

   ■ Sample Description

3. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. After selecting appropriate tests, click **Mass Results Entry** to display the Mass Results Entry window where you can enter test results.

4. The following fields are display only:

   ■ **Item** is the sampled.

   ■ **Item Description** is the description on the item master.

   ■ **Date Drawn** is the date and time the sample was drawn.

   ■ **Disposition** is the current sample disposition.

   ■ **Retain As** indicates whether the sample type is an Archive, Reserve, or required sample.

   ■ **Source** is the sample source.

   ■ **Lot** is the sample item lot code.

   ■ **Sublot** is the sample sublot code.

   ■ **Specification** is the specification associated to the sample.

   ■ **Specification Version** is the specification version.

   ■ **Grade** displays the grade associated to the item specification.

   ■ **Sample Quantity** displays the sample quantity taken.

- ■ **Sample UOM** displays the inventory unit of measure for the sample.

- ■ **Remaining Quantity** displays the quantity of sample remaining from the original sample quantity taken.

- ■ **Laboratory Organization** displays the quality laboratory that analyzes the sample.

- ■ **External ID** displays an alternate or cross-reference code for the variant time point sample if the sample is recorded on another test database.

- ■ **Source Comment** displays the origin of the material sampled in addition to the sample source.

- ■ **Expiration Date** displays the sample expiration date and time.

- ■ **Storage Warehouse** displays the storage warehouse for the sample.

- ■ **Storage Location** displays the validated or nonvalidated storage location for the sample.

- ■ **Sampler** displays the code for the individual that withdrew the sample.

- ■ **Sample Instance** displays the sample iteration with respect to the total number of samples in the sample group based on the applicable sampling plan.

- ■ **Samples Required** displays the total number of samples required in the sample group based on the sampling plan requirement.

- ■ **Samples Taken** displays the total number of samples already taken for the sample group. The position of this sample is indicated.

- ■ **Archived Taken** displays the total number of samples taken as archived samples.

- ■ **Reserved Taken** displays the total number of samples taken as reserved samples.

- ■ **Lot Retest** is selected if the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.

5. Additional fields displayed on the window depend on the sample source, and are the same as the source information described in "Entering Item Samples." Refer to this topic for field definitions.

6. Close the window.

▌ **To select samples for mass results entry:**

1. Select the sample group that has the samples to process.

2. Click **Mass Results Entry**. The **Mass Results Entry Test Selection** window displays.

3. The **Test** and **Description** display for each test.

4. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.

5. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

6. Click **Select All** to select all tests, or **Select** the tests you want to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the sample group.

7. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected.

6

Results

This topic provides an overview of quality results, including the process for entering them. You are shown how to composite test results, compare specifications, change quality disposition, and manage expired lots.

The following topics are covered:

- Requirements

- Solutions

- Understanding Results

- Entering Results

- Selecting Samples and Tests for Mass Results Entry

- Using the Mass Results Entry Window

- Displaying Test Details from Mass Results Entry

- Displaying Experimental Errors from Mass Results Entry

- Finding Samples from the Results Window

- Compositing Test Results

- Viewing Samples for Composited Results

- Adding Tests to Composited Results

- Comparing Specifications

- Finding Samples for Specification Comparison

- Changing Quality Disposition

- Associating Results to Another Sample

Requirements

Following are some requirements that customers have for results in Quality Management. The answers are explained in detail in the "Solutions" topic.

Can individuals who perform tests be identified?

Yes. The Results window includes a Tester field for each specific test.

Can test quantities be tracked in testing?

Yes. Manage the remaining sample quantity for testing based on actual test quantities used. Select a reserve sample if additional material is needed.

Can test kit materials be tracked in testing?

Yes. Test kit information is entered on the Results window. You can trace this material to its supplier, lot, and sublot.

Is there a traceable record of external testing providers?

Yes. Identify the lab where the test is done by an internal laboratory, or the test provider where the test is sent to an external laboratory for testing.

Can retesting and resampling activities be enforced?

Yes. Retest and resample actions are designated upon reviewing results, so that a workflow notification can be sent to perform the test, or to take another sample.

Can results be summarized using any statistical methods?

Yes. View the arithmetic mean, standard deviation, median, or range statistics for composite test results of numeric data, and the mode statistic for composite nonnumeric data.

Can lot status of an inspected item be updated automatically?

Yes. When you choose the Control Lot Attributes option, the lot status is updated automatically when all sample results are in-specification, or one of the results is out-of-specification.

Can previously analyzed samples be compared to customer requirements?

Yes. Compare sample results to another quality specification to determine item conformance, and add appropriate tests to meet the specification used for comparison.

Can results be leveraged for adjusting lot-specific unit of measure conversions?

Yes. Select the recommended lot UOM conversions based on results for designated tests.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the quality process. The following represent some of the key performance solutions for results.

Identify Individual Testers Who Perform Tests   The Results window includes a Tester field for each specific test. Each tester must be defined as a valid Oracle user. The application uses the Tester field to sort and group result data for:

- Workflow notifications
- Result entry
- Activities for e-records and e-signatures

Manage Sample Quantity Used in Testing   You can determine the sample quantity remaining after testing, and select a reserve sample to retest when there is insufficient or questionable material available.

Identify Test Kit Item, Lot, or Sublot Used in Testing   For traceability purposes, test kit information is recorded on the Results window. This provides information about the material used in preparation or execution of a test. You can enter a test kit as an inventory item in OPM. In order to enter the test kit lot or sublot, the test kit must be previously defined as a lot-controlled inventory item.

Record External Test Provider Information   Enter the facility where the test is done by an internal laboratory, or the enter the test provider where the test is sent to an external testing facility. Each test provider must be defined as a valid supplier.

Assign Retest and Resample Actions When Evaluating Results   You can select a follow-up action on reviewing a test result. By associating existing action codes to the Retest and Resample Actions on the Quality System Parameters window, the OPM Quality Testing and Sample Creation notifications are sent automatically. If the Retest Action is selected, then the test is added to the result set.

Composite Test Results to Simplify Interpretation of the Results Set   You can composite results from different samples of the same item lot within a sample group, and display individual sample results. The process of compositing results simplifies the determination and reporting of one final set of results from a set of multiple samples within a sample group.

When there are several test replicates for a test on a single sample, the most recent test replicate result is used in the composite result statistics. The result used cannot

be canceled, voided, or marked for deletion. The application calculates result statistics for numeric-based tests, including:

- Arithmetic mean

- Median

- Low, high, and range

- Standard deviation

- Mode

The Mode statistic is determined for List of Values and Text Range test types as the most frequently occurring result value. A user-definable value is enterable for Non-Validated test types.

This capability also provides options to exclude a sample or result, resample, or retest in order to derive the composite results set. You can save a new Results record that corresponds with the final set of composited results for an item and lot. The Certificate of Analysis prints the result average for each required numeric-based test that is not marked as optional on the specification.

Update Lot Status Automatically Based on Results   The application evaluates sample results to determine conformance with the associated specification. Sample disposition is updated to Accept or Reject appropriately based on the test results. The default lot status specified on the specification validity rule is used to update the lot status of the item lot tested.

Compare a Sample to Another Specification   You can compare a previously analyzed sample to another specification to determine whether the final results set meets the other specification requirements. Tests that were not performed previously and are part of the comparison specification can be added to the results set. The specification comparison capability evaluates results for a single sample across item specifications with the inventory, WIP, customer, and supplier validity rule types.

Leverage Test Results to Recommend Item Lot UOM Conversions   You can use quality test results to measure the variability of a lot attribute across item lots and to propose lot unit of measure conversions. These recommended conversions are sent using OPM Quality UOM Conversion workflow for inventory approval and adjustment.

Understanding Results

Quality results serve as the basis for measuring actual material characteristics against expected quality records, and for assigning follow-up actions to be taken throughout the supply chain. Results are logged against an individual sample, where scheduled tests are driven by the specification and additional impromptu tests can be added to the sample analysis. After a technician enters results, a Quality Manager has the option to evaluate the results set against targets and limits to determine the sample disposition based on whether the results are acceptable. The collective disposition of samples in a sample group can be used by the application for material lot usage decisions in production and inventory. Composite results and specification comparison capabilities also assist in result interpretation.

Tracing Results by Testing Materials, Instruments, and Tester

The Results window has test kit information that helps you trace the material that is used in testing. If test results need to be investigated, then you can identify both the materials used in testing and the internal or external testing resources that performed the testing.

Restricting the Decimals Displayed for the Result

Saved numeric results are restricted to the stored decimal precision or number of decimal places defined at the test or specification level.

Entering a Result

You can enter results from the:

- Quality Manager and Quality Technician menus

- Product Development application, including these windows:

  - Formula Details

  - Operation Details Activities

  - Routing Details

- Process Execution application, including these windows:

  - Batch Material Details

  - Line Allocations

- Inventory Control

  - Items, the Item Master

- Locations

- Warehouses

- Lots/Sublots

- Workflow Notifications

Assigning Result Evaluation and Sample Disposition Automatically

Test results are automatically evaluated for conformance to specification if the test is part of the specification associated to the sample. Results that are in-specification are assigned an evaluation of Accept. If the Control Lot Attributes indicator is enabled on the specification validity rule that is in effect, then the sample disposition can also update the lot status automatically. If all results are in-specification, then the sample disposition is set to Accept. If any of the results are out-of-specification, then the sample disposition is set to Reject.

Assigning Result Evaluation Manually

The following result evaluations are possible:

- **Accept** confirms that the result meets the specification requirement.

- **Accept with Variance** indicates that the result falls within an experimental error region, or outside specification limits, but is considered acceptable.

- **Reject** indicates that the result for the test is rejected.

- **Experimental Error** indicates that the result falls within the experimental error regions for the test. You can change the evaluation to another selection. Refer to the "Entering Experimental Error" topic for an explanation of experimental error. Result sets or samples cannot be marked as Complete if any evaluations remain with this result evaluation.

- **Cancel** when the test is canceled

- **Void** indicates that the test result is not reported due to a test result processing failure. The result cannot be reported because the test method itself failed.

After entering a result, you can change the Evaluation field on the Results window from:

- Accept to Void

- Accept with Variance to Reject or Void

- Reject to Accept with Variance or Void

- Experimental Error to:
  - Accept, if the result is within specification limits
  - Accept with Variance, if the result is outside specification limits
  - Reject
  - Cancel
  - Void
- Null to any evaluation except Experimental Error
- Null to Cancel or Void

Evaluating Expressions as You Report Results

Expression results cannot be entered directly. They are calculated from a mathematical expression, or by the results of tests referenced in the expression. You can calculate Expression test results before saving the results set. If all tests used in an expression have a result, then the expression is calculated irrespective of whether the result is within or outside specification limits. If tests used in an expression have replicates, then the most recent result replicate is used. Test results that are marked for deletion are not considered for expressions. The application displays a warning if the expression result is outside its limits.

Evaluating Partial Expressions

You can use Oracle SQL*Plus or a user defined PL/SQL NVL function to provide interim calculations of expressions that have missing test results.

Here is an example:

A = B + NVL(C, <numeric value>)

where C is assigned a default numeric value to be used when C is not entered.

In the example expression, A is calculated when B is entered, even without the value of C. A default numeric value is assigned to C. If at a later point, the value of C is entered, then the expression is recalculated to include the actual value of C. Use the Recalculate option to recalculate the expression on an interim basis. The application recalculates the expression when you save your work.

Compositing Test Results

The arithmetic mean of numeric results and the mode statistic for nonnumeric results can be reported on a Certificate of Analysis when results are composited. The mean, median, high, low, range, standard deviation, and mode of numeric

results are calculated statistics for numeric results. Text range results display the high, low, and mode values. You can enter text as the composite result for nonvalidated tests. If a test is replicated, then the most recent result replicate is included in the composited calculation. If a test is part of the specification that is tied to the sample and the sample group, then the composite result is evaluated automatically against the specification, and the specification information is displayed. Impromptu tests are displayed in the composite results set without specification information. You can exclude individual sample results from the calculation statistics for a test, add a test, exclude a sample, or add a sample to the composite results set.

Archive and reserve samples are not included in the composite results set. You can view results associated with a parent sample in context with composite results, however these results do not contribute to the calculated statistics.

Comparing Specifications

You can compare results for an analyzed sample to another item specification with any status. The sample may already have an association with a current specification where results were evaluated against its limits to determine if they are in-specification. A comparison specification is selected for a side by side comparison of two specifications evaluated against the samples results. Tests from the comparison specification can be added to a results set to initiate additional testing. You can make the comparison specification the current specification applied to the sample so that a new sample disposition can be recorded against the new specification, if the new specification is approved for laboratory use or for general use.

You cannot compare specifications for a monitoring sample, because you should not replace the specification tied to a monitoring sample. Similarly, you should not retrieve stability samples from the Specification Comparison window. Any changes to a stability study or stability study sample for time point testing must be tracked within the stability study functionality, and not through the Specification Comparison window.

Retesting Samples

In the case of retesting, where a previously performed test is added to the sample again, the replicate number on the Results window increases each time a test is added to the results set. For example, a test is usually run only once on a sample. The test is performed and a result is entered. If something occurs in the laboratory that requires the test to be run again, then you can add the same test to the results

set again. The test appears on the Results window with a value 2 displayed in the Replicate field. You enter the repeated test result.

Preventing Batch Step Completion

This feature prevents additional batch processing and the completion of a batch step until acceptable results are recorded and approved for the samples taken from the batch step.

You can control batch step status for quality control with a WIP specification validity rule specified for a particular routing step or batch step. Sampling at the batch step requires acceptable results for tests not marked as optional before the batch step can be completed.

Responsibilities   Formulator, Process Engineer, Production Supervisor, Quality Manager

Prerequisites

- Configure the quality system parameters, or a WIP specification validity rule to control batch step status. Required.

- Enable the Batch Creation, Batch Step Creation, and Batch Step Release workflow events. Optional.

- Enable the Production Sample Creation Notification. Optional

To prevent a batch step from completing until acceptable quality results are approved:

1. Create a formula.

2. Change the status of the formula to Approved for General Use.

3. Create a routing.

4. Change the status of the routing to Approved for General Use.

5. Create a recipe that contains the formula and routing.

6. Create a recipe validity rule for the recipe and the plant to produce the batch.

7. Change the status of the recipe and the status of the recipe validity rule to Approved for General Use.

8. Create and approve a specification for the product of the formula.

9. Create and approve a WIP specification validity rule, specifying the recipe, routing, or both, and routing step, or batch and batch step if these are already created. Ensure the Control Batch Step Status indicator is selected.

10. Create a batch from the recipe.

11. Release the batch.

    - From the Batch Steps window, the Batch Step Quality Status indicates Sample Required.

    - With the Production Sample Creation Notification workflow enabled, the application sends a notification for the creation of a WIP sample when the batch is created.

12. Release the batch step.

13. Create a sample from the open notification for the Sample Creation Notification workflow. You are not able to complete the batch step at this point, since no results are entered.

14. Enter and save results. If the sample group disposition for the batch step is Accept or Accept with Variance, then the Batch Step Quality Status is updated to Results In Spec, and you can complete the step.

15. Complete the batch step. If the batch step quality status does not reflect Results In Spec, then a message asking for override appears. Refer to "Removing the Override Control of Batch Step Completion" for additional information.

Removing the Override Control of Batch Step Completion

Designated responsibilities can override the control of batch step completion despite the quality inspection requirement. The overriding of batch step completion privilege is granted to a responsibility. For example, the Production Supervisor can be granted this privilege. You can remove this function from the application menu for this responsibility by using the System Administrator responsibility.

1. Navigate to Applications > Menu.

2. Query the appropriate menu name. For example, query GME_PRODUCTION_ SUPERVISOR.

3. On the retrieved record, search for the function Batch Steps:Certify without QC.

4. Delete the row, and save the record. This removes the override capability from this responsibility. When you try to complete a batch step, and results are not entered or in-specification, then an error message displays.

Controlling Updates to Lot Status, Grade, and Hold Date Based on Quality Test Results

This feature helps determine material usage based on updates to lot status, grade, and hold date that are driven from quality results. An Inventory Specification Validity Rule and Supplier Specification Validity Rule can control the update of lot status depending on whether results are in or out-of-specification for all samples in a sample group. A sample disposition that is marked Accept or Accept with Variance is in-specification. A sample disposition that is marked Reject is out-of-specification.

Responsibility   Quality Manager

Prerequisites

- Enable the Control Lot Attributes indicator.

- Specify the default In-Specification and Out-of-Specification Lot Statuses.

- Disable the Lot Optional on Samples indicator on the Quality System Parameters window and in an inventory or supplier specification validity rule.

- Configure the Quality System Parameter for Inventory Transaction Reason.

To update the status and grade of the sampled lot, perform the following:

1. Create and approve a specification for the item, or lot and sublot.

2. Create and approve an inventory or supplier specification validity rule. Ensure the Control Lot Attributes indicator is selected. The In-Specification Lot Status and Out-of-Specification Lot Status defaults if previously defined on the Quality System Parameters window. Clear the Lot Optional on Samples indicator so that updates can be enforced on a lot.

3. Create a sample.

   - If the Sample Creation Notification workflow is not enabled, then you can use the Get Spec function to associate the sample record to the applicable specification validity rule.

   - The lot number is required to update the lot status based on in-specification or out-of-specification results, lot grade, and hot hold release date.

4. Enter and save results for the sample.

5. Repeat the sample creation, results entry, and evaluation process if there are several samples to be taken from a single source.

6. When testing is complete for all samples required, specify or confirm the new lot status, grade, and hold date at the same time as you change the sample group disposition.

- If all samples in the sample group have the disposition of Accept, then the lot status defaults to In-Specification.

- If any of the samples have the disposition of Reject, then an Out-of-Specification lot status defaults into the Change Disposition window. This quality-driven lot status update affects all warehouses and locations of the lot or sublot.

Entering Results

The Results window lets a Quality Technician enter results for samples. For samples that are associated to a specification and version, a list of tests from the specification is provided for entry of results. You can add a test to the results set if this function is included in your responsibility. You cannot modify saved result values or the dates on which these values were saved. However, you can void a result, and add an additional test replicate to represent a new result value and date. The application validates the result against the test range or valid test values. It also validates the result against the specification range if the test is part of the specification. If the result falls into an action zone for experimental error, then an operator message displays when you try to save the result. When you enter results without a specification tied to the sample, certain business rules driven by a specification and the specification validity rule cannot be enforced.

A Quality Manager reviews results based on their conformance to specification as determined by the application. The manager can assign an evaluation of Accept, Accept with Variance, Reject, Cancel, or Void, and a follow-up action for each result. You can access the Composite Results window from this window to aggregate results of multiple samples in a sample group. You can also access the Specification Comparison window to compare results to other specifications.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

Managing Optional Tests without Results

Tests that are marked Optional on the specification do not require result entry to finalize the sample disposition as Accept, Accept with Variance, or Reject. However, if you enter a result for an optional test, then you can configure whether the result contributes to the final disposition of a sample. The GMD: Include Optional Tests in Sample Disposition profile option is globally enforced for all optional tests regardless of items or organizations. If an optional test result is included, then its result evaluation utilizes the existing business rules for changing the sample disposition. For example, an out-of-specification result for an optional test only allows the sample disposition to change to Accept with Variance, Reject, or Cancel.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Optionally, set up Quality System Parameters for action codes to resample and retest.

❑ Set up quality laboratory organizations, and associate the appropriate samples and testers.

❑ Optionally, set up the GMD: Default Lab Organization profile option.

❑ Enter a specification and a specification validity rule with a status of Approved for Laboratory Use or Approved for General Use.

❑ Enter a sample.

❑ Optionally, set up testers as application users.

❑ Optionally, set up test kits as items, lots, and sublots.

❑ Optionally, set up test providers as suppliers.

❑ Optionally, set up action codes for assigning follow-up quality actions after results are evaluated.

❑ Optionally, set up and activate the Testing Notification workflow.

◗ **To enter test results:**

1. Navigate to the **Results** window.

2. Query the **Sample** by sample number or by item and lot. The sample number consists of the organization code and the document number. Ensure that you have access to the quality lab organization listed on the sample. If you do not have access to this organization, then you cannot enter results.

3. **Composited** indicates that results for the sample are aggregated with other samples from the same sample group. Composited is hidden when results are not aggregated.

4. **Disposition** indicates the disposition of the sample as:

   ■ **Pending** when the sample is saved, and results are expected, but not yet recorded. Default.

   ■ **In Progress** when at least one result exists for the sample, but testing is not yet complete.

   ■ **Complete** when testing of all required tests and all additional tests is complete.

- **Accept** when sample testing is complete, and results are in-specification.

- **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the results reviewer has accepted this result with variance.

- **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.

- **Cancel** when the sample is canceled.

5. **Item** indicates the item code for the material sampled with its **Item Description**. These fields are blank for a monitoring sample.

6. **Lot Retest** indicates if the sample was taken for retesting a lot. This field is hidden when the sample is not taken for lot retesting purposes.

7. **Remaining Quantity** displays the remaining sample quantity with its **UOM**.

Tests

8. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.

9. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.

10. **Replicate** is the replicate number for the test. There are several result entries that correspond to the number of test replicates defined on a specification. If a test replicate is not specified for the test, then the field defaults to 1. Required.

11. Enter the **Result** for the test. You can select from the LOV for List of Test Values and Text Range test data types. The result entered must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Text Range test data types, or it must be in the list of valid values for the List of Test Values test data type. You cannot edit this field for the Expression test data type.

12. **Parent Sample** displays the parent or source sample if results are associated.

13. **Test Method Resource** displays the instrument defined for the test method associated to the test.

14. Enter the **Planned Resource** as the generic resource that is planned to be used for performing the test. This defaults from the defined test method resource.

15. Enter the **Planned Resource Instance** as the resource instance that is planned to be used for performing the test.

16. Enter the **Actual Resource** as the generic resource used for performing the test.

17. Enter the **Actual Resource Instance** as the resource instance used for performing the test.

18. **Planned Result Date** displays the date planned for result entry. This is calculated by adding the test duration from the test method to the sample date drawn.

19. **Test By Date** displays the date that the test must be completed. This is calculated by adding the test expiration time from the specification (in days, hours, minutes, and seconds) to the sample date drawn.

20. Enter the result **Date** as the date and time the result was recorded. You can use the LOV to select a data and time from the Calendar window. This field defaults to the system date and time. This date cannot be in the future, or prior to the system minimum date.

21. Enter the **Reserve Sample** if the remaining sample quantity is insufficient to complete this test. The reserve sample must belong to the same sample group as the original sample queried.

22. **Priority** indicates the test priority. This defaults from the specification or the test definition. Test priority identifies the relative priority of the test among the tests listed in the specification. If the test is not from the specification, then this field defaults from the test definition.

23. The following fields are display only:

    - **Method** indicates the test method used for the selected test, and it defaults from the specification. If there is no specification, then this field defaults from the test definition.

    - **Unit** indicates the quality test unit of measure specified at the test level for the selected test.

    - **Class** indicates the class code for this test. This field defaults from the test entered.

    - **Test Description** indicates a brief description of the selected test.

    - **Data Type** indicates the test data type for the selected test.

- **Expression** indicates the mathematical expression for the selected test. This field is hidden unless the test type is Expression.

- **Display** indicates the text displayed for the selected test. This field is hidden unless the test type is Numeric Range with Display Text.

Internal

24. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.

25. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.

26. Enter **Laboratory** as the organization where the test is performed You must have access to this laboratory to enter results. This field defaults to the current quality laboratory organization specified on the sample. Required.

27. Enter the **Tester** as the person performing the test. The tester can be different from the individual who enters results. The field defaults to the current user.

28. The following fields are display only, and default from the **Test Method** window:

    - **Instrument** displays the instrument used to perform the test.

    - **Planned Test Quantity** displays the test quantity defined on the specification, or the test quantity that defaults from the test method. This is the quantity needed to perform the test.

    - **Actual Test Quantity** displays the actual test quantity used in testing. It defaults from the planned test quantity. You can edit this field after result entry. When you save your work, the actual test quantity is subtracted from the remaining quantity of the sample selected.

    - **Test Qty UOM** displays the unit of measure for the test method. This UOM must be convertible to the primary UOM for the item.

29. Enter the **Test Kit Item** as the item number for the test kit, reagent, or other material required to perform the test.

30. Enter the **Test Kit Lot** as the test kit lot number. This entry ensures traceability to reagent lots if results require investigation. This field is only available if you enter a test kit item.

31. Enter the **Test Kit Sublot** as the test kit sublot number, if the test kit is sublot controlled, and a test kit item and lot are already entered.

Note: The Unit, Method, Test Description, Class, Data Type, and Expression or Display fields have the same definitions as those that appear in the Tests tab. Refer to the Tests tab for this information.

External

32. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.

33. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.

34. Enter the **Test Provider** as the supplier who performs the test. The LOV provides the current list of valid suppliers. **Description** displays a description of the test provider.

Note: The Unit, Method, Test Description, Class, Data Type, and Expression or Display fields have the same definitions as those that appear in the Tests tab. Refer to the Tests tab for this information.

Evaluation

35. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests.

36. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.

37. **Replicate** displays the replicate number for the test.

38. **Result** is the result for the selected test. You can select from the LOV for List of Test Values and Text Range test data types. The result entered must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Text Range test data types, or it must be in the list of valid values for the List of Test Values or Text Range test data types. You cannot edit this field for the Expression test data type.

39. **In Spec** is determined by the application as the evaluation of conformance to the specification, and is:

   ■ Selected if the result conforms to the specification requirement for the test.

   ■ Cleared if the result does not meet the specification requirement, the test is a nonvalidated test data type, or the test is not part of the specification.

   The In Spec indicators for test results that have an evaluation of Void or Cancel do not contribute to determining the disposition of the sample. For example, a sample has three tests, T1, T2, and T3. Tests T1 and T2 are in-specification, and have evaluations of Accept. Test T3 test is out-of-specification, and has an evaluation of Accept with Variance. The sample for these tests cannot have disposition of Accept at this point. However, if the evaluation of Test T3 is changed to Void or Cancel, then the sample can have a disposition of Accept.

40. Enter **Evaluation** as:

   ■ **Accept** to confirm that the result meets the specification requirement.

   ■ **Accept with Variance** if the result falls within an experimental error region, but is considered acceptable.

   ■ **Reject** to reject the result for the test.

   ■ **Experimental Error** displays if the result falls within the experimental error regions for the test. You must change the evaluation to another selection. Refer to the "Entering Experimental Error" topic for an explanation of experimental error.

   ■ **Cancel** when the test is canceled.

   ■ **Void** to indicate that the test result is not reported due to a test result processing failure. The result cannot be reported because the test method itself failed.

   Refer to the "Understanding Results" topic for a complete discussion of the business rules associated to this field.

41. **Action** displays the action code associated to the experimental error region, or the out-of-specification region for the test result. Select an action if there is no default.

42. The following fields are display only:

    - **Optional** is selected if the test result is not required for conformance to specification. You can indicate that testing is complete even if an optional test is incomplete.

    - **Target** displays the specification target, if defined, for the selected test.

    - **Minimum** displays the specification minimum in if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

    - **Maximum** displays the specification maximum in if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

    - **Priority** indicates the test priority. This defaults from the specification. Test priority identifies the relative priority of the test among the tests listed in the specification.

43. **Date** indicates the date and time for this result.

44. **Print Additional Test on COA** is selected when an additional test is included on the printout of the Certificate of Analysis.

Note: The Unit, Method, Test Description, Class, Data Type, and Expression or Display fields have the same definitions as those that appear in the Tests tab. Refer to the Tests tab for this information.

▶ **To mark a result record for purge:**

Choose Mark for Purge from the Actions menu. The result record is marked for deletion.

▶ **To edit text in a result:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To display the Item Samples or Monitoring Samples windows:**

1. Choose **Samples** from the **Actions** menu. The corresponding **Item Samples** or **Monitoring Samples** window displays for the selected results set.

2. Refer to "Entering Samples" for information on samples.

3. Close the window.

▶ **To display the Tests window:**

1. Place the cursor on the desired test line.

2. Choose **Tests** from the **Actions** menu. The **Tests** window displays.

3. Refer to the "Entering Tests" topic for information on tests.

4. Close the window.

▶ **To display the Test Methods window:**

1. Place the cursor on the desired test line.

2. Choose **Test Methods** from the **Actions** menu. The **Test Methods** window displays.

3. Refer to the " Entering Test Methods" topic for information on test methods.

4. Close the window.

▶ **To display the Specifications window:**

1. Choose **Specifications** from the **Actions** menu. The **Specifications** window displays for the selected sample.

2. Refer to the "Entering a Specification" topic for information on specifications.

3. Close the window.

▶ **To add tests:**

1. Place the cursor in the test details region.

2. Choose **Add Tests** from the **Actions** menu. The **Add Tests** window displays.

3. Enter a **Test Class** to narrow the list of tests.

4. Select the **Test** to add. The list of tests available is not limited to those tests listed on the specification.

5. **Test Qty** displays the test quantity defined on the specification or test method in its **Test Qty UOM**. If the test is not part of the specification, then you can edit this field.

6. Click **Add** to add the selected test to the results set.

7. Close the window.

▶ To assign a test group to a set of results:

1. Query the desired result set to assign a test group.

2. Choose **Add Test Group** from the **Actions** menu. You can add tests to a results set that has a sample disposition of Pending, In Progress, or Complete.

3. Query the desired **Test Group**. The window displays all tests included in that test group.

   - **Ordering** is the sequence of the test in the group as entered on the Tests window.

   - **Test** is the name of the test entered.

   - **Description** is the description of the test code.

   - **Data Type** is the test data type as described in "Understanding Tests."

   - **Qty** is the amount of material required for the test. If the test is passive and does not require a physical sample quantity, then leave this field blank.

   - **UOM** is the unit of measure for the test quantity defined in the test method.

4. Select or clear **Include** to indicate the tests in the group to be copied to the results.

5. Click **OK**. Selected tests are added to the results.

6. Save your work.

▶ To change the disposition of the sample:

1. Choose **Change Disposition** from the **Actions** menu.

2. Refer to "Changing Quality Disposition."

3. Select a new disposition for the sample.

4. Click **OK** to save changes.

5. Close the window.

▶ **To display the Composite Results window:**

This option is only available if there is at least one sample in the sample group.

1. Choose **Composite Results** from the **Actions** menu. The **Composite Results** window displays.

2. Refer to the "Compositing Test Results" topic for information on compositing test results.

3. Close the window.

▶ **To display the Specification Comparison window:**

1. Choose **Spec Comparison** from the **Actions** menu. The **Specification Comparison** window displays.

2. Refer to the "Comparing Specifications" topic for information on comparing specifications.

3. Close the window.

▶ **To associate results from another sample:**

1. Choose **Results Association** from the **Actions** menu. The Results Association window displays.

2. Query the parent sample, and review results retrieved.

3. Click **OK** to associate the parent sample results displayed to the current sample results record.

4. Close the window.

▶ **To display the parent sample for an associated result:**

1. Place the cursor on the desired test line that has a result association to a parent sample.

2. Choose **Parent Sample** from the **Actions** menu. The **Samples** window displays the parent sample for the associated result.

3. Close the window.

Selecting Samples and Tests for Mass Results Entry

The Mass Results Entry Test Selection window lets you access the Mass Results Entry window by selecting a set of samples and tests prior to mass results entry. Select samples from either the Sample Groups window or Samples By... window. You can select item, monitoring, or stability samples with a disposition of Pending, In Progress, or Complete.

You can use folders with this window.

Prerequisites

❑ Enter and save one or more samples that require multiple results to be entered.

▶ **To select samples and tests for mass entry from the Sample Groups window:**

1. Navigate to the **Sample Groups** window.

2. Select the sample group that has the samples to process.

3. Click **Mass Results**. The **Mass Results Entry Test Selection** window displays.

4. The **Test** and **Description** display for each test. You can select up to 20 tests assigned to samples at a time.

5. Enter the **Tester** as the individual who enters results. Defaults to the current user. Required.

6. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

7. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the sample group.

8. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

▶ **To select samples and tests for mass entry from the Samples By... windows:**

1. Navigate to the **Quality Workbench**.

2. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending

or In Progress. Clear this indicator to display item samples with all sample dispositions.

3. Select **View By Organization**, **Item**, **Disposition**, **Test**, **Test Class**, **Test Method**, or **Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.

4. Expand the **Samples By...** node, and select the desired top-level node that contains multiple samples. The appropriate **Samples By...** window displays.

5. Click **Mass Results Entry** next to all samples to select for entry of mass results.

6. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. The **Test** and **Description** display for each test.

7. Enter the **Tester** as the individual who enters the test result. Defaults to the current user. Required.

8. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

9. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the samples. You can select up to 20 tests assigned to samples at a time.

10. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

◗ **To select samples and tests for mass entry from the Samples Summary window:**

1. Navigate to the **Samples Summary** window.

2. Select the sample group that has the samples to process.

3. Click **Mass Results Entry**. The **Mass Results Entry Test Selection** window displays. The **Test** and **Description** display for each test.

4. Enter the **Tester** as the individual who enters the test result. Defaults to the current user. Required.

5. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.

6. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Clear **Select** to remove tests you do not want to enter for the sample group. You can select up to 20 tests assigned to samples at a time.

7. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

▶ **To select all tests for results entry:**

Click Select All on the Mass Results Entry Test Selection window to select all tests for results entry.

▶ **To clear all tests selected for results entry:**

Click Clear All on the Mass Results Entry Test Selection window to clear all tests selected for results entry.

Using the Mass Results Entry Window

The Mass Results Entry window lets you enter results in a spreadsheet array for numerous samples without the need for extensive navigation. The primary purpose of this window is for results data collection on samples requiring testing, where result entry validation, expression test calculations, experimental errors, and e-signatures are supported. The samples listed can represent the same sample group material, resource, or location, and can also span different sample groups for item and lot combinations, resources, or locations.

A sample can be listed several times in the array to correspond with the number of test replicates. You can enter results for each test in a column. Tests are assigned either by a specification, or manually added to each sample. Tests displayed are not necessarily common to each sample. You can view additional details about each sample and test, such as item, lot, and test method in context with the cell selected in the array. This unified view provides increased productivity by reducing window navigation and the requirement to drill down to enter results one at a time. It also gives you a tool to identify tests that still need to be performed on samples.

Refer to "Understanding Results" and "Entering Results" for additional features available after result entry.

Following is a typical scenario for entering mass results. Run 20 samples in duplicate for a chloride test. This generates 40 chloride test results to enter. Select the samples from the Sample Groups or Samples By... windows. Use the Mass Results Entry Test Selection window to select the chloride test for results entry. Navigate to the Mass Results Entry window. Enter the results, and save your work. If all test results are not complete, then you can return to the Mass Results Entry window, identify those samples that still require a chloride test result, perform those tests, and enter the results later on.

Prerequisites

❑   Create samples and assign a specification or add tests.

❑   Select samples for mass results entry from the Sample Groups or Samples By... windows.

❑   Select tests for mass results entry from the Mass Results Test Selection window.

▶ To use the Mass Results Entry window:

1.   Navigate to the **Mass Results Entry** window.

2.   The following fields are display only:

- **Sample** is the combination of the four-letter organization code hyphenated with the sample number.
- **Replicate** is the replicate number for the test listed.

3. Enter the test result for each test replicate.

- If the cell is disabled from result entry, then the test is not assigned to the sample.
- If a result was previously entered for the sample and test combination, then it appears with the Tester and Result Date in the array, and it cannot be edited.

4. Click **Test Details** to display the **Test Details** window where you can view detailed information for the current test and sample. Optional.

5. Click **Experimental Error** to display the Experimental Errors window where you can review any results that fall into an experimental error region and the associated action code assigned by the specification or test definition. Optional.

6. Save your work.

▌ **To calculate expression test results:**

Click Calculate Expression to calculate an expression test.

Refer to "Understanding Results" for additional information.

▌ **To display experimental errors:**

Click Experimental Error to display the Experimental Errors window.

Refer to "Displaying Experimental Errors from Mass Results Entry" for additional information.

▌ **To display test details:**

Click Test Details to display the Test Details window where you can view detailed information for the current test and sample.

Refer to "Displaying Test Details from Mass Results Entry" for additional information.

Displaying Test Details from Mass Results Entry

The Test Details window displays the sample, test, and test method information associated to a specific sample when you select a cell in the Mass Results Entry window. Each cell represents a sample and test combination. This window can remain open. It refreshes as you change cursor focus in the Mass Results Entry window to reflect the current information associated to the cell.

Prerequisites

❑ Enter and save tests.

❑ Enter and save samples.

❑ Use the Mass Results Entry window to enter sample test results.

▶ **Displaying test details from the Mass Results Entry window:**

1. Navigate to the **Test Details** window.

2. The following fields are display only:

   ■ **Sample Description** is the description for the sample.

   ■ **Item** is the item associated to the sample.

   ■ **Lot** is the sample lot with its optional **Sublot**.

   ■ **Warehouse** is the warehouse code for the sample if its source is either inventory or location.

   ■ **Location** is the location code for the warehouse if the sample source is either inventory or location.

   ■ **Resource** is the resource for the sample if its source is resource.

   ■ **Test Method** is test method assigned to the test.

   ■ **Test Unit** is the unit of measure used for reporting test results.

   ■ **Test Quantity** is the planned quantity of material required for testing. This field defaults from the test method or specification. **UOM** displays as the inventory UOM for the planned quantity.

   ■ **Optional** is selected if the test is marked as optional on the specification. Otherwise, the test is required.

   ■ **Display Label** is the text displayed for a Numeric Range with Display Text test type.

■   **Expression** is the mathematical expression used to calculate an expression test type.

3. Click **Close**.

Displaying Experimental Errors from Mass Results Entry

The Experimental Errors window summarizes any results entered on the Mass Results Entry window that fall into the experimental error regions. It also displays the assigned actions for these results as defined on a test or specification.

Refer to "Entering Experimental Error" for additional information.

Prerequisites

❏ Enter and save tests.

❏ Enter and save test samples.

❏ Use the Mass Results Entry window to enter test results.

◗ **To display experimental errors from the Mass Results Entry window:**

1. Navigate to the **Experimental Errors** window.

2. The following fields are display only:

   ■ **Sample** is the combination of the four-letter organization code hyphenated with the sample number.

   ■ **Test** is the code for the test in the current specification.

   ■ **Replicate** is the replicate number for the test. The replicate corresponds to the number of times the test is assigned or added to the sample.

   ■ **Result** is the test result entered on the Mass Results Entry window.

   ■ **Action** is the action code associated to the experimental error region for the test result.

3. Click **Close**.

Finding Samples from the Results Window

The Find Samples dialog box accessed from the Results window lets you find a sample by sample disposition, item, lot, sublot, or marked for deletion status.

Prerequisites

❑ Enter and save a sample.

▶ **To find a sample from the Results window:**

1. Navigate to the Find Samples dialog box.

2. Enter any of the following to narrow your search:

   - **Sample** as the combination of the four-letter organization code hyphenated with the sample document number, or sample document number alone.

   - **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.

   - **Item** as the item associated to the sample. The item description displays.

   - **Lot** for the item associated to the sample.

   - **Sublot** for the item associated to the sample.

3. Select **Marked for Deletion** as:

   - **Yes** to find samples that are marked for deletion.

   - **No** to find samples that are not marked for deletion.

   - Leave this field blank if you do not want to limit your search based on whether a sample is marked for deletion.

4. Click **Find**. The **Results** window displays the first sample that matches the search criteria.

Compositing Test Results

The Composite Results window lets you aggregate results across samples for the same event or sample group. This window summarizes the composite statistics for results for each test. If results were previously composited, then you can view the existing composite results. Otherwise, the composite result set is created, and it incorporates the most recent data for the samples and results in the sample group. You can view the result for each sample that contributes to the statistics for each test. You can also create samples, and add tests to the composite results set.

E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix E" for additional information on e-record and e-signature approvals associated with this window.

Prerequisites

❏ Enter results.

▎ **To composite test results:**

1. Navigate to the **Sample Groups** window.

2. Select the row of the sample group to composite. Each row begins with a **Source**, followed by the **Item** and **Description**.

3. Click **Composite Results**. The **Composite Results** window displays.

4. The following fields describe the sample group, and are display only:

   ■ **Sample Taken** indicates the number of samples taken for the event.

   ■ **Disposition** indicates the disposition of the composite results set for the current specification associated to the sample group.

   ■ **Item** indicates the item code for the material sampled.

   ■ **Lot** displays the lot number if the item is lot controlled.

   ■ **Sublot** indicates the sublot number if the item is sublot controlled.

5. The following fields describe each composite result row, and are display only:

   ■ **Test** indicates each test performed on the item listed.

   ■ **Mean** indicates the arithmetic mean of the results composited.

   ■ **Median** indicates the median value of the results composited.

- **Mode** indicates the most frequently occurring value of the results composited. If no value occurs more frequently than any other, then no value displays.

- **Low** indicates the lowest result value of the results composited.

- **High** indicates the highest result value of the results composited.

- **Range** indicates the range of values for the results composited. For numeric based tests, this is the high result value minus the low result value.

- **Deviation** indicates the standard deviation of the results composited.

- **Tests Used** indicates the number of test results that comprise the statistics. The number of tests used is equal to or less than the total number of result records used to composite the test.

6. Enter the **Non-Validated Result** for the Non-Validated test data type.

7. The following fields are display only:

- **In-Spec** indicates that the composite result is in-specification.

- **Total Tests** indicates the total number of test results available for composite results.

- **Associated Result** indicates that the composite result row reflects results associated from a parent sample group.

- **Report Precision** indicates the reporting decimal precision for the test according to the specification.

- **Unit** indicates the quality test unit of measure for the selected test.

- **Test Method** indicates the test method code for the test.

- **Test Data Type** indicates the test data type.

- **Test Description** indicates a brief description of the test.

8. Click **Save Composite** to save the composited results.

▶ **To view existing composite results:**

1. Select the row of the sample group to view.

2. Click **Composite Results**. The **Composite Results** window displays.

3. You can composite results as described in steps 4 to 6 of the previous task.

4. Click **Save Composite** to save the composited results.

◗ **To view samples contributing to the composite result for a test:**

1. Select the row in the sample event or sample group.

2. Click **View Samples** to display the samples used to composite results for the selected test. The **View Samples For Test** window displays.

3. Refer to the "Viewing Samples for Composited Results" topic to view the samples for a composited test. You can exclude samples from the composite result set and recalculate the statistics displayed on this window.

4. Close the window.

◗ **To add samples to the composited results:**

1. Click **Add Sample** to add a sample to the sample group. The **Item Samples** window displays.

2. Refer to the "Entering Samples" topic for more information on creating samples.

3. Save the window.

◗ **To add a test to the composited results:**

Click Add Test to display the Add Test To Samples window where you can add a test to the composited results.

Refer to "Adding Tests to Composited Results" for additional information.

Viewing Samples for Composited Results

The View Samples For Test window lets you view samples in the sample group that comprise the composited results for a specific test. You can exclude samples, and recalculate the statistics displayed on this window.

You can use flexfields and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Enter and save samples.

❏ Enter and save results.

❏ Create and save composite results for the sample group.

▶ **To display samples for composited results:**

1. Navigate to the **Sample Groups** window.

2. Select the row of the desired sample group.

3. Click **Composite Results**. The **Composite Results** window displays.

4. Click **View Samples**. The **View Samples For Test** window displays.

5. The following fields are display only for each selected test:

   ■ **Target** indicates the specification target. This field displays only if a target was defined, and the test is part of the current specification tied to the sample.

   ■ **Minimum** indicates the specification minimum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.

   ■ **Maximum** indicates the specification maximum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.

   ■ **Test Method** indicates the test method code for the test.

   ■ **Unit** indicates the quality test unit of measure specified at the test level for the selected test.

- **Test Data Type** indicates the test data type entered for the test.

6. The following fields list the samples that comprise the composite result for each selected test:

   - **Sample** indicates the combination of the four-letter organization code and the sample number.

   - **Result** indicates the test result for the sample.

7. Click **Exclude** to exclude the sample from the composited result for the test.

8. The following fields are display only:

   - **Result Date** indicates the date and time the result was entered.

   - **Tester** indicates the person performing the test. The tester can be different from the individual who enters results.

   - **Parent Sample** indicates the parent or source sample, if one exists.

   - **Disposition** indicates the disposition for the sample as Pending, In Progress, Complete, Accept, Accept With Variance, Reject, or Cancel.

     Refer to "Understanding Sampling" for a complete explanation of sample disposition.

   - **Reserve Sample** indicates the retained sample for reserve use that is used to perform the test. Test quantities are consumed from this sample.

9. The following fields describe each selected test, result, and sample, and are display only:

   - **Description** indicates a description of the sample.

   - **Source** indicates the source of the sample as Customer, Inventory, Location, Resource, Supplier, Stability Study, or WIP.

10. The following fields are display only and summarize the statistics of results that are not excluded from the composite:

    - **Mean** indicates the arithmetic mean of the results composited.

    - **Median** indicates the median value of the results composited.

    - **Mode** indicates the mode value of the results composited.

    - **Low** indicates the lowest result of the results composited.

    - **High** indicates the highest result for the test in results composited.

- **Range** indicates the range of values for results composited. For numeric based tests, this is the high result minus the low result.

- **Deviation** indicates the standard deviation of the results composited.

- **Tests Used** indicates the number of test results that comprise the statistics. The number of tests used is equal to or less than the total number of result records used to composite the test.

11. Click **OK**.

▶ **To recalculate composite results:**

1. Select or clear **Exclude**.

2. Click **Recalculate**. The statistics displayed recalculate according to the changes made.

3. Click **OK**.

Adding Tests to Composited Results

The Add Tests window lets you add a test to the results set of samples in the sample group. If the sample group disposition is Accept, Accept with Variance, or Reject, then tests cannot be added.

When adding a test, the planned test quantity and UOM fields default into the Results window from the Specification when the test is part of the specification, or from the Test Method when the test is not part of the specification.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Enter tests.

❑ Enter a specification.

❑ Enter samples.

❑ Enter test results.

❑ Composite test results.

▶ To add a test to the Composite Results window:

1. Navigate to the **Sample Groups** window.

2. Select the row of the desired sample group.

3. Click **Composite Results**. The **Composite Results** window displays.

4. Click **Add Tests**. The **Add Tests** window displays.

5. Enter the **Test** to add. The test **Description** displays. Required.

6. Enter the **Test Qty** as the planned quantity of material required to perform this test. **Test Qty UOM** displays the unit of measure for the test method. This UOM must be convertible to the primary UOM for the item.

7. Select **Include** to add the test to the selected sample.

8. The following fields are display only:

   ■ **Sample** is the combination of the four-letter organization code and the sample number.

   ■ **Disposition** indicates the disposition of the sample as Pending, In Progress, Accept, Accept with Variance, Complete, Cancel, or Reject.

- **Description** indicates a description of the sample.

- **Source** indicates the source of the sample as Inventory, WIP, Customer, or Supplier.

- **Target** indicates the specification target. This field displays only if a target was defined, and the test is part of the current specification tied to the sample.

- **Minimum** indicates the specification minimum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.

- **Maximum** indicates the specification maximum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.

- **Target Display** indicates the display text for the specification target for the test if it is a Numeric Range with Display Text test type.

- **Minimum Display** indicates the display text for the specification minimum for the test if it is a Numeric Range with Display Text test type.

- **Maximum Display** indicates the display text for the specification maximum for the test if it is a Numeric Range with Display Text test type.

- **Unit** indicates the quality test unit of measure specified at the test level for the selected test.

- **Method** indicates the test method entered for the test.

- **Test Data Type** indicates the test data type entered for the test.

- **Expression** indicates the expression used for the Expression type test

9. Click **Add**.

10. Close the window.

Comparing Specifications

The Specification Comparison window lets you compare the current specification associated to the sample with a comparison specification to determine how closely the results set meets the comparison specification. These comparisons are useful for:

■ Evaluating material conformance with a customer specification to determine if the current results also meet customer requirements. It is possible to add tests to the results set for this purpose.

■ Regrading an item that has failed current specification requirements for a specific grade. For example, if the results do not meet grade A, you can compare specifications for grade B and determine if the results meet that grade. If they do meet grade B requirements, then you can reassign the material to grade B. It is possible to add tests to the results set to meet the new grade requirements for the comparison specification.

The results evaluated against the current specification are displayed when you access the Specification Comparison window from the Item Samples or Results windows, since appropriate information about the sample and sample group is available. The specification comparison functionality does not apply to retained, monitoring, or stability study samples. The current specification must have a status of Approved for Laboratory Use or Approved for General Use.

With the current specification displayed for an item, you can select a comparison specification using the LOV in the Spec field of the Comparison Specification. A comparison displays. If no specification is tied to the sample and its results, then you can select a comparison specification using the Spec LOV.

You have the following options:

■ If the comparison specification is Approved for General Use, then you can review acceptability of test results, add additional tests to meet the testing requirements for the current specification, or save the comparison specification as the current specification for the sample.

■ When you save the comparison and the sample disposition is Accept or Accept with Variance, the application saves the Comparison Specification with a sample disposition of Complete.

■ If the sample disposition against the current specification is not Accept or Accept with Variance, and you attempt to save the comparison, then the application asks you if you want to make the comparison specification the driving specification for the sample and sample group. If you enter Yes, then the application saves the comparison specification with any tests

added, and it sets the sample disposition accordingly. If you enter No, then the application does not set the sample disposition, and the comparison is not saved.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites
❏ Enter tests.

❏ Enter specifications.

❏ Enter samples.

❏ Enter results against samples.

◗ **To compare results against current and comparison specifications:**

1. Navigate to the **Specification Comparison** window.

2. Query the **Sample** to use for specification comparison. Required.

3. **Disposition** indicates the disposition of the sample as:

   ■ **Pending** when the sample is saved, and results are expected, but not yet recorded. Default.

   ■ **In Progress** when at least one result exists for the sample, but testing is not yet complete.

   ■ **Complete** when testing of all required tests and all additional tests is complete.

   ■ **Accept** when sample testing is complete, and results are in-specification.

   ■ **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.

   ■ **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.

   ■ **Cancel** when the sample is canceled.

4. **Item** displays the item associated to the sample.

5. **Lot** displays the lot number if the item is lot controlled.

6. **Sublot** displays the sublot number if the item is sublot controlled.

7. Enter **Spec** as the comparison specification for reviewing results. You can select the LOV for the Spec field to find a specification based on grade, or an Inventory, WIP, Customer, or Supplier Specification Validity Rule.

8. The following fields are display only:

   - **Version** indicates the version of the comparison specification.

   - **Grade** indicates the item grade for the comparison specification.

   - **Status** indicates the status of the comparison specification and version.

Current Specification

9. The following fields are display only:

   - **Spec** indicates the current specification associated to the sample. Required.

   - **Version** indicates the current specification version.

   - **Grade** indicates the item grade for the current specification.

   - **Status** indicates the status of the current specification.

   - **Test** indicates the code for the test in the current specification.

   - **Result** indicates the latest result replicate for the selected test for the current specification. The result must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Expression test data types, or it must be in the list of valid values for the List of Test Values or Text Range test data types.

   - **Target** indicates the target for the current specification for the selected test.

   - **Min** indicates the specification minimum for the current specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

   - **Max** indicates the specification maximum for the current specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

   - **In Spec** is selected if the result is within the specification minimum and maximum or in conformance with the current specification. In Spec is cleared, if the result in outside the specification minimum and maximum or the test is not part of the specification.

Comparison Specification

10. The following fields are display only:

- **Target** indicates the target for the comparison specification, if defined, for the selected test.

- **Min** indicates the specification minimum for the comparison specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

- **Max** indicates the specification maximum for the comparison specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.

- **In Spec** is selected if the result is within the specification minimum and maximum or in conformance with the comparison specification. In Spec is cleared, if the result in outside the specification minimum and maximum or the test is not part of the comparison specification.

▶ **To use the comparison specification:**

1. Click **Use Comparison Spec**. The comparison specification becomes the current specification, and the sample disposition is reset to Complete. If tests are added, then the disposition is set to In Progress.

2. You have the options to:

   - Select a new comparison specification.

   - Select a new comparison specification and add tests to the results set.

   - Repeat steps 1 and 2 as required.

   - Change the disposition based on the new specification to Accept, Accept with Variance, or Reject.

3. Save the window.

▶ **To add tests to the target specification:**

1. Click **Add Tests**. The tests from the comparison specification that are not part of the current specification are added to the end of the results set.

2. If workflow is enabled, then required test notifications are sent.

3. Save the window.

▶ **To view the sample associated to the sample group:**

1. Click **View Sample** to display the **Item Samples** window. The Item Samples window displays.

2. Refer to the "Samples" topic for more information on samples.

3. Close the window.

▶ **To display the current specification:**

1. Choose **Display Current Spec** from the **Actions** menu. The **Specifications** window displays for the current specification.

2. Refer to the "Specifications" topic for information on specifications. You can only view the specification.

3. Close the window.

▶ **To display the comparison specification:**

1. Choose **Display Comparison Spec** from the **Actions** menu. The **Specifications** window displays.

2. Refer to the "Specifications" topic for information on specifications. You can only view the specification.

3. Close the window.

▶ **To change disposition:**

1. Choose **Change Disposition** from the **Actions** menu. The **Quality Change Disposition** window displays.

2. Refer to the "Changing Quality Disposition" topic for information on changing the disposition of a sample.

3. Close the window.

▶ **To display the Item Samples window:**

1. Choose **Sample** from the **Actions** menu. The **Item Samples** window displays.

2. Refer to the "Samples" topic for information on samples.

3. Close the window.

▶▶**To display the E-Record Generic Query:**

1. Choose **E-Record Details** from the **Actions** menu. The **E-Record Generic Query** displays if this option is available in your application.

2. Refer to "Appendix E" for information on e-records.

3. Close the window.

◗ **To display the Composite Results window:**

1. Choose **Composite Results** from the **Actions** menu. The **Composite Results** window displays.

2. Refer to the "Compositing Test Results" topic for information on compositing results.

3. Close the window.

Finding Samples for Specification Comparison

The Find Samples dialog box lets you find a sample that is currently associated to a specification that you can use for comparison to another specification.

Prerequisites

❑ Enter and save a specification.

❑ Enter and save samples.

❑ Enter and save results for samples.

◗ **To find samples for specification comparison:**

1. Navigate to the Find Samples dialog box.

2. Enter any of the following to narrow your search:

   ■ **Sample** as a combination of the four-letter organization code and the sample number.

   ■ **Item** as the item sampled.

   ■ **Lot** as the lot sampled.

   ■ **Sublot** as the sublot sampled.

   ■ **Disposition** as Pending, In Progress, Accept, Accept with Variance, Complete, Cancel, or Reject. If you leave this field blank, then it does not include sample disposition in the search.

3. Click **Find**. The **Specification Comparison** window displays any current specification that matches the parameters entered.

Changing Quality Disposition

The Quality Change Disposition dialog box lets you change the disposition of a sample, or sample group to indicate the final review of the Quality Manager. When the sample or sample group disposition is finalized to Accept, Accept with Variance, Reject, or Cancel, then the result records cannot be edited, and additional tests cannot be added. Changing to a final sample group disposition of Accept, Accept with Variance, or Reject can also update lot status, grade, hold date, and the item lot UOM conversion factors between UOM classes. The disposition of a sample or sample group can be assigned automatically or manually according to preseeded business rules. Sample groups that have only one sample have the same disposition as the single sample in that group.

You can access this dialog box from the following windows:

- Item Samples

- Monitoring Samples

- Results

- Specification Comparison

- Composite Results

Assigning Sample Disposition Automatically

The sample disposition is set automatically based on the status of sampling and testing as follows:

- Changes from Pending to:

    - In Process if at least one result exists.

    - Complete if all results are recorded.

    - Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.

    - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.

    - Reject if all results are recorded and at least one is not acceptable.

- Changes from In Process to:

    - Complete if all results are recorded.

- Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.

- Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.

- Reject if all results are recorded and at least one is not acceptable.

- Changes from Complete to:

    - Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.

    - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.

    - Reject if all results are recorded and at least one is not acceptable.

- Changes from Accept to:

    - In Process if a test is added and no result is entered yet.

    - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.

    - Reject if all results are recorded and at least one is not acceptable.

- Changes from Accept with Variance to:

    - In Process if a test is added and no result is entered yet.

    - Reject if all results are recorded and at least one is not acceptable.

Assigning Sample Disposition Manually

You can change the sample disposition manually as follows:

- Change from Planned to:

    - Retain

    - Pending

    - Cancel

- Change from Retain to Pending, or Cancel

- Change from In Progress to Complete, or Cancel

- Change from Complete to:
  - Accept
  - Accept with Variance
  - Reject
  - Cancel

Assigning Sample Group Disposition Automatically

The sample group disposition reflects the disposition of the samples that comprise the sample group for an event. This includes receiving, batch step release, and lot expiration. Disposition is set to:

- Planned if all the samples in the sample group are planned, but not yet taken.
- Pending if all the samples in the sample group are created, but not yet analyzed, or if all of the result evaluations are marked as Cancel.
- In Progress if at least one sample in the sample group has a result entered, but testing is not yet complete for all samples.
- Complete if all samples in the sample group have testing completed for all required and impromptu tests.
- Accept if all samples in the sample group have testing complete and have a sample disposition of Accept.
- Accept with Variance if all samples in the sample group are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
- Reject if all samples in the sample group have testing complete and have a sample disposition of Reject.

Assigning Sample Group Disposition Manually

You can change the sample group disposition manually as follows:

- Change from In Progress to Complete, or Cancel.
- Change from Complete to Accept, Accept with Variance, Reject, or Cancel.

Changing Lot Status

The application evaluates and defaults the lot status of a sampled lot based on whether or not the sample group meets the associated specification. You can also

change the lot grade if the results meet the specification grade. Lot status and grade are used to allocate inventory properly for production and shipment, or to prevent failed lots from being sold or shipped. These decisions are based on your individual business requirements.

Changing Lot Hold Date

The Hold Date field on the Quality Change Disposition dialog box lets you update the hold release date for the sampled lot in the inventory application when finalizing the sample group disposition. The lot and optional sublot must be defined on the sample in order to display the hold release date.

Selecting an Inventory Transaction Reason Code

When you select an inventory transaction reason code on this window, you can only display those reason codes that you were granted permission to access. In order to view a reason code on this window, your responsibility must have security enabled for STSI and GRDI document types.

Entering UOM Conversions

Refer to the "Using Lot UOM Conversions Based on Quality Results" for a complete explanation of how to enter lot unit of measure conversions based on quality results.

Refer to the *Oracle Process Manufacturing Inventory Management User's Guide* for more details on changing lot status and grade.

Requirements for Entry of Lot and Sublot

Lot and Sublot are required fields if:

- You access this window from the Composite Results window for a sample group or from the Item Samples window if the sample is the only sample in the sample group.

- The Source field is Supplier, Inventory, or WIP for the sample or sample group.

- The item is lot controlled. You can enter sublot if the item is sublot controlled and you entered a lot.

- There is no lot specified on the sample or sample group, and Lot Optional on Sample is selected.

- Delayed Lot Entry is selected for the supplier, inventory or WIP specification validity rule associated to the sample.

- The current disposition is changed to a final disposition of Accept, Accept with Variance, or Reject. An error message displays if the lot is entered and the sample disposition is not updated.

Prerequisites

❑ Enter and save a sample.

❑ Optionally, enter results against the sample.

◗ **To change the quality disposition of a sample:**

1. Navigate to the Quality Change Disposition dialog box.

2. The following fields are display only:

    - **Sample** indicates sample number as a combination of the four-letter organization code and the sample number. This field is blank for a sample group.

    - **Item** indicates the item sampled.

    - **Lot** indicates the lot sampled.

    - **Sublot** indicates the sublot sampled.

    - **Spec** displays the specification, if one is associated to a sample, and the specification **Version**.

Disposition

3. **Current Disposition** displays the present disposition of the sample.

4. Enter **Change Disposition To** as:

    - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

    - **In Progress** when at least one result exists for the sample, but testing is not yet complete.

    - **Complete** when testing of all required tests and all additional tests is complete.

    - **Accept** when sample testing is complete, and results are in-specification.

    - **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.

- **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.

- **Retain** when the sample is reserved and put in storage. Typically, results do not exist for a sample with this disposition.

- **Cancel** when the sample is canceled.

Required.

5. Select **Schedule Specification Tests** when you are changing an archive sample from a disposition of Retain to Pending.

- Select this indicator to add all tests listed on the associated specification to the Results window.

- Clear this indicator to add tests directly to the sample on the Results window.

6. Enter **Change Lot Status To** as the new lot status. This field defaults to the In Spec Lot Status or the Out-of-Spec Lot Status that is defined on the specification validity rule if the Control Lot Attributes indicator is selected.

7. Enter **Change Lot Grade To** as the new lot grade. This field defaults to the grade specified on the associated specification if the Control Lot Attributes indicator is selected on the specification validity rule.

8. Enter a **Reason Code** for a lot status change, grade change, or both. This defaults from the Quality System Parameters window, and is restricted by reason code security.

9. Enter a **Hold Date** when the lot is released from quality hold for inspection. This date defaults from the Lot/Sublot window in the OPM Inventory application, and can be changed to reflect the expedition or delay in testing.

UOM Conversions

10. Select **Recommend** to indicate that you approve the displayed item lot UOM conversion to be stored and sent for consideration as the item lot UOM conversion. Clear this indicator to indicate that you do not want the conversion to be sent to OPM Inventory Control.

11. **Test** displays the test used to process the conversion. This can be a numeric or an expression test. Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for an explanation of how this test is entered and how it is used in the UOM conversion process.

12. **From UOM** displays the item primary UOM on the specification. Each of the conversions corresponds to a test on the specification where the Calculate UOM Conversion indicator is selected, the result value is entered, and the result status is not Cancel or Void. For example, the From UOM is in kilograms which is defined as a Mass unit of measure type. The base unit of measure for Mass is pounds.

13. **Current** conversion displays the value of the existing lot UOM conversion for the item lot between the item primary UOM and the To UOM (the unit of measure to convert to). If this conversion exists, it must be converted to the item primary UOM and the To UOM since conversions are stored in the base units.

14. **Proposed** conversion displays the test result or proposed value of the existing lot UOM conversion for the item. The result for the specification test is used to calculate the UOM conversion.

15. **To UOM** displays the unit of measure to convert to as specified in the test listed in the specification. For example, the To UOM is in liters which is defined as a Volume unit of measure type. The base unit of measure for Volume is gallons.

16. **Conversion in Base UOM** is Item Base UOM (first field) equal to the calculated conversion factor (second field) multiplied by the base To UOM (third field). For example, one pound equals X gallons, where X is the calculated conversion factor. The second line is the inverse conversion.

17. Click **OK**.

Associating Results to Another Sample

The Result Association window lets you associate test results from a parent (source) sample, to a child (target) item sample. You can associate results for a sample or sample group. This process prevents redundant data entry, and it maintains an association to the parent test result or parent composited test result. One of the benefits of results association is to leverage intermediate results for finished goods reporting.

In the results association process, all test results that are common to the parent and child sample or sample groups are associated. Parent sample or sample group results can be associated repeatedly in several other child samples or child sample groups. You cannot undo a result association after the child sample results are saved. If you make a mistake in associating a result, then you can delete the child sample, or void the result that was inherited through the association.

After results are associated to the child sample, you can review them and add new tests or replicates as required. Enter results for these additions and save your work. Generate a Certificate of Analysis based on the revised child sample.

Associated results appear on the Quality Workbench indicating the parent sample number. Tests with inherited results do not initiate OPM Quality Test Workflow Notifications, and do not contribute to the composite result statistics when the child sample results are aggregated.

Prerequisites

❏ Create the parent sample.

❏ Enter and save test results for the parent sample. The parent sample must have a disposition of Accept, Accept with Variance, or Reject.

❏ Create the child sample, and change its disposition to Pending.

◗ **To associate results for a single sample from the Results window:**

1. Navigate to the **Results** window.

2. Query the child **Sample**.

3. Choose **Result Association** from the **Actions** menu. The **Result Association** window displays.

4. Select any of following fields to find a parent sample:

   ▪ **Item** is the sample item and its description.

   ▪ **Lot** is the optional sample lot.

■ **Sublot** is the optional sample sublot.

5. Enter **Source** as the source of the parent sample:

   ■ **Customer** indicates that the sample source is from a customer.

   ■ **Inventory** indicates that the sample source is from inventory.

   ■ **Supplier** indicates that sample source is from a supplier.

   ■ **WIP** indicates that the sample source is from work in process.

6. Select the desired **Parent Sample Group** based on the selection criteria. Required. The **Organization**, **Creation Date**, and disposition of the sample group is retrieved.

Include

7. Select **Text** to include text associated from the parent sample to the child sample.

8. Select **Flexfield** to include the flexfield associated from the parent sample to the child sample.

9. Select **Attachment** to include the attachment associated from the parent sample to the child sample.

Result Association

10. The following fields are display only:

   ■ **Test** displays the predefined test code for each result.

   ■ **Parent Replicate** is blank because a composite result is used.

   ■ **Result** displays the composite test result from the parent sample group.

   ■ **Result Date** displays the date the result was entered on the parent sample.

   ■ **Child Replicate** displays the replicate number for the result in the child sample.

11. Click **OK** to associate the parent sample results to the child sample.

▶ **To associate results from the Composite Results window:**

1. Navigate to the **Composite Results** window.

2. Query the child **Sample Group**.

3. Choose **Result Association** from the **Actions** menu. The **Result Association** window displays.

4. Query any of following fields to find a parent sample group:

   - **Item** is the sample item and its description.

   - **Lot** is the optional sample lot.

   - **Sublot** is the optional sample sublot.

5. Enter **Source** as the source of the parent sample group:

   - **Customer** indicates that the sample group is from a customer.

   - **Inventory** indicates that the sample source is from inventory.

   - **Supplier** indicates that sample source is from a supplier.

   - **WIP** indicates that the sample source is from work in process.

6. Select the desired **Parent Sample** based on the selection criteria by entering the organization code and sample group number. Required.

Include

7. Select **Text** to include text associated from the parent sample group to the child sample group.

8. Select **Flexfield** to include the flexfield associated from the parent sample group to the child sample group.

9. Select **Attachment** to include the attachment associated from the parent sample group to the child sample group.

Result Association

10. The following fields are display only:

    - **Test** displays the predefined test code for each result.

    - **Parent Replicate** displays the highest acceptable replicate of the most recent result for the parent sample.

    - **Result** displays the test result.

    - **Result Date** displays the date the result was saved.

    - **Child Replicate** is blank because a composite result is used.

Parent Group Samples

11. The following fields are display only:

   ■ **Organization** is the organization where the sample is drawn.

   ■ **Sample** is the combination of the four-letter organization code hyphenated with the sample number.

12. Click **OK** to associate the composited results to the target sample group.

▶ **To display the parent sample for an associated result:**

1. Place the cursor on the desired test line that has a result association to a parent sample.

2. Choose **Parent Sample** from the **Actions** menu. The **Samples** window displays the parent sample for the associated result.

3. Close the window.

7

Reports and Inquiries

This topic explains several preformatted reports that assist you in identifying items that need quality attention. Reports display results obtained from quality test samples taken from inventory, customers, suppliers, and production. A Certificate of Analysis or Certificate of Conformance report provides documentation that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer. A sample storage inquiry helps you determine the physical storage warehouse and location for each sample.

The following reports and inquiries are discussed:

- Requirements

- Solutions

- Running the Item/Location Required Analysis Report

- Running the Item/Location Test Results Report

- Running the Customer/Supplier Test Results Report

- Running the Production Test Results Report

- Running the Certificate of Analysis or Conformance Report

- Making a Sample Storage Summary Inquiry

- Generating Sample Labels

Requirements

Following are some requirements that customers have for reports in Quality Management. The answers are explained in detail in the "Solutions" topic.

Is there a report that identifies inventory that is near expiration?

Yes. Use the Item/Location Required Analysis report to monitor inventory that is close to expiration, or requires retesting.

Can inventory test results be identified separately from other test results?

Yes. Use the Item/Location Test Results report to display test results for inventory samples.

Can supplier or customer sample test results be printed?

Yes. Use the Customer/Supplier Test Results report to print the test results for customer or supplier samples.

Can production sample test results be viewed while material is being processed?

Yes. Use the Production Test Results report to display the test results for production samples.

Does the application offer both Certificate of Analysis and Certificate of Conformance reports?

Yes. Use the Certificate of Analysis/Conformance report to provide verification that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer.

Can sample storage warehouse and location be identified?

Yes. Use the Sample Storage Summary inquiry to display the physical storage warehouse and location of a sample taken for quality testing purposes.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the production process. The following represent some of the key performance solutions for reports.

Use the Item/Location Required Analysis Report to Monitor Inventory   The Item/Location Required Analysis report identifies inventory that requires retesting and items that require evaluation of expiration dating.

Use the Item/Location Test Results Report to Display Test Results for Inventory Samples   The Item/Location Test Results report displays the results obtained from quality samples taken against inventory.

Use the Customer/Supplier Test Results Report to Display Test Results for Customer or Supplier Samples   The Customer/Supplier Test Results report displays the test results for customer or supplier samples.

Use the Production Test Results Report to Display Production Sample Test Results   The Production Test Results report displays the test results for production samples.

Use the Certificate of Analysis/Conformance Report to Verify Test Procedures and Quality Specifications   The Certificate of Analysis/Conformance report provides verification that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer.

Use the Sample Storage Summary Inquiry to Identify Where Samples are Stored The Sample Storage Summary inquiry lets you display the physical storage warehouse and location of a sample taken for quality testing purposes.

Running the Item/Location Required Analysis Report

The Item/Location Required Analysis report allows you to identify inventory that needs attention. This includes items that require retesting and items that require evaluation of their expiration dating. The report lists the items and locations that need attention, the date the attention is required, and the action to be taken.

There must be a specification with an inventory specification validity rule or each item and lot combination for the item to appear on the report. The report allows you to select inventory from specific warehouses by lot status. You can include expired items, and those that require retesting. You can also include items that will expire or require retesting in the future. An expired lot must contain inventory in order for it to appear on the report. This report analyzes at the item level, and lets you select inventory from specific warehouses by lot status.

▶ **To submit the Item/Location Required Analysis report:**

1. Navigate to the **Submit Request** window.

2. Enter **Item/Location Required Analysis Report** in the Name field. The Parameters dialog box displays.

3. Enter any of the following fields to narrow the scope of the report:

   ■ **From Whse** is the warehouse starting point for the report.

   ■ **To Whse** is the warehouse ending point for the report. This defaults initially to the From Warehouse.

   ■ **From Status** is the starting status code to include on the report.

   ■ **To Status** is the ending status code to include on the report. This defaults to the From Status.

   ■ **Expired Items** includes inventory items that expired.

   ■ **Retest Items** includes inventory items that require retesting.

   ■ **Future Expire** lets you display items that expire within a specified number of days from the current date and time. If you select **Yes**, then enter the specific number of days in the **Expire Within** field. If you select **No**, or leave this field blank, then do not make an entry in the Expire Within field.

   ■ **Future Retest** lets you display items that require retesting within a specified number of days from the current date and time. If you select Yes, then enter the specific number of days in the **Retest Within** field. If you select No, or leave this field blank, then do not make an entry in the Retest Within field.

- ■ **Exclusive Test** lets you exclude inventory already tested within a specified number of days from the current date and time. If you select **Yes**, then enter the specific number of days in the **Exclusive Within** field. If you select **No**, or leave this field blank, then do not make an entry in the Exclusive Within field.

4. Click **OK**. The **Submit Request** window displays.

5. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

Item/Location Required Analysis Report Description

The first page of the report summarizes the report parameters submitted. The following fields are displayed on subsequent pages:

- ■ **Item** displays the item sampled and a brief description.

- ■ **Lot** displays the lot sampled, if the item is lot controlled.

- ■ **Sublot** displays the sublot sampled, if the item is sublot controlled.

- ■ **Warehouse** displays the warehouse of the item sampled.

- ■ **Location** displays the location in the warehouse where the item was sampled, if the warehouse is location controlled.

- ■ **Lot Status** displays the current lot status of the item.

- ■ **Retest Date** displays the scheduled retest date for the item.

- ■ **Expire Date** displays the current expiration date of the item.

- ■ **Test** displays the test name from the specification.

- ■ **Target** displays the specification target, if one is defined for the test.

- ■ **Min. Value** displays the specification minimum value defined for the test.

- ■ **Max. Value** displays the specification maximum value defined for the test.

- ■ **Unit** displays the test unit of measure for the test.

Running the Item/Location Test Results Report

The Item/Location Test Results report displays the results obtained from quality samples against inventory.

▶ **To submit the Item/Location Test Results report:**

1. Navigate to the **Submit Request** window.

2. Enter **Item/Location Test Results Report** in the Name field. The Parameters dialog box displays.

3. Enter **Orgn** as any valid organization that you have privileges to access. Defaults from the GMA: Default Organization profile option. Required.

4. Enter any of the following fields to narrow the scope of the report:

   ■ **From Sample** is the starting sample number for the report.

   ■ **To Sample** is the ending sample number for the report.

   ■ **From Item** is the starting item code for the report.

   ■ **To Item** is the ending item code for the report.

   ■ **From Lot** is the starting lot for the report.

   ■ **To Lot** is the ending lot for the report.

   ■ **From Sublot** is the starting sublot for the report.

   ■ **To Sublot** is the ending sublot for the report.

   ■ **From Whse** is the starting warehouse for the report.

   ■ **To Whse** is the ending warehouse for the report.

   ■ **From Location** is the starting location for the report.

   ■ **To Location** is the ending location for the report.

   ■ **From Result Date** is the starting result date for the report. The date defaults to the current date and time.

   ■ **To Result Date** is the ending result date for the report. The date defaults to the current date and time.

   ■ Select one of the following to **Include** or exclude results as follows:

   All Results to include all results on the report, including those that are not in-specification.

Most Recent Final to include only one result with the most recent result date for each test and exclude any results that are not in-specification from appearing on the report.

■ Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:

None to prevent the printing of specification text and result text on the report.

Result Text to print result text on the report. specification text is not printed.

Spec Text to print specification text on the report. Result text is not printed.

Spec Text/Result Text to print both specification text and result text.

■ **From Result Date** and **To Result Date** display the system date as default. If you enter additional selection criteria such as From Sample, To Sample, From Item, or To Item, then the selection criteria must coincide with the From Result Date and To Result Date in order to generate a meaningful report.

5. Click **OK**. The **Submit Request** window displays.

6. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

Item/Location Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields are displayed on subsequent pages:

■ **Item** displays the item sampled and a brief description.

■ **Lot** displays the lot sampled, if the item is lot controlled.

■ **Sublot** displays the sublot sampled, if the item is sublot controlled.

■ **Warehouse** displays the warehouse of the item sampled.

■ **Location** displays the location in the warehouse where the item was sampled, if the warehouse is location controlled.

■ **Test** displays the test name from the specification.

■ **Target** displays the specification target for the test.

■ **Unit** displays the quality unit of measure for the test.

- **Minimum** displays the specification minimum value defined for the test.

- **Maximum** displays the specification maximum value defined for the test.

- **Target** displays the text label for the specification target.

- **Min** displays the minimum label for the specification minimum.

- **Max** displays the maximum label for the specification maximum.

- **Effective From** displays the starting effective date for the specification validity rule.

- **Effective Thru** displays the ending effective date for the specification validity rule.

- **Specification Text** displays text associated to the specification used.

- **Result** displays the test result.

- **Unit** displays the quality unit of measure for the result.

- **Result Date** displays the date the result was recorded.

- **In-Spec** indicates whether the result was in or out-of-specification.

  - Selected indicates the sample was in-specification.

  - Cleared indicates the sample was out-of-specification.

- **Sample Number** indicates the sample number corresponding to the result displayed.

- **Quantity** displays the sample quantity.

- **UOM** displays the inventory unit of measure for the sample.

- **Sample Date** displays the date the sample was created.

- **Result Text** displays text associated with the results entered.

Running the Customer/Supplier Test Results Report

The Customer/Supplier Test Results report displays the results of the quality test sample results entered for customers or suppliers.

▶ **To submit the Customer/Supplier Test Results report:**

1. Navigate to the **Submit Request** window.

2. Enter **Customer/Supplier Test Results Report** in the Name field. The Parameters dialog box displays.

3. Select the **Report Type** to indicate the type of test results report:

   ■ **Customer** for a customer report.

   ■ **Supplier** for a supplier report.

4. Enter any of the following fields to narrow the scope of the report:

   ■ **From Customer/Supplier** is the starting customer or supplier number.

   ■ **To Customer/Supplier** is the ending customer or supplier number.

   ■ **From Item** is the starting item code for the report.

   ■ **To Item** is the ending item code for the report.

   ■ **From Lot** is the starting lot for the report.

   ■ **To Lot** is the ending lot for the report.

   ■ **From Sublot** is the starting sublot for the report.

   ■ **To Sublot** is the ending sublot for the report.

   ■ **From Result Date** is the starting result date for the report. The date defaults to the current date and time.

   ■ **To Result Date** is the ending result date for the report. The date defaults to the current date and time.

   ■ **From Sample** is the starting sample for the report.

   ■ **To Sample** is the ending sample for the report.

   ■ Select one of the following to **Include** results as follows:

     All Results to include all results on the report, including those that are not in-specification.

Most Recent Final to include only one result with the most recent result date for each test and exclude any results that are not in-specification from appearing on the report.

■ Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:

None to prevent the printing of specification text and result text on the report.

Result Text to print result text on the report. specification text is not printed.

Spec Text to print specification text on the report. Result text is not printed.

Spec Text/Result Text to print both specification text and result text.

5. Click **OK**. The **Submit Request** window displays.

6. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

Customer/Supplier Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields display on subsequent pages:

■ **Item** displays the item sampled and a brief description.

■ **Lot** displays the lot sampled, if the item is lot controlled.

■ **Sublot** displays the sublot sampled, if the item is sublot controlled.

■ **Warehouse** displays the warehouse of the item sampled.

■ **Location** displays the location in the warehouse where the item was sampled, if the warehouse is location controlled.

■ **Test** displays the test name from the specification.

■ **Target** displays the specification target for the test.

■ **Unit** displays the quality unit of measure for the test.

■ **Minimum** displays the specification minimum value defined for the test.

■ **Maximum** displays the specification maximum value defined for the test.

■ **Target** displays the text label for the specification target.

■ **Min** displays the minimum label for the specification minimum.

- **Max** displays the maximum label for the specification maximum.

- **Effective From** displays the starting effective date for the specification validity rule.

- **Effective Thru** displays the ending effective date for the specification validity rule.

- **Specification Text** displays text associated to the specification used.

- **Result** displays the test result.

- **Unit** displays the quality unit of measure for the result.

- **Result Date** displays the date the result was recorded.

- **In-Spec** indicates whether the result was in or out-of-specification.

  - Selected indicates the sample was in-specification.

  - Cleared indicates the sample was out-of-specification.

- **Sample Number** indicates the sample number corresponding to the result displayed.

- **Quantity** displays the sample quantity.

- **UOM** displays the inventory unit of measure for the sample.

- **Sample Date** displays the date the sample was created.

- **Result Text** displays text associated with the results entered.

Running the Production Test Results Report

The Production Test Results report displays all of the results obtained from quality test sample results entered for production samples.

▶ **To submit the Production Test Results report:**

1. Navigate to the **Submit Request** window.

2. Enter **Production Test Results Report** in the Name field. The Parameters dialog box displays.

3. Enter any of the following fields to narrow the scope of the report:

    ■ **From Sample** is the starting sample for the report.

    ■ **To Sample** is the ending sample for the report.

    ■ **From Batch** is the starting batch for the report.

    ■ **To Batch** is the ending batch for the report.

    ■ **From Formula** is the starting formula for the report.

    ■ **To Formula** is the ending formula for the report.

    ■ **From Formula Version** is the starting formula version for the report.

    ■ **To Formula Version** is the ending formula version for the report.

    ■ **From Routing** is the starting routing for the report.

    ■ **To Routing** is the ending routing for the report.

    ■ **From Routing Version** is the starting routing version for the report.

    ■ **To Routing Version** is the ending routing version for the report.

    ■ **From Routing Step Number** is the starting routing step number for the report.

    ■ **To Routing Step Number** is the ending routing step number for the report.

    ■ **From Operation** is the starting operation for the report.

    ■ **To Operation** is the ending operation for the report.

    ■ **From Item** is the starting item for the report.

    ■ **To Item** is the ending item for the report.

    ■ **From Lot** is the starting lot for the report, if the item is lot controlled.

- **To Lot** is the ending lot for the report, if the item is lot controlled.

- **From Sublot** is the starting sublot for the report, if the item is sublot controlled.

- **To Sublot** is the ending sublot for the report, if the item is sublot controlled.

- **From Result Date** is the starting result date for the report. The date defaults to the current date and time.

- **To Result Date** is the ending result date for the report. The date defaults to the current date and time.

- Select one of the following to **Include** results as follows:

  All Results to include all results on the report, including those that are not in-specification.

  Most Recent Final to include only one result with the most recent result date for each test and exclude any results that are not in-specification from appearing on the report.

- Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:

  None to prevent the printing of specification text and result text on the report.

  Result Text to print result text on the report. Specification text is not printed.

  Spec Text to print specification text on the report. Result text is not printed.

  Spec Text/Result Text to print both specification text and result text.

4. Click **OK**. The **Submit Request** window displays.

5. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

Production Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields are displayed on subsequent pages:

- **Batch** displays the batch number of the sample.

- **Formula** displays the formula used to produce the sample.

- **Version** displays the formula version.

- **Routing** displays the routing used to produce the sample.

- **Version** displays the routing version.

- **Step** displays the batch step number of the sample.

- **Charge** displays the charge number of the sample.

- **Operation** displays the operation used to produce the sample.

- **Version** displays the operation version.

- **Item** displays the item sampled and a brief description.

- **Lot** displays the lot sampled, if the item is lot controlled.

- **Sublot** displays the sublot sampled, if the item is sublot controlled.

- **Warehouse** displays the warehouse of the item sampled.

- **Location** displays the location in the warehouse where the item was sampled, if the warehouse is location controlled.

- **Test** displays the test name from the specification.

- **Target** displays the specification target for the test.

- **Unit** displays the quality unit of measure for the test.

- **Minimum** displays the specification minimum value defined for the test.

- **Maximum** displays the specification maximum value defined for the test.

- **Target** displays the text label for the specification target.

- **Min** displays the minimum label for the specification minimum.

- **Max** displays the maximum label for the specification maximum.

- **Effective From** displays the starting effective date for the specification validity rule.

- **Effective Thru** displays the ending effective date for the specification validity rule.

- **Specification Text** displays text associated to the specification used.

- **Result** displays the test result.

- **Unit** displays the quality unit of measure for the result.

- **Result Date** displays the date the result was recorded.

- **In-Spec** indicates whether the result was in or out-of-specification.

- ■ Selected indicates the sample was in-specification.

- ■ Cleared indicates the sample was out-of-specification.

- ■ **Sample Number** indicates the sample number corresponding to the result displayed.

- ■ **Quantity** displays the sample quantity.

- ■ **UOM** displays the inventory unit of measure for the sample.

- ■ **Sample Date** displays the date the sample was created.

- ■ **Result Text** displays text associated with the results entered.

Running the Certificate of Analysis or Conformance Report

The Certificate of Analysis or Certificate of Conformance report verifies that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer. A process manufacturer authorizes a Certificate of Analysis or Certificate of Conformance for shipment of supplies that usually require inspection upon receipt.

The Certificate of Analysis or Certificate of Conformance report presents data derived from quality management information. These reports are created primarily for items that are included on sales orders and shipped to customers. A customer may require certification of tests that were performed, and results generated on specific products sold to them. Potential customers sometimes review results certification before ordering products. Specifications with inventory or customer specification validity rules impact these reports. Production specification validity rules have no impact.

Depending on the item lot status, certificate type specified on the specification validity rule that is in effect, and availability of information about a specific item, either a Certificate of Analysis or a Certificate of Conformance report is generated.

The Certificate of Analysis Report

This report shows that certain tests were performed on an item, which specification limits or targets are required, what the test results are, and the date each result was entered. A Certificate of Analysis report is only generated when:

■ The item is active and lot controlled.

■ The certificate type on the specification validity rule is set to Certificate of Analysis.

■ Sampling event disposition is Accept or Accept with Variance.

■ Specifications and results exist for the item and lot selected.

■ Print Spec and Print Result are selected on the specification.

■ Sample Disposition is Approved.

■ Results are within specification, have an evaluation of Accept or Accept with Variance, and are not marked optional or for deletion. The most recent replicate and composited result average is reported.

■ Sales Order shipment status is not VOID if a Sales Order, Bill of Lading, or shipping information are supplied as parameters.

■ Items selected are not scheduled for deletion.

- Appropriate selection criteria are entered on the Certificate of Analysis Report window.

- Certificate of Analysis is selected on the Results window.

The Certificate of Conformance Report

This report shows the tests that are performed on a specific item and what specification limits or targets are required. A Certificate of Conformance report can be generated when:

- The item is active.

- The certificate type on the specification validity rule is set to Certificate of Conformance.

- Specifications exist for the item and tests on the specification are not marked as optional.

- Print Spec is selected on the specification.

- Appropriate selection criteria are entered on the Certificate of Analysis Report window.

Impact of Customer Specification Validity Rules on the Certificate of Analysis Report

For specifications that have a customer specification validity rule in effect:

- The results on the Certificate of Analysis are based on the specification with a customer specification validity rule, even if the sample was analyzed against another specification validity rule type. The decimal precision selected is used in the report.

- If a customer specification validity rule does not exist, then the inventory specification validity rule in effect for the item is used. If the inventory specification validity rule is used, then the organization, lot, item, and warehouse must be specified as report parameters before running the Certificate of Analysis report.

- The organization, item, lot, sublot, and customer must be specified as report parameters before running the Certificate of Analysis report.

- The Print Spec and Print Result indicators on the specification determine which tests and results are printed on the Certificate of Analysis.

- The customer-specific test aliases are printed instead of the test code on the Certificate of Analysis.

■ The report prints without the requirement for entry of item and lot criteria.

◗ **To run the Certificate of Analysis report:**

1. Navigate to the **Certificate of Analysis Report** window.

2. Enter the **Organization**. A brief description of the organization displays to the right of this field. Required.

Selection Criteria

3. As you enter data in the following fields, some of the fields fill automatically. This occurs in cases where a specific order, shipment, item, or lot is identified from the data supplied. Enter at least one of the following additional parameters to run the report:

   ■ **Ship Date** indicates the From Ship Date in the first field, if this date is available, and the To Ship Date in the second field. Both the From Ship Date and To Ship Date default to the current system date and time. If you know the Actual Ship Date, then enter it in both fields. If the Actual Ship Date is not available, then the Scheduled Ship Date displays on the report.

   ■ **Sales Order Number** is the number of the sales order that contains the item.

   ■ **Customer** is the customer number. The customer name entered on the sales order detail line displays if it is available.

   ■ **Shipment Number** is the sales order shipment number.

   ■ **Item** is the item sampled and a brief description.

   ■ **Lot** is the lot number. A brief description of the lot appears to the right of this entry.

   ■ **Sublot** is the sublot number, if the item is sublot controlled.

   ■ **Warehouse** is the warehouse code. A brief description of the warehouse appears to the right of the entry.

Print Text Options

4. Specification and result text that is added through the Edit Text feature on the Actions menu of the Specifications or Results windows appears only if the appropriate Print Text Options are selected on the Certificate of Analysis Report Parameters window. Select one of the following to print the report:

   ■ **No Text** to suppress printing the Edit Text on the report.

- ■ **All Text** to include Specification and result text on the report.

- ■ **Specification Text Only** to include only specification text on the report.

- ■ **Result Text Only** to include only result text on the report.

Print Options

5. To print the report, enter the number of **Copies** to print. If you want to view the report, enter **0**, and no hard copy is generated.

6. Enter the name of the **Printer**. **Style** displays the default report style.

7. Click **OK**.

▶ **To view the Certificate of Analysis report:**

1. Select **Requests** from the **View** menu.

2. Select **All My Requests**, and click **Find**.

3. Select the current record indicator next to the requested **Certificate of Analysis** report to view. Make sure that the report phase is completed.

4. Click **View Output**. The report selected displays. The output defaults to a *.pdf file, but can be changed by the System Administrator.

Certificate of Analysis or Conformance Report Description

Depending on the report, certain fields are blank when information is not available. The following are descriptions of the fields displayed:

Report Title

One of the following titles prints on the report:

- **Certificate of Analysi**s displays when selected as the certificate type on the specification validity rule.

- **Certificate of Conformance** displays when selected as the certificate type on the specification validity rule.

Report Body

- **Organization** displays the name of the organization running the report.

- **Customer** displays the ship-to customer number and name from the sales order detail line.

- **Customer PO** displays the purchase order number from the sales order header.

- **Order Number** displays the customer sales order number from the sales order header.

- **Shipment Number** displays the bill of lading number from the shipment header.

- **Shipment Date** displays the actual shipment date if it is available. If this date is not available, then this field displays the scheduled shipment date.

- **Item** displays the item sampled and a brief description.

- **Warehouse** displays the From Warehouse abbreviation and its description.

- **Lot** displays the lot sampled, if the item is lot controlled.

- **Sublot** displays the sublot number and its description if the item is sublot controlled.

- **Quantity Ordered (Qty1)** displays the quantity and unit of measure ordered.

- **UOM** displays the primary unit of measure for the quantity ordered.

- **Qty2** displays the number of items ordered in the secondary unit of measure, if the item is dual unit of measure controlled.

- **UOM2** displays the secondary unit of measure for the quantity ordered.

- **Quantity Shipped (Qty1)** displays the quantity and unit of measure shipped.

- **UOM** displays the primary unit of measure for the quantity shipped.

- **Qty2** displays the number of items shipped in the secondary unit of measure, if the item is dual unit of measure controlled.

- **UOM2** displays the secondary unit of measure for the quantity shipped.

- **Test** displays the test name and description on which the result or specification is based. The test alias appears if it is defined for the test or for a specific customer.

- **Unit** displays the quality unit of measure for the target.

- **Result** displays the result value. Numeric results are rounded according to the decimal precision defined on the specification. The text equivalent is shown for the Numeric Range with Display Text test data type. This information appears on the Certificate of Analysis, but it does not appear on the Certificate of Conformance. Target values for tests without a minimum and maximum appear in the Minimum column.

- **Result Date** displays the date the result was recorded.

- **Specifications Text** displays any Edit Text associated with the current specification when Specification Text Only or All Text are selected as Print Text Options.

- **Result Text** displays any Edit Text associated with the current Result when Result Text Only or All Text are selected as Print Text Options.

Making a Sample Storage Summary Inquiry

The Sample Storage Summary window lets you display the physical storage warehouse and location of a sample taken for quality testing purposes. Sample attributes displayed are: item code, lot, sublot, sample number, sample quantity and unit of measure, date the sample was drawn, sampler, organization, and sample source.

▶ **To display a summary of samples stored:**

1. Navigate to the **Sample Storage Summary** window.

2. The following fields are display only:

   - **Whse** displays the name of the warehouse that stores the sample.

   - **Location** displays the physical sample location within the warehouse.

   - **Item** displays the item sampled and a brief description.

   - **Lot** displays the lot number, if defined for the sample item.

   - **Sublot** displays the sublot number sampled, if the sample is sublot controlled.

   - **Sample** displays the name of the sample tested.

   - **Sample Qty** displays the quantity of material taken for the test.

   - **UOM** displays the unit of measure for the sample quantity.

   - **Sample Date** displays the date and time the sample was entered for testing.

   - **Sampler** displays the User ID of the individual who took the sample.

   - **External ID** displays the sample test identification assigned by an external testing facility. This assists in tracing test results.

   - **Org** displays the name of the organization that owns the sample.

   - **Sample Source** displays source-specific information about the sample.

3. Close the window.

Generating Sample Labels

The Sample Label Generation report produces a character delimited flat file that you can load into a generic form processor or documentation template designer to make commercial labels for samples. You can enter a character to delimit the alphanumeric output.

Prerequisites

❏ Enter samples.

▌ **To generate sample labels:**

1. Navigate to the **Submit Request** window.

2. Enter **Sample Label Generation** in the Name field. The Parameters dialog box displays.

3. Enter the **Organization Code**.

4. To generate a set of consecutive labels, enter the starting sample number in the **Sample Number From Range**, and the ending sample number in the **Sample Number To Range**.

5. Enter an ASCII character as **File Delimiter**.

6. Click **OK**.

7. Complete the fields on the **Submit Request** window and click **Submit**.

▌ **To view the Sample Label Generation report:**

1. Select **Requests** from the **View** menu.

2. Select **All My Requests**, and click **Find**.

3. Select the current record indicator next to the requested **Sample Label Generation** report to view. Make sure that the report phase is completed.

4. Click **View Output**. The report selected displays. The output defaults to a specified file type. Your System Administrator can change this file type for purposes of submitting the character delimited flat file output to a generic form processor.

5. The organization code, sample number, and sample description are included with the other listed character-delimited flat file output. The following is an example of the report output for the sample label generator:

```
ORGN_CODE ,SAMPLE NO,SAMPLE DESC,SAMPLE QTY,SAMPLE UOM,PRIORITY,SOURCE,WHSE
CODE,LOCATION,LOT NO,SUBLOT NO,QC LAB ORGN,DATE DRAWN,EXPIRATION DATE,LOT
RETEST IND,STORAGE WHSE,STORAGE LOCATION,SAMPLE INSTANCE,PLANT CODE,BATCH
NO,FORMULA NO,FORMULA VERS,OPRN NO,OPRN VERS,RECIPE NO,RECIPE
VERSION,ROUTING NO,ROUTING VERS,CUSTOMER NAME,OPERATING UNIT,SHIP TO
SITE,ORDER TYPE ,ORDER NO  ,LINE NO  ,SUPPLIER CODE  ,SUPPLIER NAME
,SUPPLIER SITE  ,PO NUMBER  ,PO LINE NUMBER  ,RECIEPT NUMBER  ,RECIEPT LINE
NUMBER
"OPME","000089009","Bulk Tomato
Ketchup","10","LT","","Inventory","","","100200300-01","","GMD1","11-OCT-02"
,"","","","","2"," "," "," "," "," "," "," "," "," "," "," "," "," "," "," "
," "," "," "," "," "," "," "," "," "," "," "
"OPME","000089010","no controls
******","100","LT","Normal","Inventory","","","100200300-B2","","GMD1","11-O
CT-02","","","","","","","","","","","","","","","","","","","","","","","","",""
," "," "," "," "," "," "," "," "," "," "," "
"OPME","000089011","Bulk Tomato
Ketchup","100","LT","Normal","Inventory","","","100200300-B2","","GMD1","11-
OCT-02","","","","","","","","","","","","","","","","","","","","","","","",""
," "," "," "," "," "," "," "," "," "," "," "
"OPME","000089012","CN
Item","1","KGM","Normal","Inventory","ACW","","","","","11-OCT-02","","","",
"","8"," "," "," "," "," "," "," "," "," "," "," "," "," "," "," "," "," "," "
," "," "," "," "," "," "
```

8

Stability Studies

This topic provides procedures for creating and managing stability studies including when they are performed, and what essential guidelines exist for stability testing programs. The topic also provides an overview of the stability study lifecycle management, including the creation of test interval plans and the creation of a storage condition plan. You are given guidance on the creation and management of a stability study, including the assignment of its material sources, editing stability study variants and time points, and defining its storage packages.

The following topics are covered:

- Requirements

- Solutions

- Understanding Stability Studies

- Managing the Stability Study Lifecycle

- Understanding the Stability Study Change Status Workflow

- Creating Test Interval Plans

- Generating a Series of Testing Periods

- Finding Test Interval Plans

- Creating a Storage Condition Plan

- Finding Storage Condition Plans

- Defining Storage Packages

- Finding Storage Packages

- Creating and Managing a Stability Study

- Finding Stability Studies

- Assigning Stability Study Material Sources
- Editing Stability Study Variants
- Finding Stability Study Variants
- Editing Variant Time Points

Requirements

Following are some requirements addressed in defining and managing stability testing in Quality Management. The answers are explained in detail in the "Solutions" topic.

Does the OPM stability studies capability adhere to the regulatory recommendations for a written testing program?

Yes. The stability study functionality is designed to assess the stability characteristics of products, and helps you evaluate product storage conditions and expiration dating. By supplying a repository for the collection and processing of this information, OPM stability studies assists in the documentation of a written testing program. You can use the Oracle attachments functionality to link written materials to the stability study.

Can sample size and test intervals be set up to evaluate the statistical criteria for each separate attribute?

Yes. Each of the statistical variables for the stability study can be set up to evaluate the effects of sample size, test interval, and the impact of environmental variables on each individual variant in the stability study.

Is there a capability to allow for additional retained samples?

Yes. You can set up the stability study for additional retained samples that are not tested as part of the study, but are retained for historical purposes.

Does OPM help identify that reliable, meaningful, and specific test methods were used in the stability study?

Yes. Test reliability can be assessed through standard procedures that document test performance. These measures include test sensitivity, test specificity, and test linearity. You can set up specifications for each test referencing a test method. By comparing the results of these individual tests to accepted reference tests, you can assess the correlation to these methods as a measure of test accuracy.

Can several packages be investigated in the same study?

Yes. You can set up one or more packages or container closure systems to be investigated in the stability study.

Can an adequate number of batches of each product be tested in a single study to determine an appropriate expiration date?

Yes. You determine the acceptable number of batches to evaluate in the study. Records of all data for expiration dating is maintained in a single referenced study for rapid retrieval and analysis.

Can accelerated stability studies be run simultaneously with materials in the recommended storage conditions?

Yes. You can set up the recommended storage condition variants in parallel to the accelerated studies. This information lets you evaluate basic stability information on the components, products, and container closure systems. You can use this information to support tentative expiration dates when the full shelf life studies are not yet available. This indicative information helps you initiate long-term studies such as clinical investigations.

Solutions

Quality Management provides solutions to help resolve issues at every stage of the quality process. The following represent some of the key performance solutions for stability testing.

Use the Stability Study Window as a Launch Pad for the Entire Study The Stability Study window lets you enter preliminary information about the study including its document number, description, and storage condition plan. You can display the status of the study, the master item specification used to evaluate product performance, the laboratory organization conducting the study, and the owner of the study. Display additional information, including the number of variant material sources, storage conditions investigated, and packaging configurations investigated in the study. Once the study is launched, you can monitor all the dates associated to the study. At the completion of the study, the Stability Study window lets you enter recommendations for shelf life and storage specification for the material tested. Use Oracle attachments to link written materials to the stability study.

Create a Test Interval Plan, Storage Condition Plan, and Variants The Test Interval Plan window lets you simulate, evaluate, and select test intervals for the study to help you plan for statistical evaluations of study data. Use the Storage Condition Plans window to structure a set of storage conditions to apply to a study. Each storage condition includes a monitoring specification for the environmental chamber and the test interval plan. The application creates a variant for each storage condition, sample material source, and storage package combination. You can edit these variants on the Variant window.

Use Sample Disposition to Indicate Sample Retention Use sample disposition to indicate samples to retain in storage prior to stability testing.

Trace Results Back to Test Methods OPM Quality Management lets you trace a test result directly to the tester and test method used. The traceability of test method attributes includes the quantity of material required, the instrument used to perform the test, the number of replicates used, the identification of the test kit, the duration of the test, and the decimal precision of the result. Enter realistic test targets and acceptable ranges of test performance that meet or exceed the performance of accepted reference test methods by setting up specifications for each test performed. By incorporating control materials in each test run, you monitor test performance. Use control materials to evaluate correlation to reference test method performance as an assessment of test accuracy.

Enter Package Configurations on the Stability Study Window   You enter the Packages field as the total number of packaging configurations that you plan to use to build the study. The default is one package. You can study individual package closure systems to compare and contrast product performance in various packaging configurations.

Use the Material Source Field to Define Materials to Test   The required number of source materials is defined on the Stability Study window. You can identify the item, lot and sublot, and batches that become the basis for the stability study. Source materials can exist in inventory, or can be requested from production for the study.

Use Storage Condition Plan and Variants to Deliver Both Standard and Accelerated Stability Testing   Create a robust storage condition plan that includes both the standard and accelerated environmental storage conditions for materials to be tested in the stability study. Variants can then be tested in all specified environments simultaneously to deliver both standard and accelerated stability study test results.

Understanding Stability Studies

Stability studies are performed in life sciences, chemical, and food and beverage industries to determine the effects of environmental conditions on product quality. Environmental conditions can impact product shelf life, and the viability of product formulation. Stability studies provide the supporting data that companies can use to establish product storage requirements and expiration dating.

When are stability studies performed?

Stability studies are performed at various stages of the product development process. Early stages of stability testing are typically performed on laboratory materials to determine if the material to be produced has any inherent sensitivities to storage or shipping environments. Many manufacturers perform accelerated stability testing at relatively high temperatures and humidities as a worst case scenario to determine what types of degradation products may experience after long-term storage. Materials produced in a full production run are tested under controlled temperature and humidity storage conditions that simulate environmental extremes. Results of testing on these materials provide valuable information about overall product stability, and serve as a basis for product claims on storage requirements and shelf life.

What are the essential guidelines for a stability program?

There are a number of key national and international standards, laws, regulations, and guidelines for Good Manufacturing Practice (cGMP). The U.S. Food & Drug Administration (FDA) provides compliance guidelines for drugs and medical devices. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a consortium of regulatory authorities from Europe, Japan, the United States, and experts from the pharmaceutical industry worldwide. This group discusses scientific and technical aspects of product registration. The ICH makes recommendations on how to come into agreement or harmony on the interpretation and application of technical guidelines and requirements for product registration.

Section 211.166 of the FDA guidelines requires companies who produce finished pharmaceutical products to have a written stability program. The results of this program are to be used in determining appropriate storage conditions and product expiration dating. This guideline specifies what must be included in a stability program. The following summarizes some of the essentials presented in this guideline. Read the full guideline for complete information.

- A written testing program must be produced that is designed to assess the stability characteristics of drug products.The results of this stability testing program are to be used in determining appropriate drug product storage conditions and expiration dating.

- The written program must be followed, and it must include:

  - Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability.

  - Storage conditions for samples that are retained for testing.

  - Reliable, meaningful, and specific test methods.

  - Testing of the drug product in the same container closure system as that in which the drug product is marketed.

  - Testing of drug products for reconstitution at the time of dispensing as directed in the labeling as well as after they are reconstituted.

  - Testing of an adequate number of batches of each drug product to determine an appropriate expiration date. Records of this data must be maintained.

  - Accelerated studies, combined with basic stability information on the components, drug products, and container closure system, can be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted.

  - Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

Example of a Stability Program for Product X

In the following program, both study protocols are run concurrently, so that expiration dating does not factor into the interpretation of results.

Stability Study Protocol A

Measure of Active Ingredients Under Controlled Room Temperature and Humidity   There are two testing procedures to run:

- Within-lot stability at 25 deg C/30% RH - Batch 1, Lot X, Sublot A

A typical monitoring specification can be set up for temperature and humidity as follows:

- The temperature range is -10 deg C to 100 deg C. The target for a monitoring specification is 25 deg C, with a minimum of 24 deg C, and a maximum of 26 deg C.

- The humidity range is 0% RH to 100% RH. The target for a monitoring specification is 30% RH, with a minimum of 29% RH, and a maximum of 31% RH.

- Between-lot stability at 25 deg C/30% RH - Batch 2, Lot Y Sublot B, Batch 3, Lot Z, Sublot C. You can use the same monitoring specification that was designed for within-lot stability testing.

Stability Study Protocol B

Measure of Active Ingredients Under Stressed Conditions   A robust stability study can contain within-lot and between-lot investigations for various combinations of temperature and humidity. This approach provides an extensive profile of material stability at a variety of temperatures and relative humidities. The following is an example of this type of study:

- Within-lot stability at specified ICH conditions for Batch 1, Lot X, Sublot A

  - 25 deg C/40% RH

  - 25 deg C/60% RH

  - 30 deg C/35% RH

  - 30 deg C/60% RH

  - 40 deg C/20% RH

  - 40 deg C/75% RH

  - 60 deg C/20% RH

  - 60 deg C/75% RH

- Between-lot stability at specified ICH conditions for - Batch 2, Lot Y Sublot B, Batch 3, Lot Z, Sublot C

  - 25 deg C/40% RH

  - 25 deg C/60% RH

  - 30 deg C/35% RH

- 30 deg C/60% RH
- 40 deg C/20% RH
- 40 deg C/75% RH
- 60 deg C/20% RH
- 60 deg C/75% RH

OPM Quality Management stability studies let you create both simple and robust stability studies. The stability study owner remains in full control of the variants created for each time point, and can monitor the progress of the study through workflow notifications. The workflow and Oracle E-Records events associated with the stability study document critical decisions to support the written study program.

Managing the Stability Study Lifecycle

Following are stages that define a typical stability study lifecycle:

- Setting Up for a Stability Study
- Planning a Stability Study
- Performing Initial Sampling and Testing
- Approving a Stability Study Plan
- Launching a Stability Study
- Performing Stability Study Testing
- Evaluating a Stability Study

Setting Up for a Stability Study

Following are steps that describe the process of setting up for a stability study:

Step 1: Create a test interval plan. Define one or more test interval plans before creating a storage condition plan for a stability study. Each test interval plan represents a unique set of testing time points that list the junctures at which you plan to test samples in the stability study. The frequency or intervals between time points vary depending on the purpose of a storage condition. For example, long-term, intermediate, or accelerated storage conditions can have very different frequencies between time points.

All test interval plans that use the storage conditions of a stability study must be either a base interval plan or an overlay of the base interval plan assigned to the storage condition plan. Define interval periods as the testing frequencies required by the storage condition.

- Define base test interval plan as the total set of testing time points used by each of the stability study storage conditions. If all storage conditions test the sample material at the same frequency or time intervals, this is the only test interval plan you define.

- Define an overlay test interval plan when a stability study storage condition performs time point tests with a different set of time intervals from those defined in the base test interval plan. You can enter additional time points for the overlay interval plan. You cannot delete time points on the overlay interval plan that come from the base interval plan, however, you can exclude them.

Step 2: Create monitoring specifications. Create specifications to define the environmental monitoring criteria for the storage conditions. These are called monitoring specifications. A monitoring or nonitem specification must be created to include one or more tests that support each required storage condition detail such as ambient temperature, relative humidity, and atmospheric pressure. Assign tests to the monitoring specifications. Create a specification validity rule to specify the resource or location to be monitored.

Step 3: Create a storage condition plan. Create the required set of storage conditions. These conditions include a unique combination of temperature and relative humidity measurements that differentiate testing conditions for a stability study. The storage conditions created require the environmental monitoring of a defined equipment resource such as a refrigerator or a warehouse location. The planned and actual storage condition parameters must be monitored for each storage condition combination. For example, 30 deg C/60% RH requires the monitoring of both the 30 deg C refrigeration and 60% RH ambient moisture content.

Define the two components of a storage condition plan:

■ A monitoring specification to define the details of the storage condition for each one of the variants in the stability study

■ A test interval plan to define testing time points by indicating the test intervals for each variant in the stability study

Step 4: Create the storage packages. Decide on the package to use for the container closure system for the product to be tested. Create a storage package configuration.

Step 5: Create base and overlay item specifications for the stability study. Create base and overlay item specifications that contain the tests you use in stability testing. These are usually based on the product release specifications which are a combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of a product at the time of its release. The base specification serves as the default item specification when you create the stability study. You can associate the overlay specifications to time points when the stability testing requirements vary from the base specification.

Step 6: Set up for sample numbering. Set up document ordering for the SMPL document type in the organization where you plan to perform sampling.

Step 7: Set up for stability study numbering.   Set up document ordering for the STBL document type in the stability study organization.

Planning a Stability Study

Following are steps that describe the planning of a stability study:

Step 1: Create a stability study.   Create a stability study with the following information:

- Item to test in the stability study

- Master item specification to use in evaluating item performance in the stability study

- Study name to record a unique identifier for the stability study entity

- Protocol to enter as part of the study description to capture the purpose of the stability study

- Study start, notification lead time, testing grace period, and completion dates to define the beginning and end dates for study

- Study owner for subsequent approvals and notifications

- Study approval process with status control. Stability study status controls sample pull and testing notifications, and specifies how all associated samples are consumed, allocated, or used for testing in the study

Refer to the "Creating and Managing a Stability Study" topic for more information on creating a stability study.

Step 2: Assign storage condition plan to the stability study.   Assign the storage condition plan to the stability study. This plan consists of the monitoring specification that provides the details of the storage condition for each one of the variants in the stability study, and a test interval plan that defines the testing time points.

Step 3: Identify source materials to be used in the stability study.   Identify the item, lot and sublot, and batches that serve as the basis for the stability study. The source material can already exist in inventory as lots and sublots, or it can be selected, or requested as batch. Batches can be initial production batches for a new formulation, or a portion of routine production batches that are pulled for stability testing. This information includes the item, lot and sublot, batch number, date of

manufacture or product yield date, sample quantity and UOM, recipe, recipe version used, and sample quantity.

Step 4: Plan stability study variants and time points. Plan all variant storage conditions for each time point sample or sample group. Variants are defined by the unique combination of the stability study storage condition, the test interval plan, the package, and material source. Specify the default item specification, number of stability samples per time point, and the number of retained samples for the variant.

Performing Initial Sampling and Testing

Following are steps that describe initial sampling and testing in a stability study:

Step 1: Acquire initial samples from source materials. When acquiring the initial material to be used as a basis for a stability study, the item lots must be allocated or reserved as inventory for use only in the stability study. Material must be physically stored in a warehouse, location, and container, or moved directly from the manufacturing floor to a staging area where initial testing can be performed. Samples used in stability studies reflect inventory consumption and sample movement into a storage warehouse locations to manage environmental variants. An initial stability sample can be retained, or moved into a storage warehouse and location.

Step 2: Test initial samples and assign sample disposition. Define the test criteria to perform for the initial stability sample. If an approved, prerelease, laboratory specification exists for the material to be tested, then use that specification. If an approved production specification exists for the product, then use it for the initial sample testing. The selected sample specification must be entered as the base item specification defined in the stability study. The outcome of these tests determines whether an item lot, sublot, or batch should be used for continuing the stability study. Initial sampling and testing must indicate acceptable source material before the stability study can be launched.

Step 3: Select the initial sample group to associate initial samples with material sources. Associate the initial samples with a material source by selecting the appropriate sample group. Only initial sample groups with a disposition of Accept or Accept with Variance are listed. You must make this association prior to launching the stability study.

Approving a Stability Study Plan

Following are steps required to approve a stability study plan:

Step 1: Approve the stability study.   Use the Change Status action on the Stability Study window to request stability study approval. This initiates the Stability Study Change Status workflow which notifies the study owner of the request for status change in the stability study. The process of changing the status from NEW to a status of Stability Study Plan Approved is managed by the workflow. Oracle E-Records works with the workflow to enforce generation of an electronic record and capture of electronic signatures for each status change.

If material source lots and sublots are identified, then stability sample groups and samples are created automatically by the application for the planned variants and time points. These samples are based on the:

- Number of samples per time point

- Number of retained samples for a variant

- Sample quantity and UOM defined for a variant

These system-generated item samples are automatically associated to a stability study as identified by the sample source fields. You cannot create stability samples manually through the Samples window.

If the material source is requested as a batch, then the appropriate workflow initiates for batch and sample creation. Prior to launching the stability study, specify a lot on the Material Sources window. If the material is sublot controlled, then you must also specify a sublot.

Step 2: Schedule variant and time point testing.   The application generates the schedule dates for all the testing time points based on the stability study scheduled start date. A sample group is generated for each testing time point to permit the assignment of a final disposition to each point.

Step 3: Finalize acceptable material sources.   Finalize the availability and acceptability of the lots and sublots for every material source listed on the Material Sources window. Specify the lot and sublot for any batch that was requested to be produced as a material source. Prior to launching the stability study, each material source must have an acceptable initial sample group. If you cannot finalize all material sources at this time, then finalize them before you launch the stability study.

Step 4: Generate testing time point labels.   The Testing Time Point Label Generation report produces a character delimited flat file that you can load into a generic form processor or documentation template designer to make commercial labels for samples. You can enter a character to delimit the alphanumeric output. For each testing time point the report produces the name of the stability study, variant, testing time point, sample number, time point scheduled date, and sample quantity.

You can generate this report for:

- All testing time points for variants of a stability study

- All testing time points for an individual variant

- A specific time point for an individual variant

Regenerate the report for a specific variant time point if you add a time point to a variant during the study.

Step 5: Put sample materials in storage packages and place them into variant storage conditions.   If packaging is specified for the variant, then put the sample material for each variant time point in individual packages. If labels were generated, then apply them to the sample storage package. Place the materials in the defined variant storage conditions. Update the storage date of stability samples for each variant.

Step 6: Verify sufficient stability sample quantities.   Determine that there are sufficient sample materials to conduct the stability study. The total sample quantity must be validated to determine if there is sufficient quantity of material for each variant time point sample. This validation ensures that there is sufficient material to complete the required analysis. Positive material identification is essential to a fully traceable stability study.

Launching a Stability Study

Following are steps required to launch a stability study:

Step 1: Verify that material sources are finalized.   If material sources are not finalized, then repeat steps 2 through 6 in the "Approving the Stability Study Plan" topic.

Step 2: Launch the approved stability study.   Once all source materials have an initial sample group with an acceptable disposition, the stability study owner can launch the approved stability study.

Performing Stability Study Testing

Following are steps needed to perform stability study testing:

Step 1: Put the study in progress.   Change the status of the stability study to In Progress.

Step 2: Receive notification to pull samples.   You receive notification to pull samples for stability study testing. The Stability Study Testing Notification master workflow governs this process.

Step 3: Pull and test samples at each time point until testing is complete. Identify samples that require testing on the scheduled time point dates, and use the specification assigned to the time point to test the samples. If necessary, assign a retained sample for a variant to a point for time point testing.

Step 4: Monitor variant environmental conditions throughout the stability study. Use the monitoring specification to evaluate the environmental conditions used in the study. The Sample Group Rejection workflow notifies you when either a monitoring sample group, or a stability study time point sample group is rejected.

Step 5: Evaluate samples and sample groups used in the stability study.   Enter results for time point testing and evaluate them against the specification assigned to the time point. The Sample Group Rejection workflow notifies you when either a monitoring sample group, or a stability study time point sample group is rejected.

Evaluating a Stability Study

Following are steps that describe the evaluation of a stability study:

Step 1: Complete stability study time point testing.   The Stability Study disposition is complete when the scheduled testing time points have a final disposition required to perform the stability study analysis. The stability study owner determines that testing is complete when all scheduled testing time points variants have a final disposition, or when a sufficient number of testing time points have a rejected disposition for a specific variant, in which case it would be unnecessary to continue testing.

Step 2: Review test result data.   The stability study owner reviews all test result data.

Step 3: Determine whether additional testing is required.   The stability study owner determines whether additional testing is required for any of the time points in the study.

Step 4: Conclude the stability study.   The stability study owner concludes the stability study by:

- Changing the status of the stability study to Completed
- Entering a study end date
- Entering the recommended shelf life derived from the results of tests performed on variants in the study that met the item specification
- Entering the recommended storage conditions derived from the monitoring specification used for the variants in the study that met the item specification

Step 5: Communicate the results of the stability study.   The stability study owner communicates the results of the stability study to appropriate individuals within the enterprise.

Understanding the Stability Study Change Status Workflow

When the OPM Quality Stability Study Change Status workflow is activated in Quality Management, the stability study requires a series of approvals that result in reassigning status through a predefined approval process.

Stability study statuses are preseeded. Refer to the "OPM Quality Stability Study Change Status Workflow" topic in "Appendix D" for additional information.

Setting Up the Workflow

Contact a system administrator if you are not sure that this is set up.

Enabling the Workflow

Enable the Stability Study Change Status workflow by setting it up in the System Administration application. The workflow is activated initially by changing the status of a stability study from New to Request Approval of Stability Study Plan.

▶ **To run the workflow:**

1. Upon creation of a stability study, the default **Status** is **New**.

2. To submit the stability study plan for approval, choose **Stability Study Plan Approved** from the **Actions** menu. The status displays as **Request Approval of Stability Study Plan**.

   - If the stability study plan is approved, then the status changes to **Stability Study Plan Approved**. Proceed to step 3.

   - If the stability study plan is rejected, then the status changes to **Revise Stability Study Plan**. Repeat this step.

3. To submit the stability study for launch, choose **Launch Approved** from the **Actions** menu. The status displays as **Request Approval to Launch**.

   - If the stability study launch is approved, then the status changes to **Launch Approved**. Proceed to step 4.

   - If the stability study launch is rejected, then the status changes to **Revise Launch**. Repeat this step.

4. To perform stability study testing, choose **In Progress** from the **Actions** menu.

5. To complete the stability study, choose **Completed** from the **Actions** menu.

6. To cancel the stability study at **Stability Study Plan Approved**, **Launch Approved**, or **In Progress**, choose **Canceled** from the **Actions** menu. The status displays:

   - **Request Approval to Cancel from Approved Plan** if the stability study plan is approved, but not yet launched.

   - **Request Approval to Cancel From Approved Launch** if the stability study has an approved launch, but is not yet in progress.

   - **Request Approval to Cancel From In Progress** if the stability study is in progress.

The following depicts the previously described workflow:
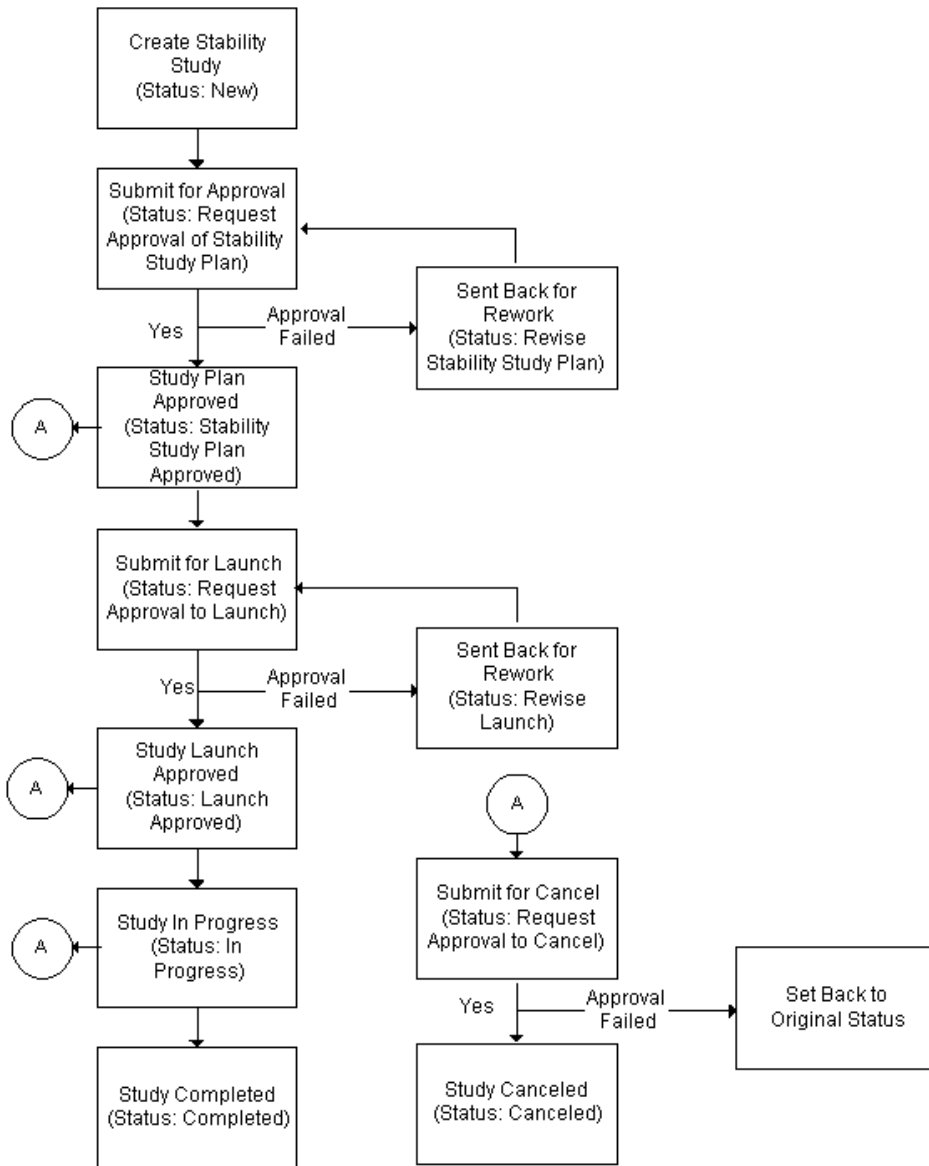
Creating Test Interval Plans

The Test Interval Plan window lets you simulate a set of test interval periods to be used in a stability study. The initial test interval plan saved becomes a candidate base test interval plan. Once you save a base test interval plan, you can reuse it to create an overlay test interval plan. The overlay can exclude time periods, or add time periods to the base plan.

Creating an Overlay Test Interval Plan

MONTH_12 is a test interval plan that includes 12 periods spaced at one month each as follows:

MONTH-1, MONTH-2, MONTH-3, MONTH-4, MONTH-5, MONTH-6, MONTH-7, MONTH-8, MONTH-9, MONTH-10, MONTH-11, MONTH-12

When you recall MONTH_12, you can make it the base plan for MONTH_13, an overlay test interval plan that adds an additional month to the one year testing cycle. For example, MONTH_13 includes 13 periods spaced at one month, with the last interval being MONTH-13.

With this approach, you can create many variations of test interval plans by entering a base test interval plan and modifying the overlay test interval plan to meet your specific requirements.

For example, 2_YEAR is a test interval plan with a two year duration as follows:

- 1 WEEK
- 2 WEEKS
- 3 WEEKS
- 1 MONTH
- 2 MONTHS
- 3 MONTHS
- 6 MONTHS
- 12 MONTHS
- 18 MONTHS
- 2 YEARS

Use the Generate Test Intervals dialog box to enter a series of periods by defining a total duration and a frequency to repeat each period. The interval periods are

resorted in ascending order by the simulated date when you save your work. Refer to the "Generating a Series of Testing Periods" topic for more information.

You can use flexfields with this window.

See: *Oracle Applications Flexfields Guide*

Prerequisites

❑ Determine the baseline plan for all test intervals.

❑ Identify the plan variations for different testing frequencies.

▶ To enter a base test interval plan:

1. Navigate to the **Test Interval Plan** window.

2. Enter a name for the **Test Interval Plan**. Required.

3. Enter a **Description** of the base test interval plan. Required.

4. Do not select **Overlay** for the entry of a base test interval plan.

5. **Duration** displays a simulated measure of the total duration of the test interval plan after the interval periods are entered and saved.

6. **Simulation Start Date** is a baseline time when testing is required for the period if the stability study variant starts on the date displayed. This field defaults to the current system date with the time truncated to the hour for a new record. This tool helps you simulate actual dates for planning purposes. Required.

Interval Period

7. Enter a **Period** as the name of the period. For example, enter MONTH-1 to indicate a period that is one month. When the Generate Test Intervals dialog box is used to enter periods, then this field has a period name prefix added to each interval period generated in the list. Required.

8. The following fields are used collectively to define an exact time point when testing is required from the start date. Each of the time intervals calculated from the start represent the sum of years, months, weeks, days, and hours from the simulation start date as follows:

   ■ Enter **Years** as the number of years from the simulation start date.

   ■ Enter **Months** as the number of months from the simulation start date.

   ■ Enter **Weeks** as the number of weeks from the simulation start date.

- Enter **Days** as the number of days from the simulation start date.

- Enter **Hours** as the number of hours from the simulation start date.

For example, to define a period that is 1 year, 3 months, and 15 days from the simulation start date, enter a period name such as 1YR-3MO-15DA, and enter 1 in the Years field, 3 in the Months field, and 15 in the Days field.

9. **Simulated Date** displays the simulated calendar date and time for the period.

10. **From Base** indicates that the period displayed is from the base test interval plan. This field is disabled for the base test interval plan.

11. **Exclude** is disabled for the base test interval plan.

12. Save the window.

◗ **To define an overlay test interval plan:**

Define an overlay test interval plan when stability study variants require a set of time intervals that are different from those defined in a base test interval plan. Overlay test interval plans let you exclude periods from a base test interval plan and add new periods.

1. Enter a name for the overlay **Test Interval Plan**. Required.

2. Enter a **Description** for the overlay test interval plan. Required.

3. Select **Overlay**. Required.

4. Enter the **Base Test Interval Plan** to use for the overlay test interval plan.

5. **Duration** displays the simulated measure of the total duration for the overlay test interval plan.

6. **Simulation Start Date** is a baseline time when testing is required for the period if the stability study variant starts on the date displayed. This field defaults to the current system date with the time truncated to the hour for a new record. This tool helps you simulate actual dates for planning purposes. Required.

7. Periods for the base test interval plan are marked with the **From Base** indicator.

8. **Exclude** can only be selected or cleared if the period displayed is from a base test interval plan. This lets you keep the period in the test interval plan. You can:

- Select the box to exclude the period from any variants created using the overlay test interval plan.

- Clear the box to include the period in any variants created using the overlay test interval plan.

9. The following fields are display only if the time point is derived from the base test interval plan:

- **Years** displays the number of years from the simulation start date.

- **Months** displays the number of months from the simulation start date.

- **Weeks** displays the number of weeks from the simulation start date.

- **Days** displays the number of days from the simulation start date.

- **Hours** displays the number of hours from the simulation start date.

You can enter these fields for interval periods that are added to this overlay test interval plan.

10. **Simulated Date** displays the simulated calendar date and time for the period.

11. Save the window.

▶ **To include all periods from the base test interval plan:**

Click Include All to include all periods from the base test interval plan in the overlay.

▶ **To exclude all periods from the base test interval plan:**

Click Exclude All to exclude all periods from the base test interval plan from the overlay.

▶ **To add a new interval period to an overlay test interval plan:**

1. Click the **Add Row** window control icon.

2. Enter a new interval period from the scheduled start date.

3. Save your work.

▶ **To mark a test interval plan for deletion:**

Choose Mark for Purge from the Actions menu. The test interval plan is marked for deletion.

▶ **To generate a series of testing periods:**

1. Choose **Generate Mass Intervals** from the **Actions** menu. The Generate Test Intervals dialog box displays.

2. Refer to the "Generating a Series of Testing Periods" topic for more information.

Generating a Series of Testing Periods

The Generate Test Intervals dialog box provides a rapid way to enter a series of periods by defining a total duration and a frequency to repeat each period. You can select this action as long as the test interval plan is not referenced by another overlay plan. If referenced, then you cannot modify the plan. For example, to enter 12 one-month periods, you can enter a 1 year duration with a frequency of 1 month. Or, you can enter a 12 month duration with a 1 month frequency.

The following conventions are used to generate testing periods:

- 1 year = 365 days
- 1 month = 30 days

You can adjust these periods once they are generated. These conventions distribute test interval periods uniformly for the study.

1. Navigate to the Generate Test Intervals dialog box.

2. Enter **Frequency** as the number of times to repeat a period in the defined duration. Select the **Frequency Unit** as Year, Month, Week, Day, or Hour. For example, for a frequency of three months, enter 3 and select Month. Required.

3. Enter **Duration** as the total of time to divide into periods. Select the **Duration Unit** as Year, Month, Week, Day, or Hour. For example, for a duration of 2 years, enter 2 and select Year.

4. Enter the **Period Name Prefix** as the interval period name to be appended as a prefix to each period listed.

5. Click **OK**.

6. The series of periods defined by the frequency and duration are displayed on the Test Interval Plan window. For example, if you enter Test as the Period Name Prefix, assign a Frequency of 2 months, and a Duration of 1 year, the window displays six rows of periods named: Test-1, Test-2, Test-3, Test-4, Test-5, and Test-6.

▶ **To generate contiguous sequences with the sample prefix:**

1. Generate the first sequence of periods.

2. Save the **Time Interval Plan**.

3. Generate the next contiguous sequence of periods.

4. Save the **Time Interval Plan**.

Finding Test Interval Plans

The Find Test Interval Plans dialog box lets you find test interval plans, base test interval plans, overlays, and those test interval plans that are marked for deletion.

1. Navigate to the Find Test Interval Plans dialog box.

2. Make no entries to find all test intervals plans. Enter any of the following parameters to narrow the search:

   - **Test Interval Plan** as the name of test interval plan.

   - **Base Test Interval Plan** as the name of the base test interval plan.

   - **Marked for Deletion** to determine all test interval plans that are marked for purge.

3. Select **Overlay** to find overlays of test interval plans.

4. Click **Find**.

Creating a Storage Condition Plan

The Storage Condition Plan window lets you structure a plan for the storage conditions to be used in a stability study. The plan relates each condition to a monitoring specification. A storage condition plan is not associated to any specific item, and can be reused for several stability studies.

You must define the two components of a storage condition plan:

- A monitoring specification to define the details of the storage condition for each one of the variants in the stability study. Refer to the "Understanding Specifications" topic for more information.

- A test interval plan to define testing time points by indicating the test intervals for each time point. Refer to the "Creating Test Interval Plans" topic for more information.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Identify the storage condition requirements for the stability study.

❑ Create a monitoring specification for each of the storage conditions.

❑ Optionally, define the resource and resource instance, or warehouse and location that provide and maintain the required storage conditions.

❑ Create a test interval plan.

▶ To create a storage condition plan:

1. Navigate to the **Storage Condition Plan** window.

2. Enter the **Storage Condition Plan** name. Required.

3. Enter a **Description** for the storage condition plan. Required.

4. **Base Test Interval Plan** displays the default base test interval plan. You can select any appropriate base test interval plan from the LOV. You cannot select an overlay test interval plan. Required.

5. **Duration** displays the total duration of the base test interval plan.

Storage Details

6. Enter the **Monitoring Spec** and **Version** for each storage detail. The monitoring specification lists the tests, test targets, minimums, and maximums for the environmental condition required by the specified storage condition. Each monitoring specification entered here cannot have a status of Obsolete or On Hold.

7. Enter either a Resource or a Warehouse and Location combination:

   ■ **Resource** that can meet the requirements for the storage condition. For example, enter a refrigerator that can meet the requirements for the monitoring specification. You can enter a generic resource that can be reassigned later on in the stability study.

   ■ **Warehouse** and a **Location**, if the warehouse is location-controlled, that can meet the requirements for the storage condition.

8. **Test Interval Plan** displays the default base test interval plan. You can select an overlay test interval plan that is associated to the base test interval plan to override the default.

9. **Duration** is the default from the test interval plan.

10. Save the window.

◗ **To mark a storage condition plan for deletion:**

Choose Mark for Purge from the Actions menu. The storage condition plan is marked for deletion.

◗ **To edit text in the storage condition plan:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

Finding Storage Condition Plans

The Find Storage Condition Plans dialog box helps you find existing storage condition plans by name or by the base test interval plan associated to them. You can also find storage condition plans that are marked for deletion.

Prerequisite

❏ Enter and save storage condition plans.

▶ **To find a storage condition plan:**

1. Navigate to the Find Storage Condition Plans dialog box.

2. Make no entries to find all storage condition plans. Enter any of the following parameters to narrow the search:

   ■ **Storage Condition Plan** as the name of a storage condition plan to find.

   ■ **Base Test Interval Plan** as the name of the base test interval plan associated to storage condition plans.

   ■ **Marked for Deletion** as those storage condition plans that are marked for purge.

3. Click **Find**. The **Storage Condition Plan** window displays any current storage condition plans that match the parameters entered.

Defining Storage Packages

The Storage Packages window lists all existing packages and lets you define the packages for variants. A storage package is the package material (item) or container closer system (formula) that the material is stored in for stability testing. Each package applies to a single variant. You can select these packages when you create or plan variants. Reuse these package definitions for multiple stability studies.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisite

❑ Enter a packaging formula if there are multiple components to the storage package, or container closure system.

▌ To define a storage package:

1. Navigate to the **Storage Packages** window.

2. Enter the package **Name**. For example, enter one package as Glass Vial Closure and another package as Plastic Vial Closure. You can define multiple storage packages when the stability study evaluates material in different container closure systems. Required.

3. Enter **Item** as the package material in which stability samples are stored. The item **Description** displays. The item is the container closure system.

4. Enter the packaging **Formula** and its **Version**. This represents the bill of materials for a container closure system. The product of the formula is the packaging configuration for stability sample storage.

5. Enter **Qty** as the quantity of material required for each testing time point sample in its **UOM**. This represents the total quantity of sample in the storage package. If you change the UOM, then the UOM entered must be convertible to the primary UOM for the item. Required.

▌ To mark a storage package for deletion:

Choose Mark for Purge from the Actions menu. The storage package is marked for deletion.

▌ To edit text in the storage packages:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

Finding Storage Packages

The Find Storage Package dialog box lets you find storage packages by name, item, or formula. You can also find deleted storage packages.

Prerequisites

❑ Enter and save storage packages.

◗ **To find a storage package:**

1. Navigate to the Find Storage Package dialog box.

2. Make no entries to find all storage packages. Enter any of the following parameters to narrow the search:

   - **Package** is the package name.

   - **Item** is the package material in which stability samples are stored.

   - **Formula** is the bill of materials for the container closure system. The product of the formula is the packaging configuration for stability sample storage.

3. Select **Yes** to find **Deleted** storage packages that meet the criteria entered, or select **No** to find current storage packages that meet the criteria entered.

4. Click **Find**. The application retrieves all storage packages that meet the criteria entered.

Creating and Managing a Stability Study

The Stability Study window lets you create and manage a stability study. Refer to the "Managing the Stability Study Lifecycle" topic for an overview of the creation and management of a stability study.

To create a stability study, enter preliminary information about the study including its document number, description, and storage condition plan. Specify the item to be tested and its base item specification.

Once the study is created, you can assign material sources to the study and create all the variants to investigate. At least one material source is required to create a stability study. Once the stability study is underway, use this window to view other pertinent information about the study, including its actual and revised start and end dates. This window also serves as a repository for assigned shelf life recommendations.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Set up STBL and SMPL document numbering for the organization that owns the stability study.

❏ Create a storage condition plan.

❏ Create a master item specification for stability testing.

❏ Identify at least one storage package for the stability study.

❏ Enable the stability study workflows as described in "Appendix D".

▌ **To create a stability study:**

1. Navigate to the **Stability Study** window.

2. **Stability Study** has two fields. The first field displays the default organization code. You can enter any organization you have access to. The second field displays the default value assigned to the document number. For manual numbering of the STBL document type, enter a number. For automatic numbering of the STBL document type, this field is protected. It displays the stability study number when you save the window. Required.

3. Enter a **Description** for the stability study.

4. After entering all relevant information, and saving the stability study with the default **Status** of **New**, return to this window to change stability study status by selecting **Change Status** from the **Actions** menu. The Status Approval workflow must be enabled for stability study approval. You can request the following actions in the order presented from the **Actions** menu:

   - **Approved Launch** to launch the stability study.

   - **Canceled** to initiate the stability study cancellation process. The response to this change depends on the status of the current stability study. It can be canceled from an approved plan, an approved launch, or an in progress study. Refer to the "OPM Quality Stability Study Change Status Workflow" topic in "Appendix D" for an explanation of the stability study workflow statuses.

   - **Stability Study Plan Approved** to approve the planned stability study.

     Required.

5. Enter the **Storage Condition Plan** to use for the stability study. Refer to the "Creating a Storage Condition Plan" topic for more information on how to structure a plan for the storage conditions. Required.

6. Enter the **Item** as the material tested in the stability study. The item can be experimental, but it must be active and lot or sublot controlled. The initial sample material tested must be the same as the item entered here. The item **Description** displays as it appears on the item master. Required.

7. Enter the **Master Item Spec** as the item specification containing the list of tests performed throughout the entire stability study. This must be a base specification, and it must have a status of:

   - Approved for Lab Use, for a laboratory item such as an experimental item

   - Approved for General Use, for a production item

   This specification serves as the default item specification when variants are loaded initially.

   Required.

8. Enter the **Lab Organization** as the research and development laboratory organization that creates, manages, and owns the stability study. This is typically the same facility that formulates the item, defines its recipes, and creates its specifications. This field defaults to your default lab organization. Required.

9. Enter the **Owner** of the stability study. This field defaults to the user who creates the stability study. The user must be associated with the stability study lab organization. The individual who creates the stability study can specify the owner. Required.

10. Enter the **Notification Lead Time** as the amount of advance notice you need prior to each scheduled testing time point using the OPM Stability Study Time Point Scheduling Notification workflow. For example, if a testing time point is scheduled for March 15, and you enter a 3-day notification lead time, you are notified of the scheduled time point on March 12. The notification lead time applies to all time points for all variants.

11. Enter **Testing Grace Period** as the lag time that can be added to each scheduled time point to create a window of opportunity for testing the item. If testing is not done within this testing grace period, then the Stability Study Late Time Point Scheduling Notification starts to notify appropriate individuals that testing is late. The testing grace period applies to all time points for all variants.

Variant

12. Enter **Material Source** as the required number of material sources for the stability study. This entry must be a whole positive integer greater than zero. The default for this field is 1. Identify the item, lot and sublot, and batches that serve as the basis for the stability study. The source material can already exist in inventory as lots and sublots, or it can be selected, or requested as batch. Batches can be initial production batches for a new formulation, or a portion of routine production batches that are pulled for stability testing. This information includes the item, lot and sublot, batch number, date of manufacture or manufacturing release date, batch size, recipe, and recipe version used. Required.

13. **Storage Conditions** displays the number of storage conditions required by the stability study. This field defaults from the number of storage conditions defined for the storage condition plan entered for the stability study.

14. Enter **Packages** as the number of packaging configurations that you plan to use to build the stability study. A minimum of one packaging configuration is required. If you plan to study more than one packaging configuration, then enter the total number of packages. For example, if you plan to study an amber vial and clear glass vial closure system, enter 2, since these are two separate packaging configurations.

15. **Count** displays the actual number of variants created.

Dates

16. Enter the **Scheduled Start** date for the stability study. This date cannot be changed after the stability study has a status of Stability Study Plan Approved. This scheduled start date is used to calculate the scheduled end date. Variants created by the application use the scheduled start date as the variant start date unless the material source has a yield date. Required.

17. **Scheduled End** date is calculated by adding the longest time point identified across all the time intervals in the storage condition plan to the scheduled start date. You can only change this date until the stability study is approved. Required.

18. **Revised Start** date displays a revision to the Scheduled Start date. You can only enter this field after the stability study has reached a status of Stability Study Plan Approved, but does not yet have a status of Approved for Launch. This revised start date is used to calculate the revised end date.

19. **Revised End** date displays the revision to the scheduled end date based on the revised start date.

20. The **Actual Start** date is entered when the stability study is changed to a status of In Progress and defaults to the system date. The stability study can only reach this status when the:

   ■ Required number of initial samples for each material source have a disposition of Accepted or Accepted with Variance

   ■ Required number of variants are created

   ■ Stability study has a status of Approved for Launch

21. **Actual End** date displays the date the stability study has a status of Completed.

Recommendations

22. Recommended **Shelf Life** displays the recommended shelf life for the item tested in the stability study. You can enter this field when the stability study has a status of Completed. Enter a recommended shelf life in years, months, weeks, days, or hours.

23. Recommended **Storage Spec** displays the ideal storage condition for the item tested in the stability study by entering the recommended storage specification and **Version** for the material. Enter this field when the stability study has a status of Completed.

24. Save your work to create a stability study with the status of **New**.

25. Choose **Change Status** from the **Actions** menu to select appropriate statuses.

26. Assign material sources as described in the "Assigning Stability Study Material Sources" topic.

27. Edit variants as described in the "Editing Variants for the Stability Study" topic.

▶ **To assign material sources to the stability study:**

1. Identify the item, lot and sublot, and batches to serve as the basis for the stability study as described in the "Planning a Stability Study" topic.

2. Query the stability study to assign material sources.

3. Click **Material Source**. The **Material Sources** window displays.

4. Refer to the "Assigning Stability Study Material Sources" topic for additional information.

▶ **To edit variants for the stability study:**

1. Identify the unique combinations of the stability study storage conditions, the test interval plan, and the package.

2. Query the stability study to edit variants.

3. Click **Variants**. The **Variant** window displays.

4. Refer to the "Editing Variants for the Stability Study" topic for additional information.

▶ **To edit text in the stability study:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

▶ **To mark the stability study for purge:**

Choose Mark for Purge from the Actions menu. The record is marked for deletion.

▶ **To change the status of the stability study:**

1. Choose **Change Status** from the **Actions** menu.

2. Select the desired status.

      3. Save the window.

▶ **To display the master item specification:**

      1. Choose **View Master Item Specification** from the **Actions** menu. The master item displays in the **Specifications** window.

      2. Close the window.

▶ **To display the storage condition plan:**

      1. Choose **View Storage Condition Plan** from the **Actions** menu. The storage condition plan displays in the **Storage Condition Plan** window.

      2. Close the window.

Finding Stability Studies

The Find Stability Studies dialog box helps you find stability studies by study status, item tested, lab organization, or owner.

Prerequisites

❏ Enter and save stability studies.

▶ **To find stability studies:**

1. Navigate to the Find Stability Studies dialog box.

2. Make no entries to find all stability studies. Enter any of the following parameters to narrow the search:

   ■ **Study** has two fields. Enter the first field as the default organization code. Enter the second field as the STBL document type number.

   ■ Select **Status** as:

   New to find stability studies that are created, but not yet approved.

   Request Approval of Stability Study Plan to find stability studies that are submitted for the stability study plan approval process using the workflow.

   Revise Stability Study Plan to find stability studies that are under revision for stability study plan approval.

   Stability Study Plan Approved to find stability studies that have an approved stability study plan.

   Request Approval to Launch to find stability studies that are submitted for stability study launch approval using the workflow.

   Revise Launch Request to find stability studies that are under revision for stability study launch approval.

   Launch Approved to find stability studies that have an approved stability study launch.

   In Progress to find stability studies that are in-progress.

   Request Approval to Cancel to find stability studies that are submitted for stability study cancellation before the stability study plan is approved:

   Request Approval to Cancel From Approved Plan to find stability studies that are submitted for stability study cancellation when the study has a status of Stability Study Plan Approved.

Request Approval to Cancel From Approved Launch to find stability studies that are submitted for the stability study cancellation when the study has a status of Launch Approved.

Request Approval to Cancel From In Progress to find stability studies that are submitted for stability study cancellation when the study has a status of In Progress.

Canceled to find stability studies that are canceled.

Completed to find stability studies that are completed.

- **Item** as the material tested in the stability study.

- **Lab Organization** as the research and development laboratory organization that creates, manages, and owns the stability study.

- **Owner** as the individual responsible for the stability study.

3. Click **Find**. The application retrieves all stability studies that meet the criteria entered.

4. Press the down arrow to display each study that was found.

Assigning Stability Study Material Sources

The Material Sources window lets you specify the source of sample material for the stability study. This window displays the details for the number of material sources entered on the Stability Study window. The batch that produces the sample material for the stability study is specified in one of two ways:

- Request batch, if the material needs to be produced. Specify the plant, or plant and recipe, or plant, recipe, and recipe version.

- Select lot and sublot, if the material is produced and is assigned a specific lot and sublot.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❑ Create and save a stability study.

❑ Identify material sources to be used in the stability study.

▶ **To enter material source details:**

1. Navigate to the **Material Sources** window.

2. Enter the **Plant** as the plant code where the sample material is produced. If the material is not yet produced, then this is the plant that is assigned to produce the material. If you leave this field blank, then specify the lot and sublot, or the recipe and version for the material source.

3. Enter the **Batch** number. The plant code must be specified before you can enter this field. The batch status must be WIP or Completed. You can only select a batch that contains a stability study item identified as a product or byproduct.

4. Enter the **Lot** when material already exists in inventory. You can update this field after the source material is produced by the specified recipe and recipe version. Required if Batch is entered.

5. **Sublot** displays based on the lot entered if the item is sublot controlled.

6. Enter the **Recipe** as the recipe to be used when the source material is planned for the stability study. There must be an active recipe validity rule for the organization where the stability study is created. If you leave this field blank, then the application retrieves the appropriate recipe validity rule for the item in the plant entered.

7. Enter the recipe **Version** as the version of the recipe to be used when the source material is planned for the stability study. If you leave this field blank, then you indicate that any version of the recipe can be used to produce the material.

8. **Yielded Date** displays the date that the specified lot and sublot is yielded from the specified batch.

9. **Sample Qty** displays the total sample quantity required for stability testing of each material source identified in the item primary **UOM**.

10. Save the window.

▶ **To update the sample quantity required:**

Enter the number of samples per time point and the sample quantity to put into storage package for all study variants.

1. Choose **Calculate Sample Quantity** from the **Actions** menu. The **Sample Qty** field displays an updated sample quantity for the selected material source.

2. Evaluate sample quantity to make certain there is sufficient material to complete the stability study.

▶ **To display all stability study variants:**

Click Study Variants to open the Variant window where all stability study variants for all material sources are displayed.

▶ **To select initial samples:**

1. Choose **Select Initial Sample Group** from the **Actions** menu. The **Select Initial Sample Group** window displays a list of sample groups that have a disposition of Accept or Accept with Variance for the selected material source.

2. Select the desired initial sample group.

3. Click **OK**.

▶ **To edit text in the material sources:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.

2. Make appropriate text changes.

3. Save the window.

◗ **To mark the material sources for purge:**

Choose Mark for Purge from the Actions menu. The record is marked for deletion.

Editing Stability Study Variants

The Variant window lets you edit stability study variants. This window displays all variants that the application creates when the stability study is created. The total number of rows displayed on this window depends on the number of unique combinations of:

- A specific batch.

- A specific storage condition such a combination of temperature and humidity. For example, 30 deg C and 60% RH.

- A specific storage package. It is possible to set up a stability study for several storage packages, however at least one package is required.

You can delete or add variants until the stability study plan is approved. Resources or locations identified for variant storage conditions can also be replaced if they do not meet environmental monitoring requirements.

Creating Variants

Each row on the Variant window represents an individual material source, storage condition, and storage package combination. Based on the variant count for a new stability study, the application creates a variant for each of these combinations. It is assumed that stability study sample material from each source is stored in each storage condition and storage package combination for the specified duration. Sample material from a batch is stored at one or several storage conditions, depending on the scope of the stability study.

Planning Variants

You can plan or edit variants once material sources are defined. However, changes to the number of acceptable material sources can affect the number of planned variants before a stability study plan is approved. You can add, edit, or delete variants until the stability study plan is approved. Once the stability study is in progress, you can only edit the variant end date, or replace the resource or location for a storage condition.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites

❏ Define base and overlay item specifications for stability testing.

❏ Define the resource and resource instance, or warehouse and location that provide and maintain the required storage conditions.

❏ Define at least one storage package.

❏ Create a stability study.

◗ **To edit variants in a stability study:**

1. Navigate to the **Variant** window.

2. Query the stability **Study** to enter variants.

3. **Status** must be **New** or **Revise Stability Study Plan** to edit variants.

4. The following fields are display only:

   ■ **Item** displays the material tested in the stability study. The item description displays as it appears on the item master.

   ■ **Variant Count** displays the total number of variants for the stability study. Each time you add or delete a variant, this number displays the current number of variants saved.

Variant

5. **Num** displays a unique variant number that is generated by the application. Numbers are generated in a series with increments of one to provide a unique number for each variant. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.

6. Enter **Default Item Spec** as the item specification for the variant, and the specification **Version**. These fields default from the master item specification entered on the **Stability Study** window. If an overlay specification exists for the master item specification, then you can enter the overlay specification. The default item specification applies to all time points for a variant. You can also configure it more specifically on the **Variant Time Points** window. Required.

7. Enter **Start Date** as the default start date from the material source yield date. This changes to the scheduled start date of the stability study when the stability study has a status of **New**.

8. Enter **Samples Per Time Point** as the default number of samples for each time point that is associated to the variant selected. The default is one sample per time point.

9. Enter **Retained Samples** as the number of samples that are retained for a variant in the eventuality that unscheduled testing is required. The default value is zero. You can assign retained samples for a variant at a specific time point on the **Variant Time Points** window.

Material Source

10. The following fields are display only:

   ■ **Num** displays a unique variant number that is generated by the application. Numbers are generated in a series with increments of one to provide a unique number for each variant. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.

   ■ **Plant** displays the plant code where the sample material is produced.

   ■ **Batch** displays the batch document number where the stability study item is identified as a product or byproduct.

   ■ **Recipe** displays the recipe to be used when the source material is requested for the stability study, and its **Version**.

   ■ **Lot** and **Sublot** display the lot and sublot of stability study material source, if the item is sublot controlled.

Storage Condition

11. The following fields are display only:

   ■ **Num** displays a unique variant number that is generated by the application. Numbers are generated in a series with increments of one to provide a unique number for each variant. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.

   ■ **Storage Spec** displays the monitoring specification and **Version** for a storage condition that defaults from the storage condition plan.

   ■ **Resource** displays the storage resource specified on the storage condition plan. You can override this entry. For example, enter a refrigerator that can meet the requirements for the monitoring specification if the default

resource cannot meet this requirement. This field defaults from the storage condition plan.

- **Instance** displays a specific resource instance identified for the storage condition specified in the monitoring specification. For example, this field can display a specific environmental chamber.

- **Warehouse** displays a warehouse that can meet the storage condition requirements for the variant. This field defaults from the storage condition plan.

- **Location** displays the warehouse location if the warehouse is location controlled. This field defaults from the storage condition plan.

12. Enter the **Storage Date** that samples are placed in the variant storage condition. This date can also represent the date that the resource or location for a storage condition is modified after the start of the stability study. You can reenter this field after the stability study plan is approved and launched until samples are put in the variant storage condition.

Package

13. **Num** displays a unique variant number that is generated by the application. Numbers are generated in a series with increments of one to provide a unique number for each variant. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.

14. Enter **Package** as the selected the storage package used to store the variant of the item.

15. **Formula** displays the formula and formula **Version** if a formula is defined for the storage package.

16. Enter **Quantity** as the quantity of sample for each variant and the **UOM**. These fields default from the **Storage Packages** window. You can reenter them for each variant. Required.

17. Save the window.

◗ **To add a variant:**

1. Query the **Study**. Status must be **New** or **Revise Stability Study Plan** to edit variants.

2. Select a row to add a variant. Variants insert below the row selected.

3. Choose **New** from the **File** menu.

4. Select the material source from the Material Source dialog box. Required.

5. Click **OK**.

▶ **To delete a variant:**

1. Query the **Study**. Status must be **New** or **Revise Stability Study Plan** to edit variants.

2. Select the variant to delete.

3. Choose **Delete** from the **Edit** menu. All time points associated to the selected variant are deleted.

4. Save the window.

▶ **To display the item specification associated to the variant:**

1. Click **Item Spec**. The default item **Specifications** displays the default item specification for the selected variant.

2. Close the window.

▶ **To display the storage specification associated to the variant:**

1. Click **Storage Spec**. The **Specifications** window displays the monitoring specification of the storage condition for the selected variant.

2. Close the window.

▶ **To display time points associated to the variant:**

1. Select the variant.

2. Click **Time Points**. The **Variant Time Points** window displays.

3. Refer to the "Editing Variant Time Points" topic for more information.

4. Close the window.

▶ **To display the stability study samples associated to a variant.**

1. Select the variant.

2. Click **Samples**. The **Samples Summary** window displays.

3. Close the window.

▶ **To display monitoring samples for a storage specification:**

1. Select the variant.

2. Choose **View Storage Spec Samples** from the **Actions** menu. The **Samples Summary** window displays.

3. Close the window.

▶ **To modify the resource or location for a storage condition:**

1. Choose **Modify Storage Condition** from the **Actions** menu. The Modify Storage Conditions dialog box displays.

2. The **From Storage Condition** displays the current:

   ■ **Resource** that can meet the requirements for the storage condition. This defaults initially from the storage condition plan, but you can override it.

   ■ **Instance** of a specific resource identified for the storage condition specified in the monitoring specification.

   ■ **Whse** that can meet the requirements for the storage condition. This defaults initially from the storage condition plan, but you can override it.

   ■ **Location** in the warehouse that can meet the requirements for the storage condition, if the warehouse is location controlled.

   ■ **Start Date** as the date when samples are placed in the variant storage condition, resource, or location. This date reflects modifications to the start of the stability study.

   ■ **End Date** as the date when samples are removed from the variant storage condition, resource, or location. When you save the window, this field updates to reflect the start date entered for the To Storage Condition.

3. Enter a **To Storage Condition** for a resource and resource instance, or for a warehouse and location to change the current value displayed. Following is a list of conditions you can enter:

   ■ **Resource** that can meet the requirements for the storage condition. When you enter a new resource, the resource instance field is cleared if an instance was entered previously.

   ■ **Instance** that can meet the storage condition specified in the monitoring specification.

   ■ **Whse** that can meet the requirements for the storage condition.

■ **Location** that can meet the requirements for the storage condition, if the warehouse is location controlled.

■ **Start Date** when samples are placed in the variant storage condition.

4. Click **OK** to modify the resource or location storage conditions.

▶ **To display the history of storage condition resource and location changes:**

1. Choose **View Storage History** from the **Actions** menu. The View Storage Condition dialog box displays the history of **Resource**, **Instance**, **Whse**, **Location**, **Start Date**, and **End Date** replacements or the variant.

2. Review the history.

3. Close the window.

▶ **To assign a retained sample from the variant to a testing time point:**

1. Select the variant.

2. Choose **Assign Sample to Time Point** from the **Actions** menu The Assign Sample to Time Point dialog box displays.

3. **Variant** defaults from the **Variant** window.

4. Enter the **Sample** to be assigned to the target time point. The organization code for the sample defaults to the sample organization identified for the material source.

5. **Target Time Point** displays the time interval that the retained sample is assigned to.

6. Click **OK**.

Finding Stability Study Variants

The Find Variants dialog box lets you find stability study variants.

1. Navigate to the Find Variants dialog box.

2. Make no entries to find all variants. Enter any of the following parameters to narrow the search:

   ■ **Study** as the name of the stability study.

     Enter the first field as the default organization code. You can enter any organization you have access to.

     Enter the second field (the stability study number) as the number of the STBL document type.

   ■ **Status** as the status of the stability study. Refer to the "Finding Stability Studies" topic for a complete explanation of stability study status.

   ■ **Item** as the material tested in the stability study. The item can be experimental, but it must be active. The item **Description** displays as it appears on the item master.

3. Click **Find**.

Editing Variant Time Points

The Variant Time Points window displays all time intervals defined in the test interval plan that is assigned to the storage condition for each variant in the stability study. The time intervals are displayed in chronological order starting with the earliest time point to be tested.

The number and frequency of the time points are defined by the test interval plan that is assigned to the variant storage condition in the storage condition plan. You can add or remove time points from the variant at the time the variant is created, or during the revised stability study approval phase, if rework is required. After the stability study begins, you can add additional time points. You can assign retained samples to a time point, or you can move retained samples between time points.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

Prerequisites
❏ Define base and overlay item specifications for stability testing.

❏ Create a stability study and variants.

▶ **To edit variant time points:**

1. Navigate to the **Variant Time Points** window.

2. **Time Interval** displays the time interval from the variant's test interval plan that defines a testing time point.

3. Enter **Spec** as the item specification number and **Version** that is used to test sample material at the testing time point. This field displays the default item specification for the variant. You can select an overlay specification.

4. The following fields are display only:

   ■ **Scheduled Date** displays the date that the testing for the time point needs to be scheduled. This date calculated by adding the time point interval to the variant start date.

   ■ **Actual Date** displays the actual date that the testing for the time point was done. You can enter and modify this field when the stability study is in progress.

5. Enter **Samples Per Time Point** as the required number of samples for the testing time point. This field defaults from the **Samples Per Time Point** field entered on the **Variants** window.

6. **Disposition** displays the disposition of the testing time point sample group.

▌ **To add a time point to a stability study before it is approved:**

1. Select the time interval to insert the new time point. **Status** must be **New** or **Revise Stability Study Plan**.

2. Choose **New** from the **File** menu.

3. Enter the **Time Interval** name, **Spec Name**, **Version**, **Scheduled Date**, and **Samples Per Time Point** for testing the new time point.

4. Save the window.

▌ **To add a time point to a stability study after it is approved:**

1. Select the time interval to insert the new time point. **Status** must be **Revise Stability Study Plan**.

2. Choose **New** from the **File** menu.

3. Enter the **Time Interval** name, **Spec Name**, **Version**, **Scheduled Date**, and **Samples Per Time Point** for testing the new time point.

4. Assign the sample to the time point.

5. Save the window.

▌ **To display the item specification associated to the variant:**

1. Click **Item Spec**. The default item **Specification** displays.

2. Close the window.

▌ **To display the sample associated to a variant:**

1. Select the variant time point.

2. Click **Samples**. The **Samples Summary** window displays.

3. Drill down to individual item samples to view information about each one of them.

4. Close the window.

▌ **To assign a retained sample to a new testing time point:**

1. Select the new testing time point.

2. Choose **Assign Sample to Time Point** from the **Actions** menu. The Assign Sample to Time Point dialog box displays.

3. **Variant** defaults from the **Variants** window.

4. Enter a **Source Time Point**, or leave this field blank for the application to select a retained sample from the variant.

5. Enter the **Sample** to be assigned to the new testing time point. The organization code for the sample defaults to the same organization identified for the material source.

6. **Target Time Point** displays the time interval for the new testing time point created, and cannot be edited.

7. Click **OK**.

◗ **To move a retained sample to a specific time point:**

Move a retained sample from one time point to another specific time point in order to replace a sample that was damaged in transit to the laboratory, or to complete testing.

1. Select the testing time point to move the sample to.

2. Choose **Assign Sample to Time Point** from the **Actions** menu. The Assign Sample to Time Point dialog box displays.

3. **Variant** defaults from the **Variant** window.

4. Enter **Source Time Point** as the testing time point to move the sample from.

5. Enter the **Sample** assigned to the new testing time point. The organization code for the sample defaults to the same organization identified for the material source.

6. **Target Time Point** displays testing time point selected and cannot be edited.

7. Click **OK**.

A

Quality Management Navigator Paths

Although your System Administrator may have customized your Navigator, typical navigation paths are described in the following tables. In some cases, there is more than one way to navigate to a window. These tables provide the most typical default path.

Window	Path
Actions	Quality Manager:Setup:Actions
Add Tests (from Composite Results window)	Quality Manager:Sample Groups:click Composite Results:click Add Test
Certificate of Analysis Report	Quality Manager:Reports:Certificate of Analysis/Conformance
Composite Results	Quality Manager:Results:click Composite Results
Customer Display	Quality Manager:Setup:Tests:click Customer Display
Customer/Supplier Test Results Report	Quality Manager:Reports:Other Reports:Run
Experimental Error	Quality Manager:Setup:Tests:click Experimental Error
Experimental Errors	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry:click Experimental Error
Find Actions	Quality Manager:Setup:Actions:View:Find...
Find Grades	Quality Manager:Setup:Grades:View:Find...
Find Hold Reasons	Quality Manager:Setup:Hold Reasons:View:Find...
Find Sample Groups	Quality Manager:Samples:Sample Groups:View:Find...

Window	Path
Find Samples (from Item Samples window)	Quality Manager:Samples:Item Samples:View:Find...
Find Samples (from Results window)	Quality Manager:Results:View:Find...
Find Samples (from Specification Comparison window)	Quality Manager:Results:click Specification Comparison:View:Find...
Find Samples (from the Quality Workbench navigator)	Quality Manager:Quality Workbench:click the Samples tab:View:Find
Find Sampling Plans	Quality Manager:Setup:Sampling Plans:View:Find...
Find Specifications (from Specifications window)	Quality Manager:Specifications:Specifications:View:Find...
Find Specifications (from the Quality Workbench navigator)	Quality Manager:Quality Workbench:click the Specifications tab:View:Find
Find Stability Studies	Quality Manager:Stability Study:Stability Study:View:Find...
Find Stability Study Variants	Quality Manager:Stability Study:Stability Study:View:Find...:find the desired stability study:click Variants
Find Status Codes	Quality Manager:Setup:Status Codes:View:Find...
Find Storage Condition Plans	Quality Manager:Stability Study:Setup:Storage Condition Plan:View:Find...
Find Storage Package	Quality Manager:Stability Study:Setup:Storage Package:View:Find...
Find System Parameters	Quality Manager:Setup:System Parameters:View:Find...
Find Test Classes	Quality Manager:Setup:Test Classes:View:Find...
Find Test Interval Plans	Quality Manager:Stability Study:Setup:Test Interval Plan:View:Find...
Find Test Methods	Quality Manager:Setup:Test Methods:View:Find...
Find Test Units	Quality Manager:Setup:Test Units:View:Find...
Find Tests	Quality Manager:Setup:Tests:View:Find...

Window	Path
Find Validity Rules	Quality Manager:Specifications:Specifications:find the specification:clickValidity Rules:use Query by Example to find validity rules
Find Variants	Quality Manager:Stability Study:Stability Study:click Variants:View:Find...
Generate Test Intervals	Quality Manager:Setup:Test Interval Plan:Actions:Generate Test Intervals
Grades	Quality Manager:Setup:Grades
Hold Reasons	Quality Manager:Setup:Hold Reasons
Inventory Quantities Mass	Quality Manager:Expired Lot Status Change
Item Samples	Quality Manager:Samples:Item Samples
Item/Location Required Analysis Report	Quality Manager:Reports:Other Reports:Run
Item/Location Test Results Report	Quality Manager:Reports:Other Reports:Run
Lot Genealogy	Quality Manager:Inquiries:Lot Genealogy
Mass Results Entry	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry Quality Manager:Quality Workbench:select Show Active Samples:select appropriate View By...:expand Samples By...:select desired sample group:Samples By...:click Mass Results Entry:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry Quality Manager: Samples:Sample Groups:click View Samples:Samples Summary:click Mass Results Entry:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry
Mass Results Entry Test Selection	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results Quality Manager:Quality Workbench:select Show Active Samples:select appropriate View By...:expand Samples By...:select desired sample group:Samples By...:click Mass Results Entry Quality Manager: Samples:Sample Groups:click View Samples:Samples Summary:click Mass Results Entry

Window	Path
Material Sources	Quality Manager:Stability Study:Stability Study:query the desired stability study:click Material Sources
Monitoring Samples	Quality Manager:Samples:Monitoring Samples
Production Test Results Report	Quality Manager:Reports:Other Reports:Run
Quality Change Disposition	Quality Manager:Samples:query a sample:Actions:Change Disposition Quality Manager:Results:query a result:Actions:Change Disposition
Quality System Parameters	Quality Manager:System:Setup:System Parameters
Quality Workbench	Quality Manager:Quality Workbench
Results	Quality Manager:Results:Results
Result Association	Quality Manager:Results:Results:Find Samples:Actions:Result Association
Sample Groups	Quality Manager:Samples:Sample Groups
Sample Label Generation	Quality Manager:Reports:Other Reports:Run
Sample Storage Summary	Quality Manager:Inquiries:Samples Storage
Samples By...	Quality Manager:Quality Workbench:click Samples tab:select View By...:expand Samples By... node:expand desired node:click desired object
Samples Summary	Quality Manager:Samples:Sample Groups:click View Samples
Sampling Plan	Quality Manager:Setup:Sampling Plans
Specification Comparison	Quality Manager:Results:Specification Comparison
Specification Summary	Quality Manager:Quality Workbench:select View By Specifications:expand Specifications node:click specification
Specifications	Quality Manager:Specifications:Specifications
Stability Study	Quality Manager:Stability Study:Stability Study
Status Codes	Quality Manager:Setup:Status Codes
Status Details	Quality Manager:Setup:Status Codes:click Status Details

Window	Path
Storage Condition Plan	Quality Manager:Stability Study:Setup:Storage Condition Plan
Storage Packages	Quality Manager:Stability Study:Setup:Storage Package
Test Classes	Quality Manager:Setup:Test Classes
Test Details	Quality Manager:
Test Interval Plan	Quality Manager:Stability Study:Setup:Test Interval Plan
Test Methods	Quality Manager:Setup:Test Methods
Test Units	Quality Manager:Setup:Test Units
Tests	Quality Manager:Setup:Tests
Validity Rules for Item Spec	Quality Manager:Specifications:View:Find...:select Spec Type as Item:click Find:select the desired specification:click Validity Rules:select a validity rule:click Edit
Validity Rules for Monitoring Spec	Quality Manager:Specifications:View:Find...:select Spec Type as Monitor:click Find:select the desired monitoring specification:click Validity Rules:select a validity rule:click Edit
Validity Rules Summary for Item Spec	Quality Manager:Specifications:query specification:click Validity Rules
Validity Rules Summary for Monitoring Spec	Quality Manager:Specifications:View:Find...:select Spec Type as Monitor:click Find:select the desired monitoring specification:click Edit to edit an existing monitoring specification, or click New to enter a new monitoring specification
Variant	Quality Manager:Stability Study:Variants and Time Points
Variant, Time Point	Quality Manager:Stability Study:Variants and Time Points:select the desired variant:click Time Points
View Samples for Test (from Composite Results window)	Quality Manager:Samples:Sample Groups:click Composite Results:click View Samples

B

Quality Management Profile Options

During your implementation, you set a value for selected profile options to specify how your Quality Management application controls access to and processes data. Quality Management uses the listed profile options:

- GMD: Exact Specification Match

- GMD: Include Optional Tests in Sample Disposition

- GMD: Specification Version Control

You can set up these profile options when you set up other applications prior to your Quality Management implementation. Refer to the other product user's guides for more details on how these products use these profile options.

Your System Administrator sets user profile options at one or more of the following levels: Site, Application, Responsibility, and User. Use the Personal Profile Options window to view or set your profile options at the user level. You can consult the *Oracle Process Manufacturing Implementation Guide* for a complete description of the profile options listed. Consult your *Oracle Applications System Administrator's Guide* for a list of profile options common to all Oracle Applications.

C

Quality Management Business Rules

The following topics are covered:

- Specification Matching Business Rules
- Finding Customer Specifications in Specification Matching

Specification Matching Business Rules

These topics summarize the business rules used to find the appropriate specification version and specification validity rule in effect for quality inspection of material. This specification matching logic is performed when associating a specification to a sample in OPM Quality Management, and when running the Customer Specification Matching inquiry in Oracle Order Management. There are two sets of business rules for:

- Item Specification Matching
- Monitoring Specification Matching

Item Specification Matching

The following discussions pertain to item specification matching:

Local and Global Specification Searches

To match a specification with a specific sample, the Samples window uses the base hierarchy. Local specifications are searched before global specifications at each level of the specification matching hierarchy.

Grade Control in Specification Matching

Specifications with no grade specified are searched for items that are not grade-controlled. For grade-controlled items, specification matching searches for a specification with a matching grade. If one is not found, then the application searches for a specification with no grade specified for the closest match. This rule applies to all specification matching hierarchies for inventory, WIP, customer, and supplier.

Customer Specification Matching

To match a specification with a customer sample, the Samples window uses the base hierarchy and considers local versus global specifications. While matching a customer sample, if the customer specification is not found based on the following hierarchical criteria, then the application searches for an inventory specification. The search hierarchy is:

1. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID

2. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID

3. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line

4. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line

5. Local Organization + Customer + Operating Unit + Ship-To + Order Number

6. Global Organization + Customer + Operating Unit + Ship-To + Order Number

7. Local Organization + Customer + Operating Unit + Order Number

8. Global Organization + Customer + Operating Unit + Order Number

9. Local Organization + Customer + Operating Unit + Ship-To Location

10. Global Organization + Customer + Operating Unit + Ship-To Location

11. Local Organization + Customer

12. Global Organization + Customer

Specification Matching from the Pick Lots Window

To find a customer specification from the Pick Lots window, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. The Pick Lots window searches only for a customer specification. It does not search for an inventory specification if the customer specification is not found. The search hierarchy is:

1. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID

2. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID

3. Other Organizations + Customer + Operating Unit + Ship-To + Order Number + Order Line ID

4. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line

5. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line

6. Other Organizations + Customer + Operating Unit + Ship-To + Order Number + Order Line

7. Local Organization + Customer + Operating Unit + Ship-To + Order Number

8. Global Organization + Customer + Operating Unit + Ship-To + Order Number

9. Other Organizations + Customer + Operating Unit + Ship-To + Order Number

10. Local Organization + Customer + Operating Unit + Order Number

11. Global Organization + Customer + Operating Unit + Order Number

12. Other Organizations + Customer + Operating Unit + Order Number

13. Local Organization + Customer + Operating Unit + Ship-To Location

14. Global Organization + Customer + Operating Unit + Ship-To Location

15. Other Organizations + Customer + Operating Unit + Ship-To Location

16. Local Organization + Customer

17. Global Organization + Customer

18. Other Organizations + Customer

Inventory Specification Matching

To find an inventory specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. The following is the hierarchy used by the inventory specification matching program.

1. Local Organization + Lot + Sublot + Warehouse + Location

2. Local Organization + Lot + Sublot + Warehouse

3. Local Organization + Lot + Sublot

4. Global Organization + Lot + Sublot

5. Local Organization + Lot + Warehouse + Location

6. Local Organization + Lot + Warehouse

7. Local Organization + Lot

8. Global Organization + Lot

9. Local Organization + Warehouse + Location

10. Local Organization + Warehouse

11. Local Organization + Item

12. Global Organization + Item

Supplier Specification Matching

To find a supplier specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. If no supplier specification is found that matches a supplier sample, then the application searches for a matching inventory specification. The following is the hierarchy used by the supplier specification matching program.

1. Local Organization + Supplier + Supplier Site + PO Number + PO Line Number

2. Global Organization + Supplier + Supplier Site + PO Number + PO Line Number

3. Local Organization + Supplier + Supplier Site + PO Number

4. Global Organization + Supplier + Supplier Site + PO Number

5. Local Organization + Supplier + Supplier Site

6. Global Organization + Supplier + Supplier Site

7. Local Organization + Supplier

8. Global Organization + Supplier

WIP Specification Matching

To find a WIP specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. If no WIP specification is found that matches a WIP sample, then the application searches for a matching inventory specification. WIP specifications are searched using the following priorities:

1. Charge

2. Step

3. Routing + Version

4. Routing

5. Formula Line

6. Formula + Version

7. Formula

8. Recipe + Version

9. Recipe

10. Batch

11. Operation + Version

12. Operation

Based on the previous search priorities, a routing takes precedence over a formula, recipe, batch, or operation. When a recipe is defined, the formula and optional routing are associated to it. When a batch is defined from a recipe, a formula and optional routing are associated to it. The WIP specification matching program uses the inventory specification matching program as the base hierarchy and searches based on the previous priorities as follows:

1. Local Organization + Lot + Sublot + Warehouse + Location

2. Global Organization + Lot + Sublot + Warehouse + Location

3. Local Organization + Lot + Warehouse + Location

4. Global Organization + Lot + Warehouse + Location

5. Local Organization + Lot + Sublot + Warehouse

6. Global Organization + Lot + Sublot + Warehouse

7. Local Organization + Lot + Warehouse

8. Global Organization + Lot + Warehouse

9. Local Organization + Lot + Sublot

10. Global Organization + Lot + Sublot

11. Local Organization + Lot

12. Global Organization + Lot

13. Local Organization + Warehouse + Location

14. Global Organization + Warehouse + Location

15. Local Organization + Warehouse

16. Global Organization + Warehouse

17. Local Organization + Item

18. Global Organization + Item

Monitoring Specification Matching

Monitoring specifications are created for resources or locations that you need to assess as part of your quality operations in the enterprise. The following is the hierarchy used by the monitoring specification matching program.

Location

The search hierarchy is:

1. Organization + Warehouse + Location

2. Organization + Warehouse

3. Organization

Resource

The search hierarchy is:

1. Resource + Resource Organization + Resource Instance

2. Resource + Resource Organization

3. Resource

Finding Customer Specifications in Specification Matching

Customer specification matching is available through Oracle Order Management. The application searches for an existing customer specification and displays the specification if one exists. The following is an example of customer specification creation and matching:

Step 1: Create a customer specification for an item. This specification can be a general specification for the item and customer, or it can be for a specific operating unit, ship-to location, order, or order line.

Step 2: Samples are created for the item and lot. Valid sample sources are from customers, production, or inventory. All required tests on the customer specification must have an evaluation of Accept or Accept with Variance. The sample disposition must be Accept or Accept with Variance. Several samples can be taken for an item and lot. Only the most recent results are used.

Step 3: The application finds a customer specification, and searches for samples created for the item, lot, warehouse, and location specified. If no samples are found, then the application searches for an item and lot, and warehouse combination. If this search is not successful, then the application searches for samples that match only the item and lot.

Step 4: If a results set is identified, then the application validates all tests listed in the specification that are represented with an evaluation of Accept or Accept with Variance. Tests in the results set that are not found in the specification are ignored. If duplicate tests are performed, then only the most recent one is used.

Step 5: A customer order is created. View available inventory from the Sales Order Allocations window on the Sales Order Pad or from the Transact Process Move Orders window. When available lots are displayed, the application finds the specification, and searches for matching results. If results for all tests are in-specification, then a match is made. The application displays Acceptable or Unacceptable. If no results are found, then the Quality Match information remains blank.

Step 6: Drill down, as needed, to the matched results, and compare them to the customer specification. Then, select the best lot for the customer's requirements.

D

Quality Management Workflows

This topic introduces you to the concept of a workflow process and refers you to the documentation that fully explains Oracle workflows. It presents an understanding of the OPM Quality Management workflows, how to set them up, how to start them, and how to use the Quality windows.

The following topics are covered:

- Basic Business Needs
- Technical Overview
- Understanding Workflow Processes
- Understanding OPM Quality Management Workflows
- Setting Up OPM Quality Management Workflows
- Using OPM Quality Management Workflows
- Approval Management Engine (AME) Approval Matrix

Basic Business Needs

The Quality Management application in Oracle Process Manufacturing (OPM) supports quality inspection on the raw materials, intermediates, or finished goods at any stage during inventory transaction, receiving, production, or sales cycle, from within the corresponding applications.

Using the Quality Management application, you can set up specifications, draw samples, enter test results, and perform stability studies. The following business events are supported:

- Inventory Control

  - Inventory Increase

  - Receiving into Inventory

  - Receiving into a Receiving Location

  - Lot Expiration

- Process Execution

  - Batch Creation

  - Batch Step Creation

  - Batch Step Release

- Quality Management

  - Sample Creation

  - Sample Disposition and Sample Group Disposition

  - Testing Request

  - Compositing Results

  - Specification Status Change Approval

  - Specification Validity Rule Status Change Approval

  - Customer, Inventory, Supplier, WIP, and Monitoring Validity Rule Status Change Approval

  - Stability Study

    – Status Change

    – Lot/Sublot Sampling

      – Batch Creation

      – Testing

      – Time Point Testing

      – Lot Retesting

- Item UOM Conversion

Technical Overview

OPM Quality Management workflows use two major components:

- Oracle Workflow
- Oracle Workflow Business Event Systems

The design uses the Oracle Workflow Business Event System to define an event and associate it with a subscription to the business event. The subscription initiates a workflow to perform any needed database changes, notifications, or other requirements. Events and subscriptions can be enabled or disabled by the customer as needed using the business event system. A customer can add a new subscription to an event to perform customized functionality or features.

Understanding Workflow Processes

Oracle Workflow lets you automate and continuously improve business processes by routing information according to a set of business rules. You can transmit this information to individuals both inside and outside your enterprise on an individual basis.

Refer to the *Oracle Workflow Guide* and the *Oracle E-Records Implementation Guide* for additional information on:

- Workflow Business Event System
- XML Gateway
- Oracle Approval Management Engine (AME)
- Workflow Notification Subsystem
- Workflow Automatic Notification Processing

Understanding OPM Quality Management Workflows

Sample Creation Notification

The Sample Creation Notification workflow sends a notification to draw a material sample as required by the associated sampling plan for the item specification and specification validity rule in effect. This workflow can be triggered by an inventory quantity increase, receiving transaction, batch step release, or lot expiration or retest. The notification lists the sampling plan information and includes a link to the Item Samples window, where information about the sampling event is populated.

Testing Notification

The Testing Notification workflow sends a notification to prompt you to perform a test and enter its result against a particular sample. It is initiated by the creation of a sample that is already associated to a specification or selection of the result action for retesting a certain test. Each tester for a given sample in process receives a notification for the expected test result.

Sample Disposition Notification

The Sample Disposition Notification workflow prompts for assignment of the final disposition for a sample once testing is complete. The sample disposition can be changed to accepted, accepted with variance, or rejected when all tests (if required by the associated specification) have recorded results that have been evaluated and finalized.

Sample Group Disposition Notification

The Sample Group Disposition Notification workflow notifies you that the sampling event requires a final disposition, based on the number of samples required by the sampling plan. This workflow is launched when all the samples within a sampling event have a final disposition of accept, accept with variance, reject, or cancel.

Composite Results Notification

The Composite Results Notification workflow asks you whether to composite the results across a set of samples within the same sampling event. This workflow is initiated when testing of all the samples in a sampling event (based on the number of samples required by the sampling plan) is complete and each sample has a final sample disposition. The notification provides a link to the Composite Results window, where information about the sampling event is populated.

Spec Status Change Approval Notification

The Spec Status Change Approval Notification workflow notifies the contact person when the specification status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Spec Customer Validity Rule Status Change Approval Notification

The Spec Customer Validity Rule Status Change Approval Notification workflow notifies the contact person when the customer specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Spec Inventory Validity Rule Status Change Approval Notification

The Spec Inventory Validity Rule Status Change Approval Notification workflow notifies the contact person when the inventory specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Spec Supplier Validity Rule Status Change Approval Notification

The Spec Supplier Validity Rule Status Change Approval Notification workflow notifies the contact person when the supplier specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Spec WIP Validity Rule Status Change Approval Notification

The Spec WIP Validity Rule Status Change Approval Notification workflow notifies the contact person when the WIP specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Spec Monitoring Validity Rule Status Change Approval Workflow

The Spec Monitoring Validity Rule Status Change Approval Notification workflow notifies the contact person when the monitoring specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

Sample Group Rejection Notification

The Sample Group Rejection Notification workflow notifies the contact person that either a monitoring sample group, or a stability study time point sample group is rejected.

Stability Study Change Status Notification

The Stability Study Change Status Notification workflow notifies the study owner of status changes in the stability study. The process of changing status from New to a status of Completed involves a series of workflow notifications. Oracle E-Records operates with this workflow to enforce the stability study status control business rules. The cancellation of a stability study is also controlled by the workflow.

Stability Study Lot/Sublot Sample Notification

When the stability study is approved, and specific lots or sublots of the item to be tested exist, then the Stability Study Lot/Sublot Sample Notification workflow notifies the stability study contact person to obtain samples for all required material sources. In the notification, the contact person is designated to draw and store the specified samples, and to update the sample records accordingly.

Stability Study Batch Creation Notification

When the stability study is approved, and specific lots or sublots of the item to be tested do not exist, then the Stability Study Batch Creation Notification workflow notifies the stability study contact person to request that a batch be created for the study.

Stability Study Testing

The Stability Study Testing workflow is a master workflow that governs the Stability Study Time Point Scheduling Notification workflow, and the Stability Study Late Time Point Scheduling Notification workflow. This workflow runs as a background process to monitor for any time point test that requires a workflow

notification, or a late workflow notification. The workflow raises the appropriate event for either scheduled or late time point tests.

If the stability study is canceled or the scheduled time point testing date changes, then a workflow API manages the situation. The sample group disposition is changed from a status of retained to a status of pending, and the sample pull dates are updated.

Stability Study Time Point Scheduling Notification

The Stability Study Time Point Scheduling Notification workflow notifies you to pull samples for time point testing. The notification considers the required lead time, and it requests you to change the disposition of a time point sample from Retained to Pending. When the sample disposition is changed to Pending, tests are scheduled. If the test is not performed within the grace period, then the OPM Quality Stability Study Testing master workflow raises a separate event that indicates the test is overdue.

Stability Study Late Time Point Scheduling Notification

The Stability Study Late Time Point Scheduling Notification workflow notifies you that a test is overdue. The notification considers the required grace period, and uses the OPM Quality Stability Study Testing master workflow to raise a separate event to indicate the test is late.

Quality UOM Conversion Notification

The Quality UOM Conversion Notification workflow notifies the contact person that a recommended UOM conversion exists. A link to the Item Lot/Sublot Standard Conversion window in the OPM Inventory Control application is provided. This link does not operate unless a lot number is assigned.

Setting Up OPM Quality Management Workflows

For the proper functioning of the workflows, a few administrative steps must be handled. These include setting up notification contacts for the workflow and starting the workflow engine.

In Oracle Applications, choose the Oracle Workflow responsibility and invoke the Workflow Process Activation. Enable the following workflow notifications:

- OPM Quality Sample Creation
- OPM Quality Test
- OPM Quality Sample Disposition
- OPM Quality Sample Group Disposition
- OPM Quality Composite Results
- OPM Quality Spec Status Change Approval
- OPM Quality Spec Customer Validity Rule Status Change Approval
- OPM Quality Spec Inventory Validity Rule Status Change Approval
- OPM Quality Spec Supplier Validity Rule Status Change Approval
- OPM Quality Spec WIP Validity Rule Status Change Approval
- OPM Quality Spec Monitoring Validity Rule Status Change Approval
- OPM Quality Sample Group Rejection
- OPM Quality Stability Study Change Status
- OPM Quality Stability Study Lot/Sublot Sample
- OPM Quality Stability Study Batch Creation
- OPM Quality Stability Study Testing
- OPM Quality Stability Study Time Point Scheduling
- OPM Quality Stability Study Late Time Point Scheduling
- OPM Quality UOM Conversion

Raising an Event from PL/SQL

Raising an event can be done from PL/SQL code or within a workflow. Raising events must be done before commit statements or when something has occurred. When raising an event, parameters can be sent to the event for use by the workflow.

The parameters are defined as a set of name/value pairs. These name/values are used as the attribute name/values of the workflow associated with the subscription for the specific event being raised.

Events

Use the Workflow Administrator to configure the seeded event subscription for the prebuilt inbound message if necessary.

Using the Workflow Administrator, add an event that can be raised from the PL/SQL code. This event can be due to an inventory transaction, item receiving or production, shipment picklot, etc.

Each business event is identified by a short name followed by a description. The event is referenced by the event short name across the framework and outside the framework. You need to know the event short name in order to call the API. The event is defined using the SSWA responsibility Workflow Administrator Web Applications. The owner tag of the business event is the application short name, such as GMD.

Refer to the *Oracle Workflow Guide* for details on configuring a workflow event.

Subscriptions

Use the Workflow Administrator to add a subscription that subscribes to the event as defined earlier. This subscription is associated with a specific workflow. For example, an inventory transaction can raise an event where a subscriber to that event initiates the Sample Creation workflow.

A subscription can be added to a defined local business event. The phase of the subscription determines if the subscription is synchronous or not. Phase values less than 100 are synchronous; all others asynchronous. There can be multiple subscriptions to the same business event with different functionality. A workflow can be associated with a subscription.

The Workflow Quality Manager events should have the second subscriber disabled. This enables the Quality workflow notifications to function as expected with respect to samples and sample dispositions.

Workflow

Workflows can be associated with a subscription. In the case of OPM Quality Management, a subscription for an event initiates a workflow execution.

Workflows control notifications for sample creation, sample disposition, and sample rejection. Workflows also control notifications for specification status and

specification validity rule status. Workflows monitor and execute all aspects of the stability study including notifications for study status change, lot and sublot sampling, batch creation, time point testing. If time point testing is not performed within a scheduled grace period, then workflow issues a late time point test notification.

Using OPM Quality Management Workflows

Following are the OPM Quality Management workflows:

- OPM Quality Sample Creation
- OPM Quality Test
- OPM Quality Sample Disposition
- OPM Quality Composite Results
- OPM Quality Sample Group Disposition
- OPM Quality Spec Status Change Approval
- OPM Quality Spec Customer Validity Rule Status Change Approval
- OPM Quality Spec Inventory Validity Rule Status Change Approval
- OPM Quality Spec Supplier Validity Rule Status Change Approval
- OPM Quality Spec WIP Validity Rule Status Change Approval
- OPM Quality Spec Monitoring Validity Rule Status Change Approval
- OPM Quality Sample Group Rejection
- OPM Quality Stability Study Change Status
- OPM Quality Stability Study Lot/Sublot Sample
- OPM Quality Stability Study Batch Creation
- OPM Quality Stability Study Testing
- OPM Quality Stability Study Time Point Test
- OPM Quality UOM Conversion

OPM Quality Sample Creation Workflow

The OPM Quality Sample Creation workflow notifies the workflow recipient that a sample or samples need to be taken for the item transaction.

The workflow that notifies a user about creating a sample can be instantiated by multiple applications, each with its own set of attributes and parameters. These applications include Receiving, Inventory, Production, and the resample quality action.

OPM Inventory Created Event

This business event is triggered from transferring items.

Event Name

oracle.apps.gmi.inventory.created

Event Key and Attribute

IC_TRANS_CMP.TRANS_ID

Subscriber

Subscriber Workflow: OPM Quality Sample Creation

Oracle Approval Management Transaction Name: Process Quality Inventory Transaction Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Inventory Organization
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY2	Quantity2
TRANS_QTY_UOM1	UOM1
TRANS_QTY_UOM2	UOM2
LOT_ID2	Lot ID
LOT_NO	Lot Number
SUBLOT_ID2	Sublot ID
SUBLOT_NO2	Sublot Number
WAREHOUSE	Warehouse
LOCATION	Location
GRADE	Grade

Parameter	Description
TRANSACTION_TYPE	Trans Type

Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for inventory transaction follows:

```
You have been designated to create a sample or samples based on the inventory
transaction described below:
Transaction Details
----------------------------------------------
Transaction Type:      &DOC_TYPE  -  &DOC_DESC
Transaction ID:        &DOC_ID
Transaction Quantity:  &TRAN_QTY
Transaction UOM:       &TRANS_UOM

Organization:          &ORGN_CODE  - &ORGN_NAME
Warehouse:             &WHSE_CODE  - &WHSE_NAME
Item:                  &ITEM_NO
Description:           &ITEM_DESC1
Quantity:              &ITEM_QTY
Unit of Measure:       &ITEM_UOM
Dual Quantity:         &ITEM_QTY2
Dual UOM:              &ITEM_UOM2
Lot: &LOT_NO:
Sub Lot:               &SUBLOT_NO
```

```
Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

OPM Purchase Order Receipt Created Event

This business event is triggered from the receipt transaction for an item that has the inspection required indicator enabled on the item master. The receiving transaction process flow is:

1. Receive against a purchase order line.

2. Receive material into a receiving location.

3. Quality Receiving event is raised.

4. An applicable specification is retrieved.

5. Send a notification to create a sample.

6. Sample is created.

7. Send a notification to perform tests.

8. Testing is performed and completed.

9. Sample Disposition is assigned.

10. Sample Group Disposition is assigned.

11. Go to the Receiving Transaction window to record accepted or rejected quantities and deliver material to inventory.

Event Name

oracle.apps.gml.po.receipt.created

Event Key and Attribute

rcv_transactions.transaction_id

Subscriber

Subscriber Workflow: OPM Quality Sample Creation

Oracle Approval Management Transaction Name: Process Quality Receiving Transaction Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Inventory Organization
SUB_ORG	Sub inventory
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY_UOM1	UOM1
TRANS_QTY2	Quantity2
TRANS_QTY_UOM2	UOM2

Parameter	Description
LINE_TYPE	Only products and byproducts
RECEIPT_ID	Receipt ID
RECEIPT_LINE_ID	Receipt Line ID
PO_HEADER_ID	PO Header ID
PO_LINE_ID	PO Line ID
SUPPLIER_ID	Supplier ID

Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for receiving transaction follows:

```
You are designated to create a sample or samples based on the receiving
transaction described below:
Transaction Details
------------------------------------------------------
Organization:           &ORGN_CODE  - &ORGN_NAME
Item:                   &ITEM_NO
Description:            &ITEM_DESC1
Transaction Quantity1:  &TRANS_QTY1  & TRANS_UOM1
Transaction Quantity2:  &TRANS_QTY2  & TRANS_UOM2
Receipt:                &RECEIPT_NO - &RECEIPT_LINE_NO
Purchase:               &PURCHASE_NO
Supplier:               &SUPPLIER_NO
Sampling Plan:          &SAMPLING_PLAN

Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

OPM Receiving into Inventory Event

This business event is triggered from the receipt transaction into a specific lot or sublot for an item that has the inspection required indicator enabled on the item master. The receiving transaction process flow is:

1. Receive against a purchase order line.

2. Receive material into a lot or sublot inventory location.

3. Quality Receiving event is raised.

4. An applicable specification is retrieved.

5. Send a notification to create a sample.

6. Sample is created.

7. Send a notification to perform tests.

8. Testing is performed and completed.

9. Sample Disposition is assigned.

10. Sample Group Disposition is assigned.

11. Go to the Receiving Transaction window to record accepted or rejected quantities and deliver material to inventory.

Event Name

oracle.apps.gmi.po.receipt

Event Key and Attribute

rcv_transaction_interface.transaction_id

Subscriber

Subscriber Workflow: OPM Quality Sample Creation

Oracle Approval Management Transaction Name: Process Quality Receiving Transaction Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Inventory Organization
SUB_ORG	Sub inventory
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY_UOM1	UOM1
TRANS_QTY2	Quantity2

Parameter	Description
TRANS_QTY_UOM2	UOM2
LINE_TYPE	Only products and byproducts
RECEIPT_ID	Receipt ID
RECEIPT_LINE_ID	Receipt Line ID
PO_HEADER_ID	PO Header ID
PO_LINE_ID	PO Line ID
SUPPLIER_ID	Supplier ID

Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for receiving transaction follows:

```
You are designated to create a sample or samples based on the receiving
transaction described below:
Transaction Details
--------------------------------------------------------
Organization:          &ORGN_CODE  - &ORGN_NAME
Item:                  &ITEM_NO
Description:           &ITEM_DESC1
Transaction Quantity1: &TRANS_QTY1  & TRANS_UOM1
Transaction Quantity2: &TRANS_QTY2  & TRANS_UOM2
Receipt:               &RECEIPT_NO - &RECEIPT_LINE_NO
Purchase:              &PURCHASE_NO
Supplier:              &SUPPLIER_NO
Sampling Plan:         &SAMPLING_PLAN

Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

OPM Batch Created and OPM Batch Step Created Events

When a batch or batch step is created, an event is raised to initiate the OPM Quality Sample Creation workflow. This workflow sends a notification to a contact person informing that a new batch or batch step is created and sampling is required. This includes the samples required for the batch or batch step.

At the release of each step (operation), when the batch step quality status is Sample Required, the OPM Quality Sample Creation workflow is initiated to inform the

contact person to take a sample of the production item. This notification includes a link to the Samples window.

Event Name

- oracle.apps.gme.batch.created

- oracle.apps.gme.batchstep.created

Event Key and Attribute

- GME_BATCH_HEADER.BATCH_ID

- GME_BATCH_STEPS.BATCHSTEP_ID

Subscriber

Type	Subscriber Workflow	Oracle Approval Management Transaction Name
Batch	OPM Quality Sample Creation	Process Quality Production Transaction Sample Creation
Batch Step	OPM Quality Sample Creation	Process Quality Production Transaction Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
BATCH_ID	Batch ID
BATCH_STEP_ID	Batch Step ID

Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for the production transaction follows:

```
You have been designated to create a sample or samples based on the production
transaction described below:
Transaction Details
--------------------------------------------------
Plant:              &ORGN_CODE  - &ORGN_NAME
Warehouse:          &WHSE_CODE  - &WHSE_NAME
Item:               &ITEM_NO
Description:        &ITEM_DESC1
```

```
Lot Number:              &LOT_NO
Sublot Number:           &SUBLOT_NO
Recipe:                  &RECIPE_ NO   &RECIPE_VERS
Formula:                 &FORMULA_ NO  &FORMULA_VERS
Batch:                   &BATCH_ NO
Batch Step:              &BATCH_ STEP_NO
```

```
Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

OPM Inventory Lot Expiry Date Changed Event

This business event is initiated by reaching the expiration date for an item lot.

Event Name

oracle.apps.gmi.lotexpirydate.update

Event Key and Attribute

IC_LOTS_MST.ITEM_ID||'-'||IC_LOTS_MST.LOT_ID

Subscriber

Subscriber Workflow: OPM Quality Sample Creation

Oracle Approval Management Transaction Name: Process Quality Lot Expiry Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_ID	Item ID
LOT_ID	Lot ID
LOT_NO	Lot Number
SUBLOT_NO	Sublot Number
GRADE	Grade
EXPIRE_DATE	Expiration Date

Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for Lot expiration transaction follows:

```
xYou have been designated to create a sample or samples based on the production
transaction described below:
Transaction Details
---------------------------------------------------
Plant:                  &ORGN_CODE  - &ORGN_NAME
Warehouse:              &WHSE_CODE  - &WHSE_NAME
Item:                   &ITEM_NO
Description:            &ITEM_DESC1
Lot Number:            &LOT_NO
Sublot Number:         &SUBLOT_NO
Recipe:                 &RECIPE_ NO   &RECIPE_VERS
Formula:                &FORMULA_ NO  &FORMULA_VERS
Batch:                  &BATCH_ NO
Batch Step:            &BATCH_ STEP_NO

Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

OPM Inventory Lot Retest Date Change Event

This business event is initiated by reaching the retest date for an item lot.

Event Name

oracle.apps.gmi.lotretestdate.update

Event Key and Attribute

IC_LOTS_MST.ITEM_ID||'-'||IC_LOTS_MST.LOT_ID

Subscriber

Subscriber Workflow: OPM Quality Sample Creation

Oracle Approval Management Transaction Name: Process Quality Lot Retest Sample Creation

Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_ID	Item ID
LOT_ID	Lot ID
LOT_NO	Lot Number
SUBLOT_NO	Sublot Number
GRADE	Grade
RETEST_DATE	Retest Date

Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for lot retest transaction follows:

```
You have been designated to create a sample or samples based on the lot retest
event described below:

Transaction Details
--------------------------------
Item:               &ITEM_NO
Description:        &ITEM_DESC1
Quantity:           &ITEM_QTY
Unit of Measure:    &ITEM_UOM
Dual Quantity:      &ITEM_QTY2
Dual UOM:           &ITEM_UOM2
Lot:                &LOT_NO
Sub Lot:            &SUBLOT_NO
Retest Date:        &RETEST_DATE

Click Forms to launch the Samples window. Enter the sample and save. The
Notifications window is displayed again and you can click OK to respond to the
notice.
```

Subscriber Workflow

There is a fork in the workflow. The notification is sent to the person defined in AME for the workflow's contact. The control parameter list is:

- Event Type
- Inventory Organization

- Inventory Item

- Warehouse

- Location

A contact person can be defined using at least one of the control parameters. The workflow resolves the role to at least a single user.

OPM Quality Test Workflow

This workflow is initiated by creating a sample or retesting. When a sample is created and associated to a specification, each workflow recipient receives a notification for the scheduled tests. The quality testing process is:

1. Sample is created.

2. The tester defined for each test is retrieved from AME.

3. The tests are grouped by the tester defined in AME.

4. Sends a notification to each tester with the list of the tests they need to conduct. The notification includes a link to the Forms window where the results can be entered.

The purpose of this workflow is to find the testers and send notification for testing a particular sample. In the case of a sample creation, the sample information is identified. In the retest or additional testing scenarios, the test is known.

Event Name

oracle.apps.gmd.qm.performtest

Event Key and Attribute

GMD_SAMPLES.SAMPLE_ID

Subscriber

Subscriber Workflow: OPM Perform Quality Test

Oracle Approval Management Transaction Name: Process Quality Perform Test

Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLE_ID	Sample ID
SAMPLING_NO	Sample Number
TEST_ID	Test ID

Subscriber Workflow

This workflow is spawned through the creation of sample and a specific specification for an item. This function finds the notifier associated with the test from AME. The control parameters are:

- Lab
- Item
- Test Class
- Test
- Test Method

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

Test Request Notification

The workflow sends a notification soliciting a response about the result of the tests.

```
You have been designated to perform the following test(s) on the sample
described below.

Sample Number:              &SAMPLE_NO
Sample Description:
Sample Storage Warehouse:
Sample Storage Location:
Sample Priority:
Sample Date Drawn:

Item:                       &ITEM_NO
Description:                &ITEM_DESC1
Unit of Measure:           &ITEM_UM
Lot:                        &LOT_NO
SubLot:                     &SUBLOT_NO
```

```
Tests you need to conduct
Test Name1:
Test Class1:
Test Method1:
Instrument1:
Test Quantity1:
Test UOM1:
Priority1:
Test Duration1:
Test Replication1:
Optional Test1:

Test Name2:
Test Class2:
Test Method2:
Instrument2:
Test Quantity1:
Test UOM1:
Priority2:
Test Duration2:
Test Replication2:
Optional Test2:

Click Forms to launch the Results window. You may enter the test result there.
After saving the result you will come back to the Notification screen where you
may Click the OK button to respond to the notice.
```

OPM Quality Sample Disposition Workflow

When sample testing is complete, the OPM Quality Sample Disposition workflow is initiated to prompt for a sample disposition as Accept, Accept with Variance, or Reject.

The basic process for initiating the OPM Quality Sample Disposition workflow is:

1. All required tests have results.

2. An event for the sample disposition is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to the contact person as defined in AME, along with the sample information.

Event Name

oracle.apps.gmd.qm.sample.disposition

Event Key and Attribute

GMD_SAMPLES.SAMPLE_ID

Subscriber

Subscriber Workflow: OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name: Process Quality Sample Disposition

Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLE_ID	Sample ID
SAMPLING_EVENT_ID	Sampling Event ID
RECOMMENDED_DISP	Recommended Target Disposition

Subscriber Workflow

This function finds the approver associated with the sample from AME. The control parameters are:

- QC Lab Org

- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

Sample Approval Notifications

You receive a notification soliciting a response about sample approval.

```
You have been designated to assign a disposition to the sample as described
below.

Item:                    &ITEM_NO
Description:             &ITEM_DESC1
Lot:                    &LOT_NO
Sublot:                 &SUBLOT_NO
Sample Number:          &SAMPLE_NO
Sample Plan Name:
Sample Disposition:
Sample Source:
Spec:

Click Forms to launch the Samples window. After saving the result you will come
back to the Notification screen where you may Click the OK button to respond to
the notice.
```

OPM Quality Composite Results Workflow

When testing is complete for a sampling event, the OPM Quality Composite Results workflow lets you composite the results across the samples.

The process for initiating the OPM Quality Composite Results workflow is:

1. All samples of a sampling event have a final sample disposition.

2. An event for the composite results is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.compositeresults

Event Key and Attribute

GMD_SAMPLES.SAMPLE_EVENT_ID

Subscriber

Subscriber Workflow: OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name: Process Quality Sample Composite Results

Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLING_EVENT_ID	Sampling Event ID

Subscriber Workflow

This function finds the notifier associated with the composite result from AME. The control parameters list is:

- Org
- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

Composite Results Notifications

You receive a notification soliciting a response about sample composite.

```
You have been designated to composite results for the sample described below.

Organization:          &Org
Item:                   &ITEM_NO
Description:            &ITEM_DESC1
Lot:                    &LOT_NO
Sublot:                 &SUBLOT_NO

Sample Plan Name:
Samples Taken:
Spec:
```

```
Click Forms to launch the Composite Results window. After saving the result you
will come back to the Notification screen where you may Click the OK button to
respond to the notice.
```

OPM Quality Sample Group Disposition Workflow

When all the samples in the sampling event have dispositions of accept, reject, accept with variance, or cancel, the OPM Quality Sample Group Disposition workflow is initiated to prompt for a sampling event disposition.

The basic process for initiating the OPM Quality Sample Group Disposition workflow is:

1. All sample dispositions have been changed from testing to accept, accept with variance, reject, or cancel.

2. An event for the sampling disposition is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.samplingevent.disposition

Event Key and Attribute

GMD_SAMPLES.SAMPLE_EVENT_ID

Subscriber

Subscriber Workflow: OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name: Process Quality Sample Group Disposition

Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLING_EVENT_ID	Sampling Event ID

Parameter	Description
RECOMMENDED_DISP	Recommended Target Disposition
CURRENT_DISP	Current Target Disposition

Subscriber Workflow

This function finds the notifier associated with the sampling event approval from AME. The control parameters list is:

- Org

- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

Sample Group Disposition Notification

You receive a notification soliciting a response about sample event disposition.

```
You have been designated to assign a disposition to the sampling event as
described below.

Recommended Disposition:

Item:                    &ITEM_NO
Description:             &ITEM_DESC1
Lot:                    &LOT_NO
SubLot:                 &SUBLOT_NO

Sample Plan Name:
Spec Name:

Click Forms to launch the Sample Groups window. After saving the result you will
come back to the Notification screen where you may Click the OK button to
respond to the notice.
```

OPM Quality Spec Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specifications. The basic process for initiating the OPM Quality Spec Status Change Approval workflow is:

1. A specification is status is changed.

2. An event for the specification status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.spec.sts

Event Key and Attribute

GMD_SPECIFICATIONS.SPEC_ID

Subscriber

Subscriber Workflow: OPM Quality Spec Status Change Approval

Oracle Approval Management Transaction Name: Process Quality Spec Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_NO	Item Name
ORGN_CODE	Organization Code

Request Notification

The workflow sends a notification to the contact person indicating that a specification needs approval.

```
&REQUESTER has requested a spec status change
Spec:              &SPEC_NAME
Spec Type:         &SPEC_TYPE
Description:       &DESCRIPTION
Version:           &SPEC_VRS
Current Status:    &SPEC_STATUS
Owner Organization: &OWNER_ORGN_CODE
Owner:             &OWNER_NAME
Item:              &ITEM_NO
Item Description:  &ITEM_DESC
```

```
Grade:               &GRADE

Effective From Date: &FROM_DATE
Effective To Date:   &TO_DATE

Please click on Approve to approve or click on Reject to reject.
```

OPM Quality Spec Customer Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.svr.cus.sts

Event Key and Attribute

GMD_CUSTOMER_SPEC_VRS. SPEC_VR_ID

Subscriber

Subscriber Workflow: OPM Quality Customer Spec Validity Rule Status Change

Oracle Approval Management Transaction Name: Process Quality Customer Validity Rule Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
CUST_NAME	Customer Name
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person indicating a request to approve a customer validity rule.

```
&REQUESTER has requested a spec validity rule status change
Spec:                &SPEC_NAME
Version:             &SPEC_VRS
Current Status:      &SPEC_STATUS
Organization:        &OWNER_ORGN_CODE
Validity Rule Status: &SPEC_VR_STATUS
Effective From Date: &FROM_DATE
Effective To Date:   &TO_DATE
Comments:            &GMDQSVRS_DISP_COMMENT

Please click Approve to approve or click Reject to reject.
```

OPM Quality Spec Inventory Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.svr.inv.sts

Event Key and Attribute

GMD_INVENTORY_SPEC_VRS. SPEC_VR_ID

Subscriber

Subscriber Workflow: OPM Quality Inventory Spec Validity Rule Status Change

Oracle Approval Management Transaction Name: Process Quality Inventory Validity Rule Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person indicating a request to approve an inventory validity rule.

```
&REQUESTER has requested a spec validity rule status change
Spec:                 &SPEC_NAME
Version:              &SPEC_VRS
Current Status:       &SPEC_STATUS
Organization:         &OWNER_ORGN_CODE
Validity Rule Status: &SPEC_VR_STATUS
Effective From Date:  &FROM_DATE
Effective To Date:    &TO_DATE
Comments:             &GMDQSVRS_DISP_COMMENT

Please click Approve to approve or click Reject to reject.
```

OPM Quality Spec Supplier Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name
oracle.apps.gmd.qm.svr.sup.sts

Event Key and Attribute

GMD_SUPPLIER_SPEC_VRS. SPEC_VR_ID

Subscriber

Subscriber Workflow: OPM Quality Supplier Spec Validity Rule Status Change

Oracle Approval Management Transaction Name: Process Quality Supplier Validity Rule Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
SUPP_NAME	Supplier Name
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person indicating a request to approve a supplier validity rule.

```
&REQUESTER has requested a spec validity rule status change
Spec:               &SPEC_NAME
Version:            &SPEC_VRS
Current Status:     &SPEC_STATUS
Organization:       &OWNER_ORGN_CODE
Validity Rule Status: &SPEC_VR_STATUS
Effective From Date: &FROM_DATE
Comment:            &GMDQSVRS_DISP_COMMENT

Please click Approve to approve or click Reject to reject.
```

OPM Quality Spec WIP Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.svr.wip.sts

Event Key and Attribute

GMD_WIP_SPEC_VRS. SPEC_VR_ID

Subscriber

Subscriber Workflow: OPM Quality WIP Spec Validity Rule Status Change

Oracle Approval Management Transaction Name: Process Quality WIP Validity Rule Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
RECIPE	Recipe
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person indicating a request to approve a WIP validity rule.

```
&REQUESTER has requested a spec validity rule status change
Spec:                 &SPEC_NAME
Version:              &SPEC_VRS
Current Status:       &SPEC_STATUS
Organization:         &OWNER_ORGN_CODE
Validity Rule Status: &SPEC_VR_STATUS
Effective From Date:  &FROM_DATE
Effective To Date:    &TO_DATE
Comments:             &GMDQSVRS_DISP_COMMENT

Please click Approve to approve or click Reject to reject.
```

OPM Quality Spec Monitoring Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

Event Name

oracle.apps.gmd.qm.svr.mon.sts

Event Key and Attribute

GMD_MONITORING_SPEC_VRS. SPEC_VR_ID

Subscriber

Subscriber Workflow: OPM Quality Monitoring Spec Validity Rule Status Change

Oracle Approval Management Transaction Name: Process Quality Monitoring Validity Rule Status Change Approval

Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Organization

Request Notification

The workflow sends a notification to the contact person indicating a request to approve a WIP validity rule.

```
&REQUESTER has requested a spec validity rule status change
Spec:              &SPEC_NAME
Version:           &SPEC_VRS
Current Status:    &SPEC_STATUS
```

```
Organization:        &OWNER_ORGN_CODE
Validity Rule Status: &SPEC_VR_STATUS
Effective From Date:  &FROM_DATE
Effective To Date:    &TO_DATE
Resource:            &RESOURCE
Resource Instance:    &RESOURCE_INST
Warehouse:           &WAREHOUSE
Location:            &LOCATION
Comments:            &GMDQSVRS_DISP_COMMENT

Please click Approve to approve or click Reject to reject.
```

OPM Quality Sample Group Rejection Workflow

The Sample Group Rejection Notification notifies you that either a monitoring sample group, or a stability study time point sample group is rejected.

The basic process for initiating the OPM Quality Sample Group Rejection workflow is:

1. Sample group dispositions are changed from complete to reject.

2. An event for the sampling disposition is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

OPM Quality Sample Group Rejection

The Sample Group Rejection Notification notifies the contact person that either a monitoring sample group, or a stability study time point sample group is rejected.

Event Name

oracle.apps.gmd.qm.smpl.rej

Event Key and Attribute

SAMPLING_EVENT_ID

Subscriber

Subscriber Workflow: OPM Quality Sample Group Rejection Workflow

Oracle Approval Management Transaction Name: Process Quality Sample Rejection

Recommended Attributes for Approval Configuration

Parameter	Description
WHSE_CODE	Warehouse
RESOURCE	Resource

Request Notification

The workflow sends a notification to the contact person indicating that a sample group is rejected.

In the case of Resource/Location:

```
The following sample disposition has been rejected
Resource Details
----------------------------------------------------
Resource:         &RESOURCE
Resource Instance: &RESOURCE_INST
Description:       &RESOURCE_DESC

Warehouse:        &WAREHOUSE
Location:         &LOCATION
Click on the form to open the Sample Groups window.
```

In the case of Stability Studies:

```
The following sample disposition has been rejected
Study:            &STUDY_NAME
Study Description: &STUDY_DESC
Item:             &ITEM_NO
Item Description:  &ITEM_DESC

Click on the form to open the Sample Groups window.
```

OPM Quality Stability Study Change Status Workflow

The Stability Study Change Status Notification notifies the study owner of status changes in the stability study. The process of changing the stability study status from New to a status of Complete involves a series of workflow notifications. This workflow can work in conjunction with Oracle E-Records if it is enabled.

The basic process for initiating the OPM Quality Stability Study Change Status workflow is:

1. A stability study is created with an initial status of New, depending on the default value assigned to GMA: New for the STBL document type.

2. An event for change status is raised.

3. Subscriber for the event initiates the workflow.

4. Workflow sends notification to contact person as defined in AME, along with the change status event information.

OPM Quality Stability Study Change Status Event

This business event is triggered from the Change Status dialog box accessed from the Actions menu on the Stability Study window.

Event Name

oracle.apps.gmd.qm.ss.csts

Event Key and Attribute

SS_ID

Subscriber

Subscriber Workflow: Quality Stability Study Change Status

Oracle Approval Management Transaction Name: GMDQM_STABILITY_CSTS

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

Request Notification

You receive a notification about the requested change of status for the stability study. The body of that request is:

```
&REQUESTER has requested change status for the following Stability Study
Study:                  &STUDY_NAME
Study Description:      &STUDY_DESC
From Status:           &STUDY_STATUS_INITIAL
To Status:             &STUDY_STATUS_FINAL
Storage Condition Plan: &STORAGE_PLAN
Item:                  &ITEM_NO
Item Description:       &ITEM_DESC
Base Spec:             &BASE_SPEC
Lab Organization:       &OWNER_ORGN_CODE (&OWNER_ORGN_NAME)

Notification Lead Time: &LEAD_TIME
Testing Grace Period:   &GRACE_TIME

Scheduled Start Date:
Scheduled End Date:
Revised Start Date:
Revised End Date:
Actual Start Date
Actual End Date

Study Owner:
Click Approve to approve this notification, or click Reject to reject the
notification.
```

Preseeded Stability Study Statuses

The following table lists each of the preseeded stability study statuses, a description of the status as it appears in the workflow notification process, whether status can be updated, and the listed status type:

Status	Description	Updateable?	Status Type
100	New	Yes	100
200	Request Approval of Stability Study Plan	No	200
300	Revise Stability Study Plan	Yes	300
400	Stability Study Plan Approved	Yes	400
500	Request Approval to Launch	No	500
600	Revise Launch Request	Yes	600
700	Launch Approved	Yes	700
800	In Progress	No	800

Status	Description	Updateable?	Status Type
900	Request Approval to Cancel	No	900
940	Request Approval to Cancel From Approved Plan	Yes	940
970	Request Approval to Cancel From Approved Launch	No	970
980	Request Approval to Cancel from In Progress	No	980
1000	Canceled	No	1000
1100	Completed	No	1100

OPM Quality Stability Study Lot/Sublot Sample Workflow

The Stability Study Lot/Sublot Sample Notification notifies a workflow recipient to take samples from the specified lot/sublot material source when a stability study is approved.

OPM Quality Stability Study Sample Creation

This business event is triggered by a stability study status change to Stability Study Plan Approved.

Event Name

oracle.apps.gmd.qm.ss.lot

Event Key and Attribute

SOURCE_ID

Subscriber

Subscriber Workflow: OPM Quality Stability Study Sample Creation

Oracle Approval Management Transaction Name: GMD_STABILITY_LOT

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person designating them to draw and store the listed samples, and to update the sample records accordingly. The body of the notification follows:

```
The following sample records have been created after the approval of the Sample
Source Stability Study. You are designated to draw and store these samples and
update the sample records accordingly:

Study:               &STUDY_NAME
Study Description:    &STUDY_DESC
```

```
Current Status:              &STUDY_STATUS

Organization:               &ORGN_CODE
Item:                       &ITEM_NO
Description:                 &ITEM_DESC1
Lot:                        &LOT_NO
Sub Lot:                    &SUBLOT_NO


Variant Material Source
Batch:
Recipe:
Recipe Version:

Variant Storage condition
Storage Spec:
Storage Spec Version:
Resource:
Resource Instance:
Warehouse:
Location:

Variant Package
Package
Formula
Formula Version:
Sample Quantity/UOM:
Dual Quantity:          &ITEM_QTY2
Dual UOM:               &ITEM_UOM2
Lot: &LOT_NO
Sub Lot:                &SUBLOT_NO

Click Forms to open the Source Variants window. The Notifications window is
displayed again, and you can click OK to respond to the notice.
```

OPM Quality Stability Study Batch Creation Workflow

The Stability Study Batch Creation Notification notifies a workflow recipient to create a batch as a material source when no specific lot or sublot are entered as material sources for the stability study. The workflow is triggered when a stability study is approved.

OPM Quality Stability Study Sample Creation

This business event is triggered by a stability study status change to Stability Study Plan Approved.

Event Name

oracle.apps.gmd.qm.ss.batch.cr

Event Key and Attribute

SOURCE_ID

Subscriber

Subscriber Workflow: OPM Quality Stability Study Sample Creation

Oracle Approval Management Transaction Name: GMDQM_STABILITY_BATCH

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

Request Notification

The workflow sends a notification to the contact person designating them to create a batch. The body of the notification follows:

```
You are designated to draw and store these samples and update the sample records
accordingly:

Study:                &STUDY_NAME
Study Description:     &STUDY_DESC
Current Status  Study: &STUDY_NAME
Study Description:     &STUDY_DESC

Please enter the Batch Number in the Material Sources Screen
```

OPM Quality Stability Study Testing Workflow

The OPM Quality Stability Study Testing workflow is the master workflow for two related workflows:

- OPM Quality Stability Study Time Point Scheduling Workflow

- OPM Quality Stability Study Late Time Point Scheduling Workflow

The workflow is the background process for the stability study, and it checks continuously for any time point test requiring a workflow notification (oracle.apps.gmd.qm.ss.tp) or a late workflow notification (oracle.apps.gmd.qm.ss.tplt). In each instance, it raises an appropriate event.

Scheduling the Workflow Background Process

Schedule the Workflow Background Process concurrent program to run hourly, or at an interval that is compatible with your stability study time point testing design.

1. Navigate to the **Submit Request** window.

2. Enter **Name** as **Workflow Background Process**. The Parameters dialog box displays.

3. Select **Item Type** as **OPM Quality Stability Study Testing**.

4. Select **Process Deferred** as **Yes**.

5. Select **Process Timeout** as **Yes**.

6. Click **OK**.

7. Click **Schedule...** in the **At these Times...** region. The Schedule dialog box displays.

8. Select **Periodically** in the **Run the Job...** region.

9. Enter **Start At** as the date and time to begin the stability study testing. This field defaults to the system date and time.

10. Leave **End At** blank to run the process indefinitely, or enter an appropriate time and date to end the workflow background process.

11. Enter **1** and select **Hour(s)** to check for time point testing hourly.

12. Click **OK**.

13. Click **Submit** on the **Submit Request** window to submit the request.

The time point testing workflow is triggered so that a notification is sent to a user at a time set by the stability study lead time. If the test is not performed within the grace period, then a late notification is raised as a separate event.

If the stability study is canceled or a date changes, then the wf_engine.abort workflow API is called using the combination of item_type, the eight character name of the workflow, and item_key the key used for identifying the workflow.

Sample group disposition is changed from a status of Retained to a status of Pending. Sample pull dates on the are updated.

Event Name
oracle.apps.gmd.qm.ss.test

Event Key and Attribute
SS_ID

Subscriber

Subscriber Workflow: OPM Quality Stability Study Testing

Oracle Approval Management Transaction Name: GMDQM_STABILITY_PARENTTEST

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

OPM Quality Stability Study Time Point Test Workflow

The Stability Study Time Point Test notification manages notifications for future testing and for late time point testing.

Stability Study Time Test Point Notification
The Stability Study Time Point Test Notification notifies you that a future test is required. The notification considers the required lead time. If the test is not performed within the grace period, then the OPM Quality Stability Study Testing master workflow raises a separate event that indicates the test is overdue.

Event Name

oracle.apps.gmd.qm.ss.tp

Event Key and Attribute

TIMEPOINT_ID

Subscriber

Subscriber Workflow: OPM Quality Stability Study Time Point Test

Oracle Approval Management Transaction Name: GMDQM_STABILITY_TEST

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

Request Notification

```
You are designated to draw and store these samples and update the sample records
accordingly:

Study:             &STUDY_NAME
Study Description:     &STUDY_DESC
Current Status  Study:  &STUDY_NAME
Study Description:     &STUDY_DESC

Please enter the Batch Number in the Material Sources Screen
Study:             &STUDY_NAME
Study Description:     &STUDY_DESC
Current Status  Study:  &STUDY_NAME
Study Description:     &STUDY_DESC

Click Forms to launch the Samples Summary window. After saving the result you
will come back to the Notification screen where you may Click the 'OK button to
respond to the notice.
```

Stability Study Late Time Point Test Notification

The Stability Study Late Time Point Test Notification notifies you that a test is overdue. The notification considers the required grace period, and uses the OPM Quality Stability Study Testing master workflow to raise a separate event to indicate the test is late.

Event Name

oracle.apps.gmd.qm.ss.tplt

Event Key and Attribute

TIMEPOINT_ID

Subscriber

Subscriber Workflow: OPM Quality Stability Study Late Time Point Test

Oracle Approval Management Transaction Name: GMDQM_STABILITY_LATETEST

Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

Request Notification

```
Late Time Point Testing of a Stability Study
You have been designated to pull the stability study variant time point testing
as described  below.

Study: &STUDY_NAME
Study Description:      &STUDY_DESC
Current Status:        &STUDY_STATUS

Item:                  &ITEM_NO
Description:           &ITEM_DESC1

Variant Number:
Time Interval:
Scheduled Date:
```

```
Spec:
Spec Version:
Samples Required:

Resource:
Resource Instance:
Warehouse:
Location:

Sample(s):
Study:                    &STUDY_NAME
```

OPM Quality UOM Conversion Workflow

The Quality UOM Conversion Notification notifies the workflow recipient of a recommended UOM conversion. One workflow notification is issued for each recommended UOM conversion listed on the Change Disposition window UOM Conversions tab. Click the link to the OPM Inventory Item Lot/Sublot Standard Conversions window. The item, lot, and conversion information displays on that window. The window fields are all protected from update. A lot number must be entered if it is not available for the sample group.

You can keep the workflow notification open, reenter the item lot conversion link, and enter another lot number for the same conversion. When the conversions are established for all the desired item lots, then you can close out the notification.

The basic process for initiating the OPM Quality UOM Conversion workflow is:

1. Record samples and results for all tests saved on the specification created in setting up for the unit of measure conversion process. Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for a complete discussion of this process.

2. Change the sample group disposition to Accept, Accept with Variance, or Reject.

3. An event for change status is raised.

4. Workflow sends notification to contact person as defined in AME, along with the UOM conversion event information.

5. Select the UOM Conversion tab on the Change Disposition window. The application enters all data displayed on this tab:

- If at least one test on the specification has the Calculate UOM indicator selected

- If the Change Disposition To field displays Accept, Accept with Variance, or Reject

- If the sample group source is Inventory or Supplier

Data appears on this tab even when test results are out-of-specification.

If a lot and sublot UOM conversion already exists for the lot, then the current conversion between the UOM class of the base UOM and the UOM class of the To UOM is displayed below the new proposed conversion.

6. Select the **Recommend** indicator next to the desired UOM conversions. If this indicator is not selected, then the proposed conversion is not used in inventory.

7. Click **OK** to change the disposition of the sample group.

8. Subscriber for the event initiates the workflow.

9. Provide an eSignature for the disposition change if one is required.

10. Receive the OPM Quality UOM Conversion workflow notification.

11. Click the UOM Conversion link to the OPM Inventory Control **Item Lot/Sublot Standard Conversion** window, and save to create the conversions.

12. Close the workflow notification.

OPM Quality UOM Conversion

This business event is triggered from the Change Disposition window.

Event Name

oracle.apps.gmd.qm.uomconv.csts

Event Key and Attribute

EVENT_SPEC_DISP_ID

Subscriber

Subscriber Workflow: Quality UOM Conversion

Oracle Approval Management Transaction Name: Process Quality UOM Conversion

Recommended Attributes for Approval Configuration

Parameter	Description
ORGN_CODE	Organization

Request Notification

You receive a notification about the UOM conversion. The body of that request is:

```
&REQUESTER has recommended a Quality Management Item Lot UOM conversion

Source:                  &SOURCE
Samples Taken:           &SAMPLES_TAKEN
Sample Group Disposition: &SAMPLE_GRP_DISP

Item:                    &ITEM_NO
Lot:                     &LOT
Sublot:                  &SUBLOT

Organization:            &ORGANIZATION
Warehouse:               &WAREHOUSE
Location:                &LOCATION
Supplier:                &SUPPLIER
Site: &SITE
Supplier Lot:            &SUPPLIER_LOT
PO Number:               &PO_NO
PO Line Number:          &PO_LINE_NO
Receipt Number:          &RECEIPT_NO
Receipt Line Number:     &RECEIPT_LINE_NO

Spec:                    &SPEC
Spec Version:            &SPEC_VERSION
Test Name:               &TEST_NAME

&FROM_UOM =              &PROPOSED_CONVERSION &TO_UOM

Please open the Item Lot/Sublot Standard Conversion window Link in order to
approve the UOM Conversions, form Link: ICCNVED
```

Your responsibility must have access to the Item Lot/Sublot Standard Conversion window in order to successfully complete the link.

Approval Management Engine (AME) Approval Matrix

The Oracle Approval Management framework defines the approval matrix and approval groups. AME lets you define transaction and associate attributes that control the approvers of the transaction. It also lets you define approval groups based on FND users and let these groups be associated to rules. Approval Management production rules represent business rules that determine who must approve a transaction.

Refer to the *eRecord and eSignature Developer's Guide* for details.

The process flow for creating an eRecord and eSignature Approval matrix is accomplished through the AME responsibility available in Oracle Applications.

Defining Transaction, Attributes, and Approval Groups

Each business event is associated with a set of control parameter lists. The business event is the transaction in AME while the control parameter list becomes the list of attributes. In the case of the test business event, the attributes are Lab, Item, Test Class, Test, and Test Method.

A transaction type is defined in AME, and corresponds to an Oracle workflow business event. The name of the transaction type is the same as the name of the business event. Attributes are defined for the transaction along with the associated SQL statement, which derives the values of the attributes for a given transaction.

You define approval groups that are associated to the rule in AME.

Defining AME Conditions

Define conditions in AME using the attributes. For example, the Lab is OPME.

Defining eSignature Rules

Define rules in AME using the conditions. For example, the Rule for Plant Code is used with a specific approval list. If the plant code is OPME, then the approval list defined in AME is used.

E

Oracle E-Record Events in Quality Management

OPM Quality Management supports the acquisition of electronic signatures on electronic records. Electronic documentation replaces paper with a seamless interface of business activities that improves manufacturing throughput and enhances the overall quality of operations in the enterprise. The following provides information for online and deferred events that are e-record and e-signature enabled in the OPM Quality Management application. A brief discussion of each event is provided. Refer to the *Oracle E-Records Implementation Guide* for details on setting up the events and approvals.

Events

The following table lists the events that are e-record and e-signature enabled for OPM Quality Management:

Event	Online or Deferred
Process Quality Specifications Event	Deferred
Process Quality Inventory Validity Rule Specifications Event	Deferred
Process Quality WIP Validity Rule Specifications Event	Deferred
Process Quality Customer Validity Rule Specifications Event	Deferred
Process Quality Supplier Validity Rule Specifications Event	Deferred
Process Quality Monitoring Validity Rule Specifications Event	Deferred
Process Quality Sample Creation Event	Online
Process Quality Results Entry Event	Online
Process Quality Results Evaluation	Online
Process Quality Sample Disposition	Online
Process Quality Sample Event Disposition	Online
Process Quality Sample Event Disposition Composite	Online
Process Quality Stability Study Change Status	Online

Finding Additional Oracle E-Records Information

You can find the following information in the *Oracle E-Records Implementation Guide*:

- Events
- Event Key
- Subscriptions

From the XML Gateway, using the existing Event and Event Key, you can derive the XML Map, Subscription Data, and Metadata.

Approval of Quality Specification

Making a Quality Specification active consists of two separate events: the approval of a specification, and the approval of the specification validity rule. Process Quality Inventory, WIP, Customer, and Supplier Specification Validity Rule Events apply to

item specifications. The Process Quality Monitoring Validity Rule Specifications Event only applies to the monitoring specification. Both events require the capture of e-records and e-signatures.

A specification status can be controlled through a workflow. Therefore, signatures for both creation and updates of specifications are captured deferred (electronic notifications are sent).

Data on the signoff for specifications can include:

- OPM Organization, Item, Lot and Sublot, Grade, Warehouse, Location, Resource

- Customer, Operating Unit, Ship to, Sales Order, Order Line

- Batch, Formula and Version, Routing and Version, Operation and Version, Step, Charge

- Specification Name, Specification Description

- Test Information

- Sampling Plan Information

Samples Creation

The Samples Creation e-record is sent when you try to approve a sample. The e-record provides all information about sample identification, including its priority, source, quality laboratory, sample dates, the specification tied to it, and any sampling plan information.

Data on the signoff for samples creation can include:

- Sample Number, Description, Disposition, Priority

- Item, Item Description, Source, Source Comments

- Lot, Sublot Warehouse Location

- Customer, Operating Unit, Ship To Location, Order, Order Type, Order Line

- Batch, Recipe, Version, Formula, Version, Formula Line, Routing, Version, Step, Charge, Operation, Version

- Supplier, Supplier Name, Site, PO Number, PO Line, Receipt Number, Receipt Line

- Quality Laboratory, Date Drawn, Expiration Date, Samples Occurrence, Lot Retest Sample, Update Inventory Quantity, Sample Quantity, Sample Quantity UOM, Storage Warehouse, Storage Location

- Specification Name, Spec Version

- Sampling Plan Details

  - Name, Sample Count, Sample Quantity, Sample Quantity UOM, Per

Results

Quality results entry and evaluation can also require e-signature and e-record support. After results are entered and evaluation during a session, upon saving the results, the e-signature event is raised by the window and the appropriate signoffs take place online. If all the necessary signatures cannot be fulfilled at this time, then the results cannot be committed to the database. Results for all listed tests do not have to be entered in order for the e-signature event to be raised; if one or more test results are entered and saved, then e-signature is required. If more results are entered and evaluated in subsequent sessions, then e-signature is required at that time.

Data on the signoff for results entry and evaluation includes:

- Sample Number, Item

- Test Class, Test, Test Method, Test Replicate, Lab, Tester, Test Kit

- Result, Result Date

- Specification Name, Specification Version, Specification Minimum, Spec Maximum, Test Unit

Sample and Sample Group Disposition

The Process Quality Sample Disposition event represents the final review and approval or rejection of all of the results logged against a sample. After the sample disposition is accepted, accepted with variance, or rejected, the lot status is changed to reflect this disposition. Changing to a final sample group disposition can also control the generation of recommended item lot interclass UOM conversions.

The Certificate of Analysis report and Specification Matching feature both depend on a sample group disposition being accepted. If a sample group is not accepted, then these programs do not consider the sample group. Therefore, it is important that the sample group Disposition field is updated.

Data on the signoff for Sample Approval includes:

- OPM Organization, Sample, Description, Source

- Quantity, UOM, Date Drawn, Sample Disposition

- Item, Lot and Sublot, Warehouse, Location

- Customer, Operating Unit, Ship to, Sales Order, Order Line

- Batch, Formula and Version, Routing and Version, Operation and Version, Step, Charge

- Status (Source and Target), Grade (Source and Target)

- Sample Dates

- Sample Version, Sample Priority, Sample Source

- Composite Indicator

Stability Study Change Status

The stability change status functionality allows you to change stability study status from new to approved, approved to launch, and launch to completion.

Data on the signoff for Stability Study Change Status can include:

- Study, Study Description, From Status, To Status

- Item, Item Description, Base Spec, Lab Organization, Owner

- Material Source, Storage Condition, Package

- Scheduled Start Date, Scheduled End Date, Revised Start Date, Revised End Date, Actual Start Date, Actual End Date, Notification Lead Time, Testing Grace Period

- Variant Summary

    - Variant Number, Default Item Spec, Default Item Spec Version, Variant Start Date, Samples per Time point, Retained Samples

- Variant Material Source

    - Batch, Recipe, Recipe Version

- Variant Storage Condition

    - Storage Spec, Storage Spec Version, Resource, Resource Instance, Warehouse, Location, Storage Date

- Variant Package
    - Package, Formula, Formula Version, Sample Quantity/UOM
- Variant Timepoints
    - Time Interval, Spec, Spec Version, Scheduled Date, Actual Date, Samples Required

Glossary

Action

User defined message displayed to identify the need for and type of quality related action to be taken when a lot expires, or its results are not in conformance with quality requirements. Examples of actions are: quarantine, retest, resample, and hold.

Assay

See Test.

Assay Type

See Test Data Type.

Assay Units

See Test Units.

Business Event

An event that is of interest to customers or business teams. For example, the movement of inventory to a warehouse is a business event.

Certificate of Analysis

Also, COA. Documentation issued to a customer, or for internal records, indicating the quality tests performed and results reported for item lots shipped.

Certificate of Conformance

Also, CoC. Documentation provided by a supplier or manufacturer that indicates the supplies or services meet the specified requirements. In this application, the

Certificate of Conformance lets the process manufacturer to certify shipments that meet certain quality specifications where results are not printed in the document.

Charge

One full load that can be accommodated in a single pass through the equipment. In a process manufacturing plant, the capacity of a step may be predetermined by the capacity of the equipment used in that step. For example, a mixing tank that has a maximum capacity of 1000 gallons overflows if more is added. The maximum capacity determines the total number of charges that are required to process the ingredients required for a batch. A batch size of 5000 gallons requires five charges at 1000 gallons each when the maximum capacity of the mixing tank if 1000 gallons.

CoA

See Certificate of Analysis.

CoC

See Certificate of Conformance.

Decimal Precision

The number of decimal places that are displayed for numeric data. This ranges from zero to nine decimal places, and it determines how the application manages the rounding of significant figures. A decimal number that is five or higher rounds up, while decimal numbers below five round down.

Disposition

The status of a sample or sample group with respect to analysis.

E-Records and e-signatures

To satisfy signoff requirements in regulated industries, electronic signatures are obtained before changes to records become accessible throughout the enterprise. Management configures where and when these signatures are collected by using an electronic record framework. If a signature is required, then an e-signature window displays. Application users are restricted from moving on to the next logical step or status until all required e-signatures are entered.

Event Subscription

Typically perform any or all of the following:

- Run custom PL/SQL code.
- Send the business event to a predefined workflow.

- Use Oracle Advanced Queuing for asynchronous messaging.

Refer to the *Oracle Workflow Guide* for details on subscribing to a workflow event.

Experimental Error

The error observed defines a region of uncertainty around specification limits for a test that usually requires an action. These action zones can be defined for numeric-based tests.

Expiration Date

Date or time window beyond which an item or lot expires and becomes unusable. This is defined as part of the item master and lot master in OPM.

Frequency Period

Defines the basis of frequency for a sampling plan in terms of hours, batches, lots, and kilograms produced. This corresponds to the frequency count.

Frequency Type

Identifies the type of sampling plan frequency as:

- Time-based
- Quantity-based
- Fixed Number
- Percent

Grade

Combinations of quality attributes that are defined for lot-controlled items. Also, the fitness of an item to preset attributes. For example, diamonds have color and clarity grades as measures of their quality.

Hold Reason

User defined code denoting the reason a lot has been designated as unusable.

ICH

In stability studies. International Conference on Harmonisation.

Instrument

A resource that is linked to a test method so that test results can be traced to the equipment used in the analysis.

Item Sample

See Sample.

Lot Status

Defined in the OPM Inventory Control application. Assigned to one or more lots to indicate if the lots are nettable for planning, or usable for sales, production, or shipping.

Monitoring Sample

See Sample.

Oracle Workflow

A complete workflow management system that supports business process definition, automation, and integration. This technology routes information based on user defined business rules. Notification activities deliver messages to you through e-mail or a notification web page that is accessible using any browser.

Quality Workbench

A navigator with nodes that you can expand to display groups of individual database objects. Lower level nodes, and the objects they contain, are indented to indicate that they belong to these higher level nodes. The terminal node in a branch is called a leaf node. The workbench has a data organizer that groups objects on separate tabs. Each tab has a unique icon and its own hierarchy. The Quality Management application uses tabs to group specifications and samples. When you select an unexpanded, higher level node on the data organizer, a summary view lists the contents of the container.

Result

Outcome of a quality test performed on an item or lot. Results may not be the expected results as defined in the specification. This can be used to determine that an item or lot is unsuitable to be sold or used.

Retest Date

In stability studies. The date after which samples of the drug substance must be examined to ensure that the material is still in compliance with the specification and thus suitable for use in the manufacture of a given drug product.

Retest Period

In stability studies. The period of time during which the drug substance is expected to remain within its specification and, therefore, can be used in the manufacture of a

given drug product, provided that the drug substance has been stored under the defined conditions. After this period, a batch of drug substance destined for use in the manufacture of a drug product must be retested for compliance with the specification and then used immediately. A batch of drug substance can be retested multiple times and a different portion of the batch used after each retest, as long as it continues to comply with the specification. For most biotechnological or biological substances known to be labile, it is more appropriate to establish a shelf life than a retest period. The same may be true for certain antibiotics.

RH

Relative humidity.

Sample

Portion of a lot selected to be tested. Results of tests are used to estimate the characteristics of the entire lot. The application distinguishes between an item sample and a monitoring sample. The item sample can be a physical sample with a source from inventory, WIP, a customer, or a supplier. The monitoring sample is typically a virtual sample from an instrument or other measurement device that monitors equipment such as an environmental chamber. For example, temperature and humidity readings can be monitoring samples.

Sample Group

Also, Sampling Event. Comprised of one or more samples that share a common sample source, item, lot, sublot, and are tied to the same business event such as receiving, inventory transfer, batch, and expired lot.

Sample Quantity

Total amount of material drawn for inspection, and required for all anticipated tests. It is measured in the inventory unit of measure for the item sampled. The sample quantity can include sufficient material for possible retesting.

Sample Source

Identified as the origin of the sample. For example, the material, resource, location, or stability study.

Sampling Event

See Sample Group.

Sampling Plan

Identifies how much and how often sampling must occur.

Shelf Life

In stability studies. The time period during which a product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

Specification, Item

A clear, complete, and accurate statement of the quality acceptance criteria for a material, and of the procedure to determine if the requirements are met. A quality specification includes a set of tests.

In stability studies. Limits of acceptability derived from the profile of the material as used in the preclinical and clinical batches.

Specification, Monitoring

In stability studies. A specification that defines the details of the storage condition for one of the variants of a stability study. These conditions can include, but are not limited to, the temperature, humidity, and pressure of the storage condition.

Specification Validity Rule

Includes specific information on how and when an item or monitoring specification version applies to inventory, process execution, order management, receiving operations, resources, or locations.

Stability Study

Stability Studies analyze a predefined set of tests at prescribed intervals for various parameters. These may include testing of the active ingredient, measurement of known degradation products, dissolution time, appearance, and other physicochemical criteria.

Long term, accelerated, and intermediate studies undertaken on batches according to a prescribed stability protocol to establish or confirm the retest period of a drug substance or the shelf life of a drug product.

Storage Condition

In stability studies. A set of environmental conditions to maintain a climate-controlled storage facility. The length of the studies and the storage conditions are required to cover the conditions of the item's storage, shipment, and subsequent use.

Storage Location

A validated or nonvalidated warehouse location where samples are stored.

Storage Package

In stability studies. Refers to the containers in which sample material is stored for stability testing. The packages must be the same as, or it must simulate the actual packaging used for storage and distribution of the finished product.

Storage Warehouse

A validated or nonvalidated warehouse where samples are stored.

Test

Previously, Assay. A generic term for the analysis of the physical and chemical properties of a sample. For example, you can perform a test for chloride using commercially available titrimetric or amperometric test methods.

Test Class

A grouping of tests based on a common set of meaningful characteristics.

Test Data Type

Previously, Assay Type. Categorizes the type of data expected for a test. Numeric and text based data types are available in the application.

Test Kit

Material used in preparing or running a test. For example, a reagent used in a chemical test.

Test Method

Identifies how a test is performed. For example, a test method refers to a standard American Society for Testing and Materials, or ASTM protocol for measuring the property of a material.

Test Procedures and Test Criteria

In stability studies. The testing covers those features susceptible to change during storage and likely to influence quality, safety, and efficacy.

Test Quantity

The amount of material required for a particular test method and instrument, expressed in the inventory unit of measure.

Test Replicate

An iteration of a test that is repeated on the same sample.

Test Units

Previously Assay Units. Unit of measure for quality tests. For example, pH. Test units of measure often differ from inventory units of measure.

Testing Frequency

In stability studies. Frequency of testing sufficient to establish the stability characteristics of the item. Testing under long term conditions typically is every three months, over the first year, every six months over the second year and then annually.

Validity Rule

See Specification Validity Rule.

Variant

In stability studies. The storage condition for a time point sample defined by a unique combination of the material source, stability study storage condition, test interval plan, and optional storage package.

WIP

See Work in Process.

Work in Process

Also, WIP. Batches released to production.

Index