Oracle® E-Records

Implementation Guide

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Oracle E-Records Implementation Guide, Release 11*i*

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Oracle Corporation welcomes your comments and suggestions on the quality and usefulness of this document. Your input is an important part of the information used for revision.

- Did you find any errors?
- Is the information clearly presented?
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If you find any errors or have any other suggestions for improvement, please indicate the document title and part number, and the chapter, section, and page number (if available). You can send comments to us in the following ways:

- Electronic mail: appsdoc_us@oracle.com
- FAX: 650-506-7200 Attn: Oracle E-Records
- Postal service:
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  Oracle Process Manufacturing
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  Redwood City, CA 94065
  U.S.A.

If you would like a reply, please give your name, address, telephone number, and (optionally) electronic mail address.

If you have problems with the software, please contact your local Oracle Support Services.

Preface

Audience for This Guide

Welcome to Release 11*i* of the *Oracle E-Records Implementation Guide*.

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

- The principles and customary practices of your business area.
- *Oracle E-Records*

  If you have never used *Oracle E-Records*, Oracle suggests you attend one or more of the *Oracle E-Records* training classes available through Oracle University.
- 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

This guide contains the information you need to understand and use *Oracle E-Records*.

- Chapter 1 provides an introduction to the concepts of Oracle E-Records.
- Chapter 2 details the different types of flows available in Oracle E-Records.
- Chapter 3 details the implementation steps that must be taken in order to activate Oracle E-Records.
- Chapter 4 details setting up security rules in Oracle E-Records.
- Chapter 5 describes the types of attachments you can use, and how to use them.
- Chapter 6 provides instruction on the E-Record utilities.
- Chapter 7 provides details on the E-Record reporting capabilities.
- A 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 Corporation 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.

Other Information Sources

You can choose from many sources of information, including online documentation, training, and support services, to increase your knowledge and understanding of *Oracle E-Records*.

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).

- **Online Help** - The new features section in the HTML help describes new features in 11i. This information is updated for each new release of *Oracle E-Records*. The new features section also includes information about any features that were not yet available when this guide was printed. For example, if your administrator has installed software from a mini-packs an upgrade, this document describes the new features. Online help patches are available on Oracle*MetaLink*.

- **11i Features Matrix** - This document lists new features available by patch and identifies any associated new documentation. The new features matrix document is available on Oracle*MetaLink*.
- **Readme File** - Refer to the readme file for patches that you have installed to learn about new documentation or documentation patches that you can download.

Related User's Guides

Oracle E-Records shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other user's guides when you set up and use *Oracle E-Records*.

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) available with this release of *Oracle E-Records* (and any other Oracle Applications products). 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.

User 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 Advanced Planning and Scheduling with Oracle Process Manufacturing

Oracle Process Manufacturing and Oracle Advanced Planning and Scheduling (APS) combine to provide an integrated solution for process manufacturers that can help increase planning efficiency. The integration 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 *Oracle Process Manufacturing Integration with Advanced Planning and Scheduling 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, the Oracle8 technology stack, and the Oracle8*i* Server 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's 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.

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. It describes the Oracle Application Object Library components needed to implement the Oracle Applications user interface described in the *Oracle Applications User Interface Standards for Forms-Based Products*. It also provides information to help you build your custom Oracle Forms Developer 6*i* forms so that they 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.

Multiple Reporting Currencies in Oracle Applications

If you use the Multiple Reporting Currencies feature to record transactions in more than one currency, use this manual before implementing *Oracle E-Records*. This manual details additional steps and setup considerations for implementing *Oracle E-Records* with this feature.

Multiple Organizations in Oracle Applications

This guide describes how to set up and use *Oracle E-Records* with Oracle Applications' Multiple Organization support feature, so you can define and support different organization structures when running a single installation of *Oracle E-Records*.

Oracle Workflow Guide

This guide explains how to define new workflow business processes as well as customize existing Oracle Applications-embedded workflow processes.You also use this guide to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes.

Oracle Applications Flexfields Guide

This guide provides flexfields planning, setup and reference information for the *Oracle E-Records* implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This manual 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 Manufacturing APIs and Open Interfaces Manual

This manual contains up-to-date information about integrating with other Oracle Manufacturing applications and with your other systems. This documentation includes API's and open interfaces found in Oracle Manufacturing.

Oracle Order Management Suite APIs and Open Interfaces Manual

This manual contains up-to-date information about integrating with other Oracle Manufacturing applications and with your other systems. This documentation includes API's and open interfaces found in Oracle Order Management Suite.

Oracle Applications Message Reference Manual

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

Training and Support

Training

Oracle offers a complete set of training courses to help you and your staff master *Oracle E-Records* 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 E-Records* 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 Oracle8*i* 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 Corporation 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 E-Records* and this user's guide.

Oracle values your comments and feedback. At the end of this guide is a Reader's Comment Form you can use to explain what you like or dislike about *Oracle E-Records* or this user's 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

Introduction to Oracle E-Records

The following topics are discussed:

- eSignatures
- Electronic Records
- Sign What You See
- Electronic Batch Records (EBR)
- Framework
- Online Versus Deferred Mode Capture

eSignatures

Organizations that want to maintain electronic documents must have systems that support the ability to electronically sign those documents, ensuring that the appropriate personnel have reviewed and approved them.

Good Manufacturing Practices (GMP) generally requires signatures on transactions which affect product quality. Companies can also require signatures when moving the custody of goods from one department to another, or when moving responsibility for manufacture from one department to another. So, wherever a signature is needed on a paper document, a signature is needed on the electronic document that replaces it. This document addresses the enabling of electronic signatures in OPM for static (setup), as well as transaction data.

Electronic Records

21CFR Part 11 describes the requirements for companies wanting to move from paper based record keeping to electronic record keeping. GMP describes where it's appropriate to keep electronic records and capture electronic signatures.

This document details all areas in OPM that GMP explicitly or implicitly states are important for capturing eSignatures and eRecords. There are also events where data is captured that are industry standard, or dictated by other authorities (like the DEA) that are not mentioned by GMP.

Sign What You See

Since electronic signatures are a legal and binding equivalent to handwritten signatures, it is important to review the data you are responsible for signing. The pertinent data displays at the time of eSignature capture, rather than having to review it using the transaction windows.

Detail Page Display

When an eRecord is queried, the following information displays in the header:

- Event Name displays the name of the event.
- eRecord ID displays the ID for the eRecord.
- Event Date displays the date of the event.
- Time Zone displays the time zone set in the profile option EDR: Server Timezone.
- Identifier Name displays the name of the specific identifier.
- Identifier Value display the value for that identifier.
- Style Sheet displays the style sheet name.
- Style Version displays the style sheet version.
- Print Count displays how many times the document has been printed.
- Attachments shows if there are any attachments for the eRecord, and lets you navigate to them.

The detail section of the window displays the eRecord data and signature details.

The signature details include the signer, the date the eRecord was signed, any response to the signing, reason for approval or rejection, the type of signer, any

extra comments regarding the eRecord, and the overriding details if the Workflow routing rules were used. The overriding details display who it was routed to, and where the routing sent it based on rules.

Workflow Notification Display

When a notification is sent for approval, the following information displays in the header:

- Subject is the full subject of that eRecord.
- Sent displays the date and time the notififcation was sent.
- To displays the name of the receipient of the notification.
- Style Name displays the style sheet name.
- Version displays the style sheet version.

Electronic Batch Records (EBR)

The following requirements describe what is needed for OPM to manage batch records electronically in accordance with 21 CFR Part 11:

- Processing instructions must be automatically viewable on the screen.
- Any instructions made visible during processing must be part of the EBR document that is made available for review and signing. It must also be printed any time the EBR is printed.
- A window must be easily accessible for entering text comments during processing. These comments must also be part of the EBR document that is reviewed and signed, and must print along with the EBR.
- Batch steps must be configurable such that a signoff by one or more users must be captured prior to proceeding to any subsequent steps. The signature must be in accordance with Part 11 requirements. This must not be a workflow process. It must happen on the same window as the processing step that is being recorded.
- Batch signoffs must be enabled through a workflow process, or on the same window as the batch processing taking place. Rules must be configurable to determine points in the process where signatures are required, such as pending to work in process, or completed to closed.
- Quality tests and results are included on the EBR.

- Processing parameters are included on the EBR.
- A secure document representing the batch must be created for signing and printing. This is the EBR.

Framework

Based on Good Manufacturing Practices and customer requirements, the following application windows are configured to capture eRecords or eSignatures, or both.

Application windows, along with their associated programs, must be enhanced to call the data capture framework. Events are defined within the framework. An event consists of an event name, the tables, the columns, and the data values.

If an event exists, but is disabled for eRecords or eSignatures, then the window behaves as expected. If an event exists and is enabled for eRecords or eSignatures, then the framework reacts accordingly:

- If eSignatures are enabled, then the eSignature window is displayed, requiring entry from the appropriate user.
- If eRecords are enabled, then a snapshot of the event takes place at the appropriate time:
  - If an eSignature is not required for this event, then a snapshot occurs after the data is posted (not yet committed) to the database.
  - If an eSignature is required for this event, then the snapshot takes place after the appropriate signoffs occur and the data is posted, but not yet committed, to the database.

If you have existing workflows, you can enable Oracle E-Records on these workflows using the components of the ERES framework. Refer to the *Oracle E-Records Developer's Cookbook* for details.

Framework Components

The framework consists of the flowing components:

Workflow Business Event System

Workflow Business Event system is used to define an eSignature event and associate synchronous eSignature subscription to the event.

XML Gateway

XML Gateway is used for mapping definition and generation of XML for an eRecord. Individual product teams define XML maps and DTDs for eRecord / eSignature events supported by them. These maps and DTDs are loaded into the database and source controlled under the respective product tops. The eRecord Style sheet is also defined as part of XML Gateway.

Oracle Approval Management Engine (AME)

This component is used to define conditions, rules, and approval hierarchy. It stores rule specific attributes such as electronic recording required or electronic signature is required, and what type of style sheet need to be applied for this rule. These rules are evaluated at runtime based on the transaction ID, which is the primary key for the transaction.

Oracle Applications

A generic call is available, which is called to raise an event from the window.

Workflow Notification Subsystem

Notification subsystem is used to generate the signature user interface and control the flow of the user interface and return a status back to the application.

Workflow Automatic Notification Processing

The Oracle Workflow Automatic Notification Processing automatically forwards your notifications to another role or responds to incoming notifications with a predefined response when you are not available to manage your notifications directly. This can be done on either an online or a deferred event.

The Notification Routing Rules let you define the rules for automatic notification processing. Each rule is specific to a role and can apply to any or all messages of a specific item type or message name. A rule can result in one of the following actions: reassigning the notification to another user, responding to or closing the notification, or delivering the notification to the original recipient with no further action.

When an event is signed with an overriding approver, the following happens:

- The Evidence Store contains the original approver as well as the overriding approver details with proper comments.
- The Signers list page shows the original approver as well as the overriding approver.

- The eRecords Query shows the original approver as well as the overriding approver.

E-Records Evident Store

The E-Records evident store is used for storing electronics signatures.

Online Versus Deferred Mode Capture

When windows require an eSignature, there are two methods of capturing this data. The signature can be captured in process (online) or asynchronously (deferred) through workflow notifications.

- Transaction windows (e.g., Batches, Inventory Quantities, Quality Results) require you to enter all signatures online only. If the signatures cannot be fulfilled in that session, then the new or updated transaction data is not committed to the database.
- For those objects where a status or active/inactive column exists (e.g., Items, Lots, Formulas, Recipes, etc.), a generic workflow notification exists to enable deferred mode signatures. In these cases, windows prompt you for an eSignature when appropriate. If an eSignature is not entered online, then a notification is automatically sent to the user responsible for signing that record. Once all signatures have been fulfilled, the pending rows are updated to the appropriate status (active, approved, etc.). While signatures are in progress, the OPM window prevents any updates from being made to the pending data.

Online signatures are beneficial for those real-time processes that cannot proceed without immediate authorization.

- Deferred mode signatures are useful when the signature does not need to occur immediately, the signers are not typically in the same physical location or are otherwise not immediately available at the time of the signature request, or if there are several items that the signers must verify prior to signing, thus creating a time lag between receipt of the eSignature request and the response.
- Workflow notifications can come as email or can be accessed through Oracle Applications. The use of Oracle Workflow provides an additional level of auditing - Workflow keeps an electronic history of when parties were notified and when they completed their signoff.

In order to ensure the proper signatures are captured for each document or event within each internal organization, part of the Electronic Record Framework enables secured users to associate the appropriate Users with each event.

An eRecord contains a defined set of data from a moment in time captured by the software. This set of data is unique for each application, and each event within that application. For organizations capturing eSignatures with eRecords, the intent is to present the eRecord to the application user and let them approve or reject the data along with their signature. For those not using eSignatures, eRecords are captured as a background process. Layouts for all OPM eRecords are contained within this document and is further explored within the detail designs to follow.

eRecords are captured in an XML format. XML provides portability, ultimately enabling the delivery of eRecords to the FDA electronically. XML also provides longevity of the data. This helps eliminate the need to keep old versions of programs available just to read the documents. The eRecords are generated using the XML data in an XSL format.

The eRecords are stored in an evidence store. The evidence store provides a secure storage location and links to the transaction windows.

2

E-Record Signature Flows

There are two different types of signature flows - online and deferred. The online process forces all signatures to take place at the same time before the event can continue. The deferred process lets you move on without all signatures in place. The following is a flow of the two different types of processes, using the Item Creation process as an example.

Online Flow

Following is the procedure for the online flow using Item Creation:

1. Enter a new item.
2. Save the new item.
3. Select **Approve New Item** from the **Action** menu. A dialog box displays notifying you that the item must be approved.
    a. Click **OK**. The process is incomplete and a message displays that the Electronic Signature Process abnormally terminated.
    b. Leave the dialog box, and continue to the approval windows. The **Signers List** window appears.
4. Begin the approval process in the order the approvers are set for by clicking the **Sign** button.
5. For each approver, the electronic record displays. Enter the reason, signers comments, and signature type. In addition, you can see the response history for all previous approvers.
6. Select a notification response.
    a. If **Cancel** is selected, then the previous window displays.

   b. If **Reject** or **Confirm** are selected, then the **Signers Confirmation** window displays.

7. Enter your username and password.

   a. If **Cancel** is selected, the previous window displays.

   b. If **Submit** is selected, the approval is complete, and the **Signers List** page displays for the approval process to continue. If the submission is a rejection, then the process stops, you must close the browser, and go back to the Items window.

8. Once all approvals are complete, click **Finish**.

   a. A message displays that the online process is complete.

   b. If the signature process is not complete, then a message displays that the signature process is not complete because this is an online event. You can either click **Yes** to stop the process, close the browser, and complete at a later time, or click **No**, and complete the process.

9. Close the browser.

10. Click **OK** to the dialog box on the **Items** window.

Deferred Flow

Following is the procedure for the deferred flow using Item Creation:

1. Enter a new item.

2. Save the new item.

3. Select **Approve New Item** from the **Action** menu. A dialog box displays notifying you that the item must be approved.

   a. Click **OK**. The process is incomplete and a message displays that the Electronic Siugnature Process has been abnormally terminated.

   b. Leave the dialog box, and continue to the approval windows. The **Signers List** window appears.

4. Begin the approval process in the order the approvers are set for by clicking the **Sign** button.

5. For each approver, the electronic record displays. Enter the reason, signers comments, and signature type. In addition, you can see the response history for all previous approvers.

6. Select a notification response.

    a. If **Cancel** is selected, then the previous window displays.

    b. If **Reject** or **Confirm** are selected, then the **Signers Confirmation** window displays. If **Reject** is selected, then an email is sent to the requestor and all subsequent signers that a rejection has occurred.

7. Enter your username and password.

    a. If **Cancel** is selected, then the previous window displays.

    b. If **Submit** is selected, then the approval is complete, and the **Signers List** page displays for the approval process to continue. If the submission is a rejection, then the process stops, you must close the browser, and go back to the **Items** window.

8. Click **Finish**.

    a. If the signature process is complete, then a message displays that the online process is complete.

If the signature process is not complete, then a message displays that for this event deferred is allowed, and notifications are sent to all approvers. Based on the profile options EDR: Workflow Notification Timeout (in Hours) and EDR: Workflow Notification Timeout Interval, reminders are sent out over a period of time until they are terminated.

9. Close the browser.

10. Click **OK** to the dialog box on the **Items** window. The item remains pending.

11. If you receive an email notification, then click to the approval window from the e-mail. You will not see the list of approvers, only the approval information you must complete.

3

Implementing E-Records

You must complete the following steps to enable the E-Records functionality:

1. Enabling profile options
2. Enabling the Event
3. Enabling the Subscription
4. Setting up Oracle Approval Manager Rules
5. Setting up Input Configuration Variables for Oracle Approval Manager Rules
6. Running Concurrent Programs
7. Setting up Indexed XML Elements
8. Security Rules

Enabling Profile Options

EDR: eRecords and eSignatures

You must set up the profile option EDR: eRecords and eSignatures. This profile option lets you enable the functionality for your entire system. This can be set at the Site level only. Valid values for this profile option are:

Yes - Enable eRecord and eSignature

No - Do not enable eRecord and eSignature (default value)

EDR: Server Timezone

Set the profile option EDR: Server Timezone to the time zone where the database is running. If you don not set this value, then all eRecords have a null value for the time zone.

- Ensure that the database time zone is the same as the server time zone profile option value since the system does not verify the database value.
- Once Oracle E-Records is enabled, do not reset this value.
- This value does not reflect the current user time zone value. It is always the server time zone.

> **Note:** If you had previously set the Server Timezone profile option, then you must set EDR: Server Timezone to the same value.

EDR: Workflow Notification Timeout Interval

This profile option determines the number of times you receive an e-mail notification reminder. It works in conjunction with the EDR: Workflow Notification Timeout (in Hours) profile option.

This is set at the Site level only.

EDR: Workflow Notification Timeout (in Hours)

This profile option determines the length of time between reminder notifications. It works in conjunction with the EDR: Workflow Notification Timeout Interval profile option.

This is set at the Site level only.

Example 1

EDR: Workflow Notification Timeout (in Hours) = 5

EDR: Workflow Notification Timeout Interval = 3

The result is that five hours after the initial notification is sent, three more are sent at five hour intervals. If no acknowledgement is made, then the process is terminated and e-mails are sent to all approvers and the requestor that the process was terminated.

Example 2

EDR: Workflow Notification Timeout (in Hours) = NULL

EDR: Workflow Notification Timeout Interval = 3

The notification timeout in hours overrides the number of reminders sent. Therefore, in this example no reminders are sent and the process is terminated. This is not a valid combination. You must set a timeout interval in hours.

Example 3

EDR: Workflow Notification Timeout (in Hours) = 5

EDR: Workflow Notification Timeout Interval = NULL

The result is that no notifications are sent, and at the end of the five hours the process is terminated.

EDR: Commit Size

The value set in this profile option is used to issue a commit during a mass update of eRecords if a new indexed element is turned on for query and security.

This is set at the Site level only.

EDR:Security Level High

This profile option, when set to Y, restricts access to eRecords before security rules are created for them.

EDR: eRecord Print Granted

This profile option lets you restrict access to printing eRecords. The default value, No, set at the Application level restricts everyone in that application from printing eRecords. The system administrator can set the profile option to Yes for specific users to grant printing capabilities.

Enabling the Event

The Oracle Workflow Event Manager lets you register:

- interesting business events that may occur in your applications,
- the systems among which events are communicated,
- named communication agents within those systems, and
- subscriptions indicating that an event is significant to a particular system.

You can use the Event Manager web pages to define and maintain these events, systems, agents, and subscriptions.

A business event is an occurrence in an internet or intranet application or program that might be significant to other objects in a system or to external agents. For instance, the creation of a purchase order is an example of a business event in a purchasing application. You can define your significant events in the Event Manager.

Business Event Creation

Internal Name

When you define an event in the Event Manager, you must assign it a unique internal name, which is case-sensitive. The format for these internal names is a compound structure of identifiers separated by periods (.) as follows:

oracle.apps.<product>.<component>.<object>.<event>

This format lets you organize the events you define into a classification hierarchy.

Example: oracle.apps.gme.Process.Batch.close, Process Batch Close Event

Display Name

The Display Name displays in the Edit Event list.

Description

A brief description of the eSignature event.

Status

All seed data is sent set to enabled.

Generate Function

Generate functions is NULL for all eSignature Events.

Owner Name (mandatory)

The Owner Name must be your product name.

Owner Tag (mandatory)

The Owner Tag must be your three letter product code.

Identify Event Key

Each instance of an event must be unique and is identified by an event key. The key helps to tag the transaction data with eSignature and eRecord data. The key must be

a unique identifier for an event and not hold multiple values. In most cases, it is the primary key of a table on which the event is taking place. In some cases, the primary key can be a multi part key, which is concatenated and treated as a single event key. This key is used as a business event key and is passed as a parameter to the event raise API.

Example of a single key:

Event: GME_BATCH_RELEASE

Event Key: GME_BATCH_HEADER.BATCH_ID

Example of a multi part key: (If the Batch Header table does not have BATCH_ID)

Event: GME_BATCH_RELEASE

Event Key: GME_BATCH_HEADER.PLANT_CODE

GME_BATCH_HEADER.BATCH_NO

Event key representation during API calls:

GME_BATCH_HEADER.PLANT_CODE|| GME_BATCH_HEADER.BATCH_NO

Refer to the *Oracle Workflow Guide* for details on enabling events.

Enabling the Subscription

Subscription processing can include the following types of processing:

- Run a function on the event message.
- Send the event message to a workflow process.
- Send the event message to an agent.

Add Synchronous eSignature Subscription

A synchronous subscription is added to the defined business event, which is a local subscription. The phase of the subscription determines if the subscription is synchronous or not. The phase of the subscription must be set to 0 to make sure that eSignature subscription is the first subscription executed when an event occurs. A rule function is associated to the subscription that determines if an eSignature is required and generates a snapshot of the data to be signed. The snapshot is generated as an XML document in the rule function. This is the generic rule function, which is used by all product teams while defining a subscription.

Subscriber: System
This is the local system, on which the subscription code is to run.

Triggering Condition: Source Type
Set the triggering condition to local.

Triggering Condition: Event Filter
Select the event that this subscription is for.

Triggering Condition: Source Agent
Leave blank.

Execution Control: Phase (mandatory)
Set the phase to 0.

Execution Control: Status
All seed data is sent set to disabled.

Execution Control: Rule Data
Key: the subscription requires only the event key.

Action: Rule Function (required)
Enter EDR_PSIG_RULE.PSIG_RULE. This is the rule function, which determines if eSignature is required for the event instance and generate XML document if required.

Action: Workflow Item Type and Workflow Process Name
Workflow item Type = EDRPSIGF

Workflow Process Name = PSIG_ESIGN_PAGE_FLOW

Action: Out Agent and To Agent
Leave blank.

Action: Priority
Leave blank.

Action: Parameters

The parameter column can be used to add space delimited name=value pairs, which can be accessed by rule function. The rule function looks for the following parameter and if the parameters are not, then set it. It assumes the business event Name=XML Map Name=AME transaction Type = AOL Audit Group Name

EDR_XML_MAP_CODE=<Your XML Map Code>

EDR_AME_TRANSACTION_TYPE=<AME transaction Type>

EDR_AUDIT_GROUP=<AOL Audit Group> (This is required only if you need to integrate eSignatures with AOL Audit.)

Documentation: Owner Name (mandatory)

The Owner Name must be your product name.

Documentation: Owner Tag (mandatory)

The Owner Tag must be your three letter product code.

Documentation: Description

Any information you want to document about the subscription.

Refer to the *Oracle Workflow Guide* for details on enabling subscriptions.

Setting Up Oracle Approvals Management

Oracle Approvals Management (OAM) is a self–service web application that enables users to define business rules governing the process for approving transactions in other Oracle Applications.

The purpose of Oracle Approvals Management (OAM) is to define approval rules that determine the approval processes for Oracle Applications. Rules are constructed from conditions and approvals.

AME Seed Data Setup for Attribute, Condition, Rule, and Approval Group Customizations

1. Create Transaction Attributes

   In OAM, an attribute is a named business variable such as TRANSACTION_AMOUNT, whose value OAM fetches at run time, when it constructs transactions' approver lists. OAM includes the attributes commonly required for the transaction types of each application that can use OAM.

The following steps detail adding transaction attributes:

a. Navigate to the **Attribute** tab on the **AME Application Administrator Approvals** window.

b. Select the required transaction type.

c. Click **Add Attribute** to create a new attribute for the event you want.

d. Click **Create New Name**.

e. Enter the new name and click **Continue**.

f. Select **Attribute Type = String** (Relevant data type).

g. Enter the description.

h. Select No for static usage, and enter the select statement for the attribute to map to the database column.

2. Create Conditions

In OAM, a condition specifies a list or range of attribute values required to make a rule apply to a transaction. For example:

INVENTORY_TYPE IN {'A'}

The following steps detail adding conditions:

a. Navigate to the **Conditions** tab on the **AME Application Administrator Approvals** window.

b. Select the required transaction type.

c. Click **Add Condition**.

d. Select Ordinary as the condition type.

e. Click **Continue**.

f. Select INVENTORY_TYPE attribute.

g. Click **Continue**.

h. Type in an attribute value and click **Add Text Value**. If you want to add more values, then click **Create Text Value**.

i. Click **Quit** when done.

3. Create Approval Groups

An OAM approval group is an ordered list of persons or user IDs. You can create OAM rules to include one or more approval groups in a transaction

approver list. You must create an approval group before using it in an approval-group rule.

The following steps detail adding groups:

a. Navigate to the **Groups** tab on the **AME Application Administrator Approvals** window.

b. Enter the name and description for the group.

c. Select **Active List** as static and click **Create Group**.

d. Click **Add Approver**. If it is an FND user, then select Account. If it is an HR user, then select Individual. To look for an existing user, enter the username and click **Search**.

e. Once you have the matching approver, click **Continue**.

f. Select the sequence order for the approver. This can be changed when you add another user.

g. Click **Create Approver**.

4. Define Approval Rules

In OAM, an approval rule associates one or more conditions with an approval action. The rule applies to a transaction if and only if all of the rule's conditions are true for the transaction. Each application that can use OAM defines one or more transaction types.

Each transaction type has its own set of approval rules. Several transaction types can share attribute names, while defining separate usages for those attribute names. This makes it possible for several transaction types to share conditions and rules.

The following steps detail adding rules:

a. Navigate to the **Rule** tab on the **AME Application Administrator Approvals** window.

b. Select the required transaction type.

c. Click **Add Rule**.

d. Enter the description and rule type.

e. Click **Continue**.

f. Select an approval group. For example, chain of authority includes an approval group.

g. Click **Continue**.

h. Select an approval. For example, Require approval from Mfg user.

i. Select the constraints. For example, None.

j. Select the ordinary-condition attributes. If you need more than one attribute, then select by holding down the Shift. for example, INVENTORY_TYPE and reason code.

k. Click **Continue**.

l. Select the ordinary conditions. For example, INVENTORY_TYPE in {A, B} and REASON_CODE in {BOTH}.

m. Click **Continue**.

Refer to the *Implementation Oracle Approvals Management* documentation for details on setting this up.

Setting Up the Transaction Type Configuration Variables

The Transaction Type Configuration Variables lets you add, delete, and update new variables to transactions and rules. You can also add a variable to a rule that overrides the default global value for the variable in the transaction.

Associate the eRecord output XSL to the rule. This ensures multiple style sheets can be associated to a single event based on the control parameters.

An example of this is:

Rule	Input: Value	Approvers
If Plant = 'OPME' and Product='Cyanide	'ERecord= YesEsignature=YesERecord Style Sheet = opmstylesheet.xsl	James Arthur
If Plant = 'PL1	'ERecord= YesEsignature=NoERecord Style Sheet=NULL	David Anderson

AME Transactions as ERES-enabled Events

When you create, update, or delete an input configuration variable for transaction type at the transaction or rule level, it raises the approriate event that goes through the approval process. If the approval process fails, then the transaction rolls back. If it is approved, then it is committed to the database. Refer to the *Events* appendix for details.

To view variables associated with a transaction:

1. Navigate to the **Transaction Type Configuration Variables** window.
2. Select a Transaction Name from the list of values. Required.
3. Click **Go**. The available variables are listed under the Result for Transaction section. All seeded variables can be updated but not deleted. Any custom variables can be updated and deleted, unless associated with a rule. The following transaction fields are display only:
   - Variable Name displays the name of either a seeded or custom variable.
   - Description displays the description of the variable.
   - Data Type displays the type of data for the variable.
   - Default Value displays the default value for the variable.

To view variables associated with a transaction and rule:

1. Navigate to the **Transaction Type Configuration Variables** window.
2. Select a Transaction Name from the list of values.
3. Select a Rule Name from the list of values. Only rules associated with the selected transaction type are displayed.
4. Click **Go**. The available variables are listed under the Result for Transaction and Result for Rule regions. All seeded variables can be updated but not deleted. Any custom variables can be updated and deleted, unless associated with a rule. The following rule fields are display only:
   - Variable Name displays the name of either a seeded or custom variable.
   - Description displays the description of the variable.
   - Data Type displays the type of data for the variable.
   - Default Value displays the value for the variable that overrides the value found in the transaction.

To add a transaction variable:

1. Click **Add** from the **Transaction Type Configuration Variables** window. The **Transaction Variable Definition** window displays. The Transaction Name is a display only field.
2. Enter the variable name to create. Required.

3. Enter a description for the variable.
4. Select a data type for the variable. Valid values are:
   - Boolean
   - Character
   - Date
   - Number
   - Time
   - String
5. Enter the default global value for the variable.
6. Click **Apply** to save the variable.

To add a rule variable:

1. Click **Add** from the **Transaction Type Configuration Variables** window. The **Rule Variable Definition** window displays. The Transaction Name and Rule Name are display only fields.
2. Select the input variable you want to add. If you do not see the variable, then ensure that it is already created as a global variable under transactions. The Data Type field is display only. Required.
3. Enter the value for the variable that overrides the global default value.
4. Click **Apply** the save the variable.

To update a variable for a transaction:

1. Once the transaction variables display, click **Update**. The **Transaction Variable Definition** window displays. The following fields are display only:
   - Transaction Name
   - Variable Name
   - Data Type
2. Modify the Description and Default Value as necessary.
3. Click **Apply** to save your changes.

To update a variable for a rule:

1. Once the rule variables display, click **Update**. The **Transaction Variable Definition** window displays. The following fields are display only:
   - Transaction Name
   - Rule Name
   - Input Variable
   - Data Type
2. Modify the Variable Value as necessary.
3. Click **Apply** to save your changes.

To delete a transaction variable:

1. Once the transaction variables display, click **Delete**. The **Transaction Variable Deletion** window displays. You cannot delete the four seed data variables, including:
   - EREC_REQUIRED
   - EREC_STYLE_SHEET
   - EREC_STYLE_SHEET_VER
   - ESIG_REQUIRED - you must set this to Yes to enable eSignature.

   The following fields are display only:
   - Transaction Name
   - Input Var Name
   - Description
   - Default Value
2. Click **Apply** to delete the variable. An error displays if the variable is associated with a rule. You must delete the variable from the rule first, then delete it from the transaction.

To delete a rule variable:

1. Once the rule variables display, click **Delete**. The **Rule Variable Deletion** window displays.You cannot delete the four seed data variables, including:
   - EREC_REQUIRED

- EREC_STYLE_SHEET
- EREC_STYLE_SHEET_VER
- ESIG_REQUIRED

The following fields are display only:

- Transaction Name
- Rule Name
- Input Variable
- Data Type
- Variable Value

2. Click **Apply** to delete the variable.

Refer to *Implementing Oracle Approvals Management* for more details.

Running the eRecord Event Setup Verification Report

This program logs all set up seed data for Oracle E-Record selected event into the concurrent log file. It displays the current setup for the following information:

- Event Name
- Subscription
- Profile Options
- Transaction Type
- AME Conditions and Rules
- Approval Groups
- Approvers
- Transaction Type Configuration Variables
- Generated XML

◗ To submit the eRecord Setup Verification report:

1. Navigate to the **Submit Request** window.
2. Enter **eRecord Event Setup Verification** in the Name field. The Parameters dialog box displays.

3. Enter any of the following fields to narrow the scope of the report:
   - **Event Name** is the workflow business event name.
   - **Event Key** is the business event key number.
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.

Setting Up Indexed XML Elements

The initial implementation of Oracle E-Records contains seed data for indexed XML elements. You must run a concurrent program to index these elements.

The job of the concurrent program is to index all the non-indexed elements. The indexing consists of changing the status field in the table EDR_IDX_XML_ELEMENT_B and creating a section in the InterMedia text index for the indexed XML element.

After creating or updating an indexed XML element, you must run this program again in order to index the element.

Refer to Maintaining Indexed XML Elements details on querying, updating, and deleting indexed XML elements.

Refer to Adding a New Indexed XML Element for details on adding new XML elements.

To submit the eRecord Indexed XML Element Maintenance program:

1. From the ERES Super User responsibility, navigate to the **Submit Request** window.
2. Enter **eRecord Indexed XML Element Maintenance** in the Name field.
3. Click **Submit**. View or print the report.

Security Rules

You must set up security rules on your system. Refer to the chapter "Setting Up Security Rules" for details.

4

Setting Up Security Rules

This topic describes how the eRecords stored as XML documents in the database are a repository of critical information that can be queried for reasons ranging from internal users viewing information to regulatory authorities inspecting process records.

The information contained in these eRecords can be confidential and critical to the nature of the business. Therefore, access to these eRecords must be restricted so that any unauthorized access is prevented.

The access to eRecords must be based on the contents of the eRecords. For example, you can restrict access to all eRecords having any reference to a particular formula ingredient.

The following topics are covered:

- Technical Requirements
- Setting Up Secure Elements
- Adding eRecord Security Rules
- Maintaining eRecord Security Rules
- Running the eRecord Security Policy Administration Program

Technical Requirements

The technical requirements fulfilled by the security model are:

- You cannot delete an eRecord once it is created.
- Only authorized users can update the eRecords through the Oracle Applications interface. No updates or inserts of eRecords can be done through direct interfaces like SQL*Plus.

- Only authorized users can view eRecords through the Oracle Applications interface. An eRecord cannot be viewed through direct interfaces like SQL*Plus.
- The view access is contingent on the content of the eRecord and the event for which the eRecord was created.

Setting Up Secure Elements

Before a security rule can be created using a particular XML element it has to be identified as a secure element, the XML element must be indexed, and its usage must be defined as secure element.

Refer to Setting Up Indexed XML Elements in the "Implementing Oracle E-Records" chapter.

Adding eRecord Security Rules

Once the secure elements are created, you can create security rules.

There are two modes of operation. These modes are configurable at a user site level and are determined by the profile option EDR: Security High, set at the Site level. This value can be set to Yes or No and has a default value of No.

Warning: Do not change this setting once security configuration is complete.

Restrict Mode (Low level security)

In this mode, access to eRecords is granted by default and users or responsibilities can be restricted as required. This is the default mode.

Grant Mode (High level security)

In this mode, access to eRecords is restricted by default and users or responsibilities are granted access to specific values.

Refer to Enabling Profile Options in the "Implementing Oracle E-Records" chapter.

Security Rule Examples

A security rule creates a restriction or grant statement such as:

Allow user James (user id: JASDE) to access eRecords for event Formula Approval having value Yeast for Formula Ingredient

In this example, Formula Ingredient is the secure element for the event Formula Approval. Access to the value Yeast is granted to user id JASDE. Similarly, access to a particular user can also be restricted for a specific value.

Using these security rules, access to the eRecords for specific events is restricted based on the contents of the eRecords; specifically the value of the secure elements identified at the time of secure element creation.

The comprehensive set of security rules supported by the security model lets you provide content based security as follows:

- Grant a user access to an eRecord based on its content.
- Grant a responsibility access to an eRecord based on its content.
- Restrict a user's access to an eRecord based on its content.
- Restrict a responsibility's access to an eRecord based on its content.
- Grant a responsibility, but restrict a particular user within the responsibility, access to an eRecord based on its content.
- Restrict a responsibility, but grant a user within the responsibility, access to an eRecord based on its content.

To add a security rule:

1. Navigate to the **eRecord Security Rules Setup** window by selecting **Security Rule Setup**.
2. Click **Create Security Rule**. The **eRecord Security Rule Creation** window displays.
3. Enter the information for the security rule:
   - **Secure Element** displays the name of the secure XML elements. Required.
   - **Event Name** displays the name of the event.
   - **Secure Value** displays the value of the secure element. Required.
   - **User** displays the user associated to that secure element.
   - **Responsibility** displays the responsibility associated to that secure element.
   - **Access Code** displays whether the element can be accessed or is restricted by default. Required.

- **Start Date** displays the date the security becomes active. Required.
- **End Date** displays the date security is no longer active. This can be NULL, leaving security active indefinitely.

4. Click **Apply**. A confirmation displays that the Security Rule is successfully created.
5. Run the **Security Policy Administration** program. Refer to Running the eRecord Security Policy Administration Program for details.

Maintaining eRecord Security Rules

The eRecord security rules are used to restrict or grant access to eRecords based on their content. You can search, view, create, delete, and update security rules.

The search criteria is not case sensitive and handles trailing wild cards. For example, searching for *abc* returns all matches for *abc%* and *ABC%*.

To view the security rules:

1. Navigate to the **eRecord Security Rules Setup** window by selecting **Security Rule Setup**.
2. Enter search criteria, which can include one or many of the following:
   - **Secure Element** displays any indexed XML event that has been set up with a secure usage.
   - **Event Name** displays all active events.
   - **User** displays all system users.
   - **Responsibility** displays any responsibilities set up in the system.
3. Click **Go**. The search results display. You can sort the information by clicking on any heading that is active. The following information displays for each record:
   - **Secure Element** displays the name of the secure XML elements.
   - **Event Name** displays the name of the event.
   - **Secure Value** displays the value of the secure element.
   - **User** displays the user associated to that secure element.
   - **Responsibility** displays the responsibility associated to that secure element.

- **Access Code** displays whether the element can be accessed or is restricted by default.
- **Details** lets you drill down into the details of that record.
- **Update** lets you update the record.
- **Delete** lets you delete the record.

Viewing Security Rule Details

You can view the security rule details. You cannot change any information about the security rule from this window.

To view the details of a security rule:

1. Click **Details** from the **eRecord Security Rule Setup** window. The **eRecord Security Rule Details** window displays.
2. View the detail information.
3. Click **Back** to return to the previous window.

Updating Security Rules

Security rules can be updated from this window. After security rules are changed, you must run the Security Policy Administration program for these changes to take effect.

To update a security rule:

1. Click **Update** from the **eRecord Security Rule Setup** window. The **eRecord Security Rule Update** window displays.
2. Update the desired information. You cannot update Secure Element, Event Name, Secure Value, User, and Responsibility. You can update the following:
   - **Access Code** displays whether the element can be accessed or is restricted by default. Required.
   - **Start Date** displays the date the security becomes active. Required.
   - **End Date** displays the date security is no longer active. This can be null, leaving security active indefinitely.
3. Click **Apply**.

4. Run the **Security Policy Administration** program. Refer to Running the eRecord Security Policy Administration Program for details.

Deleting Security Rules

You can delete all security rules fro this window.

To delete a security rule:

1. Click **Delete** from the **eRecord Security Rule Setup** window. The message Are you sure you want to delete this Security Rule? displays.
2. Click **Yes** to delete the rule, and **No** to cancel the delete.
3. Run the **Security Policy Administration** program. Refer to Running the eRecord Security Policy Administration Program for details.

Running the eRecord Security Policy Administration Program

You must run this program after you make any modifications to the security rules.

To run the eRecord Security Policy Administration program:

1. Navigate to the **Submit Request** window.
2. Enter **eRecord Security Policy Administration** in the Name field. The Parameters dialog box displays. The Action field is set to either Add or Drop.
3. Click **OK**. The **Submit Request** window displays.
4. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

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Using Attachments With Oracle E-Records

This topic describes using attachments with Oracle E-Records, the types of attachments available, and how attachments are stored.

The following topics are covered:

- Types of Documents
- ERP Documents
- Uploading a Non-ERP Document

Types of Documents

Electronic records store the snapshot of an ERES event in Oracle Applications. Along with capturing the main transactional details of the event in an XML format, you can store an attachment related to the key business entities involved in the ERES event. These attachments become part of the eRecord and eRecord storage.

There are two types of attachments:

ERP Documents Attachments related to the business entities involved in the transaction being snapshot by an eRecord. For example, attachments related to a recipe, which is being changed by an ERES event. These attachments are currently attached to different business entities. These attachments are already stored in Oracle Applications.

Non-ERP Documents Attachments directly related to an eRecord entity. For example, a standard operating procedure (SOP) followed during the transaction being snapshot by an eRecord. These attachments are attached only to eRecords directly. These records must be uploaded into Oracle Applications using the File Upload System.

ERP Documents

When eSignatures is enabled for a transaction that allows attachments, the attachments are sent through the signature process with the transaction. The attachment is captured as part of the eRecord, and once the signature process is complete, the attachment is stored with the eRecord.

When the eRecord is queried, either by transaction or generic, the attachment is available for viewing.

For setup information, refer to the *Oracle E-Records Developers Cookbook* available on Oracle Metalink.

Uploading a Non-ERP Document

You can upload non-ERP documents using the File Upload System. Each document is assigned a category, which contains rules for the approval process. Each category has fifteen descriptive flexfield segments that can be used to store information about the documents in that category.

When a document is in either the No Approval Required or Approved status, you can attach the document to an E-Business entity using the Oracle Applications Attachments functionality.

For XSL style sheets, there can be a subscription enabled, XSL Upload. If the subscription is enabled for the event, then after approvals are complete, the style sheet moves to the XSL repository and can be used to create new eRecords. You need to update the input configuration variables for the event to recognize the new style sheet name and version.

The File Upload System has two modes, user and administrator. Depending on how you are logged in, you can either upload, update, and delete all files, or only the files where you are the author.

- From the ERES Web Super User responsibility, you can upload, update, delete, and send for approval all documents in the system.
- From the ERES Web User responsibility, you can upload documents, and update, delete, and send for approval only those documents that you own. You can only view documents you did not author.

Document Status

There are five statuses for a document:

Not Approved This is the default value for all documents when they are first uploaded.

Approved A document is approved after all signers approve it.

Waiting for Approval A document is waiting for approval when it is in the approval process, but not all signoffs have been completed.

Rejected A document is rejected when one signer rejects the document.

Approval Not Required A document category can be for no approvals required. You must set the rules in AME for that document category to not require approvals. You

then send the document for approvals after upload, and it is automatically set to Approval Not Required.

Security

The following rules are set to determine what privileges you have based on the status of a document.

Operations	Not Approved	Approved	Waiting for Approval	Rejected	Approval Not Required
Update	Yes	No	No	No	No
Delete	Yes	No	No	No	No
Overwrite	Yes	No	No	No	No
Send for Approval	Yes	No	No	Yes	Yes

Uploading Documents

When a document is uploaded, it has an associated category. Each category can have up to 15 descriptive flexfields. This information is stored in the database with the document, and can be used to search for the document.

The list of categories can be restricted by modifying the value set EDR_FILE_ CATEGORIES to include a WHERE clause. The clause defines the categories to appear in the category list of values.

◗ To upload a document into the system:

1. Navigate to the **File Upload System** window.
2. Click **Upload File**. The **File Upload** window displays.
3. Select the **Category** for the document. The list is a value set that can be modified through the System Administration responsibility. Each category has rules set up in AME that determine the approval process. Required.
4. Based on the category selected, the window displays all descriptive flexfield segments set up for the category. Some of these fields are required. Complete all necessary fields based on the category.
5. Click **Browse** to select the document to upload. Required.

6. Enter a **Description** of the document. This field has a maximum of 255 characters and supports MLS.
7. Select the **If File Exists** option. If the file does not exist in the system, then this field can be left as Don't Overwrite. If the document does exist in the system, then you must select an option. Required. Valid values are:
   - Don't Overwrite displays an error if the document already exists in the system. You must either select a different document or select one of the other two options.
   - Overwrite replaces the last version of the document.
   - Version Existing File versions the new document based on the version label entered.
8. Enter a **Version Label**.
9. Click **Apply**. A message displays that the file is uploaded.
10. Query the documents to see the document in the list. You can update, delete, see details, or send the file for approval.

Querying Non-ERP Documents

When you query non-ERP documents, you can view all documents in the system, or narrow your search using the available criteria. The search criteria is not case sensitive and handles trailing wildcards. For example, searching for *abc* returns all matches for *abc%* and *ABC%*.

The **Advanced Search** option lets you search for the documents based on the descriptive flexfield information associated to the document.

◗ To query uploaded documents:

1. Navigate to the **File Upload System** window.
2. Search for documents in the system. You can enter criteria to narrow your search.
   - Select a file name using the list of values.
   - Select a category to see all documents in that category.
   - Select an author to see all documents uploaded by one person.

- Select a status to see all documents in a specific status. Valid values are: Approved, Not Approved, Waiting for Approval, Rejected, Approval Not Required, All

3. Click **Go**. The search results display. The following information displays for each record:
   - **File Name** displays the concatenated name of the file and the file version. For example, the file test.doc at version 1.0 is shown as file_v_1.0.doc.
   - **Original File Name** displays the name of the file when it was uploaded.
   - **Category** displays the category for the file.
   - **Approval Status** displays the status the document is currently in.
   - **Description** displays the long description of the document.
   - **Author** displays the name of the person who uploaded the file.
   - **Last Update Date** is the last time the document or information about the document was changed.
4. Click **Details** to see more information about the document and its history.
5. Click **Update** to change information about the document.
6. Click **Delete** to delete the document from the system. Refer to Security for information on which documents can be deleted.
7. Click **Send for Approval** to begin the approval process for the document.

Viewing Non-ERP Document Details

Viewing the details of a non-ERP document includes all information stored in the flexfields, as well as the information about all previous versions of the file. In addition, you can open and view all versions of the file from this window. You can view all documents and their properties logged in as either user or administrator.

To view details of a document:

1. Click **Details** for the record. The **File Details: <filename>** window displays. This window displays all information about every version of the file. The header information is the current document and all flexfields that were defined for that category. The rest of the window displays information about all other versions of the file.

2. Click the **Original File Name** attachment to see the document. The document opens using standard browser plug-ins based on the document type. You can save a copy of the document to your hard drive, but you cannot make edits to the attached copy.

Updating a Non-ERP Document

The information about the document, stored in the descriptive flexfield segments, can be updated. If you change the category of a versioned document, then that becomes the first version of a new category for that document. This is not available if the document is approved.

If you are logged into user mode, then you can only update documents you own. If you do not own the document, then the icon is disabled.

To update a document:

1. Click **Update** for the selected record on the **File Upload System** window. The **Update File: <filename>** window displays.
2. Update desired fields. If you change the category, then the flexfields change based on the new category.
3. Click **Apply**.

Deleting Non-ERP Documents

Documents can be deleted from the system based on their status. Refer to Security to see which documents can be deleted.

If you are logged into user mode, then you can only delete documents you own. If you do not own the document, then the icon is disabled.

To delete a document:

1. Click **Delete** for the selected record on the **File Upload System** window. A warning window displays.
2. Click **Yes** to delete the document.

Sending a Document for Approval

All documents must be sent through an approval process. Based on the rules set up for a category, the document runs through a deferred approval process, sending notifications to everyone who must sign a document. If a document is rejected by

anyone in the signing group, then all other notifications are closed, and a new notifications is sent to say that the document was rejected.

After a document is sent for approval, all approvers receive a notifications in their Workflow notifications list. The document is approved or rejected and signed.

If the rules for a category are set for no approvals, then you must click Send for Approvals for that document, but it is immediately set to Approval Not Required.

If you are logged into user mode, then you can only send for approval documents you own.

To send a document for approval:

1. Select the file to send for approval.
2. Click **Send for Approval**. A message displays that the document has started the approval process.

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Maintaining Oracle E-Records

Oracle E-Records has utilities that let you maintain your system. You can view XML and eRecord information from within the application. This information can be used to verify XML and XSL information, as well as eRecord layouts prior to the event being used. You can also update or delete existing indexed XML elements, or add new elements.

The following topics are discussed:

- Generating XML
- Generating eRecord Documents
- Adding a New Indexed XML Element
- Maintaining Indexed XML Elements
- Purging Temporary E-Record Tables
- Framework Verification

Generating XML

The XML Generator window is used to generate an XML document using a specific map code and document ID. The resulting XML document is then displayed for technical review, or subsequently copied into the eRecord generator with an XSL style document to view the readable electronic record.

Developers can use this utility verify their XML mapping is correct.

To generate XML:

1. Navigate to the **XML Generator** window by selecting **Generate XML**.
2. Select the map code from the list of values. The map code is created in XML Gateway.
3. Enter the document ID, which is the value for the root element.
4. Click **Search**. The XML is generated and then displays on the window.

Generating eRecord Documents

The eRecord Generator window lets you see the eRecord format based on given XML and XSL documents. If you need to make changes to your XML or XSL, once the changes are made you can then rerun this utility to see the new eRecord format. Once the XSL is correct, you must upload it into the database for it to take affect for any generated eRecords.

To generate an eRecord document:

1. Navigate to the **eRecord Generator** window by selecting **Generate eRecord Document**.
2. Paste your XML document into the XML field. Required.
3. Paste your XSL style document into the XSL field. Required.
4. Click **Apply**. The format for the eRecord document displays.

Adding a New Indexed XML Element

When creating an indexed XML element, it can be defined as a query element, a secure element, or both. A query element is used in the eRecord Query window and lets you view eRecords based on one or many elements. A secure element is used to set up securty rules. You restrict or grant access based on an element.

To add an indexed XML element:

1. Navigate to the **eRecord Indexed Element Setup** window by selecting **Indexed XML Element Setup**.
2. Click **Create Indexed Element**. The **eRecord Indexed XML Element Creation** window displays.
3. Enter the Owner Application short name. Required.
4. Enter the XML Element. Only the XML elements belonging to the ERES events of the particular application are shown in the list of values. Required.
5. Enter the name of the Document Type Definition. The DTDs in the list of values contain the element already selected. You then select a DTD knowing which event it applies to. Normally, this is left blank.
6. Enter the Display Name. This name appears in the generic query when querying eRecords and the page used to create security rules. Required.
7. Enter the Description, which is an internal descriptive name for the element.
8. Select the Query Element and Secure Element options where applicable. The Query Element option lets you see this element on the eRecord Query window, and the Secure Element option lets you use the element for setting up security rules.
9. Click **Apply**. The element is created in a non-indexed state.
10. Run the **eRecord Indexed XML Element Maintenance** program. Refer to Setting Up Indexed XML Elements for details.

Maintaining Indexed XML Elements

All eRecords are XML documents consisting of many XML elements. An XML element which is indexed and used for special purposes such as querying or creating security rules is called an Indexed XML Element.

The search criteria is not case sensitive and handles trailing wild cards. For example, searching for *abc* returns all matches for *abc%* and *ABC%*.

To query an indexed XML element:

1. Navigate to the **eRecord Indexed Element Setup** window by selecting **Indexed XML Element Setup**.
2. Search for elements in the system. You can enter criteria to narrow your search.

- Enter the **XML Element** name.
- Enter the **Display Name**.
- Enter the **Status** of the Element. Required. Valid options are:
  - **Indexed** displays only indexed XML elements
  - **Not Indexed** displays all non-indexed XML elements
  - **All** displays all XML elements

3. Click **Go**. The elements display in the **Results** section of the window. The following information displays for each record:
   - **Owner** displays the product family that owns the element.
   - **Display Name** displays the long description name of the element.
   - **XML Element** displays the name of the element.
   - **Document Type Definition** displays the DTD that the element is from.
   - Status displays whether the element is Indexed or Not Indexed. An indexed element can be used for searching eRecords and creating security rules if they have been identified as query or secure elements. A non-indexed element is indexed by running the **eRecord Indexed XML Element Maintenance** program.

Viewing Indexed XML Element Details

You can view the details for the Indexed XML elements. You cannot make any changes from this window.

To view details of an indexed XML element:

1. Click **Details** for the element. The **eRecord Indexed XML Element:<element_name>** window displays.
2. View details about the element including the General Details, Element Usage, and Event Details.

Updating Indexed XML Elements

Basic information about an element can be updated. You can add or change the Document Type Definition (DTD), add a description for the element, and modifiy whether the element is Query or Secure.

To update an indexed XML element:

1. Click **Update** from the **eRecord Indexed Element Setup** window. The **eRecord Indexed Element Update** window displays.
2. Make any modifications to the element information:
   - Add or change the Document Type Definition Name.
   - Add or change the Definition of the element.
   - Change the Query Element and Secure Element options.
3. Click **Apply**.
4. Run the **eRecord Indexed XML Element Maintenance** program. Refer to Setting Up Indexed XML Elements for details.

Deleting Indexed XML Elements

To delete an indexed XML element:

1. Click **Delete** from the **eRecord Indexed Element Setup** window. A warning window displays.
2. Click **Yes** to delete the element.
3. Run the **eRecord Indexed XML Element Maintenance** program. Refer to Setting Up Indexed XML Elements for details.

Purging Temporary E-Record Tables

In Oracle E-Records, temporary tables are populated to complete the signature process and for reporting purposes. The tables used for these purposes are EDR_ERECORDS, EDR_ESIGNATURES, and EDR_TRANS_QUERY_TEMP. Once the process is complete and all reporting is done, the data is no longer used. This program lets you clean these tables.

To purge data in temporary E-Record tables:

1. From the ERES Super User responsibility, navigate to the **Submit Request** window.
2. Enter **eRecords Temporary Data Cleanup** in the Name field.
3. Click **Submit**.

Framework Verification

The Framework Verification window lets you test the components of the framework without dependencies to any other products. This lets you validate the framework setup in an environment separate from setups in Oracle Applications.

The Framework Verification window can be used in all three modes; partial online - deferred allowed, online only, deferred.

You can use attachments with this verification utility. The attached files are shown along with the eRecord.

This window also supports descriptive flexfields. When an eRecord is generated, you can see all the flexfield information associated to that eRecord.

The following components are added to use with this window, which have no connection to any other product:

- A model to support inserts and updates from a window.
- An Oracle window that acts on the above data model with attachments and descriptive flexfields enabled.
- A business event that is raised from the above window when an insert happens.
- An Approval Management Transaction that represents the approval matrix.
- DTD and XML maps that represent the business event data.
- An XSL style sheet that represents the eRecord.
- The ability to have Multilingual Support (MLS).
- Debug mode
- Multiple Query modes

Using the Framework Verification Window

The Framework Verification window can be used for testing different aspects of the framework setup. Different fields are populated based on the part of the framework you are testing.

◗ To enable ERES for Framework Verification:

1. Verify that the EDR: eRecords and signatures profile option is set to Yes.
2. Verify that the ERES Framework Verification Event (oracle.apps.edr.framework.test) subscription is enabled.

3. Navigate to **Transaction Type Configuration Variables** and set ESIG_REQUIRED to Y.
4. Create an approval group in AME with at least two approvers.
5. Define a Rule and associate approval group. This step is mandatory to test eSignatures from the ERES Framework Verification window.

To request an eSignature on the Framework Verification window:

1. Navigate to the **ERES Framework Verification** window.
2. Enter the information for the test record:
   - **Test No.** is a new, unique, alphanumeric ID for this test record. After it is saved, it can be used again in query mode. Required.
   - **Description** is a short description of the test record.
   - **Numeric Value** is any number for testing numeric format in the framework setup.
   - **Date Value** is a date entered based on the system date cofiguration that lets you test the date format in the framework setup.
   - **Debug Mode** can be set to On or Off. If it is set on, then messages of what is happening during process display.
   - **Signature Mode** can be online only, offline only, or deferred. This is required when raising an ERES event.
   - **Query Key Type** tells the EDR_STANDARD package how to build the where clause when form call for transaction query from the eRecord Details option on the Actions menu. It is required only when you want to see the eRecord details. The valid values are:

     Append %

     When the event Key is passed to EDR_STANDARD.PSIG_QUERY, it builds dynamic SQL for the event key as ' event_key like '||event_key||'%'.

     Prepend %

     When the event key is passed to EDR_STANDARD.PSIG_QUERY, it builds dynamic SQL for the event key as ' event_key like '||'%'||event_key.

     Apply % Both Sides

When event Key is passed to EDR_STANDARD.PSIG_QUERY, it builds dynamic SQL for the event key as ' event_key like '||'%' ||event_key||'%'.

Use Equal Condition

When the event key is passed to EDR_STANDARD.PSIG_QUERY, it builds dynamic SQL for the event key as ' event_key = '|event_key.

- **Signature Status** is not an active field. It displays the current state of the test record. This field is initially blank, but changes to the status of the current record as it going through the signature process.
- The **Descriptive Flexfield** lets you enter information into a number of flexfield attributes. You can then see this information on the eRecord.

To verify partial online (deferred allowed) mode:

1. Navigate to the **ERES Framework Verification** window.
2. Enter required data.
3. Set **Signature Mode** to Deferred Allowed.
4. Save the record. The signature process starts.
5. Complete the signature process for one user and click **Finish**.
6. Close the window and respond to the message window. This sets the signature status to Pending.
7. Navigate to the worklist of the next approver and respond to the notification. If the second user also approves, then when you query the record it displays as Complete. If the second user rejects, then it displays as Rejected assuming there are only two users in the approval group.

To verify partial offline only mode:

1. Navigate to the **ERES Framework Verification** window.
2. Enter required data.
3. Set **Signature Mode** to Offline only.
4. Save the record. This sets the signature status to Pending.
5. Navigate to the approvers worklist and respond to the notification.
6. Repeat Step 5 for all approvers.

To verify online only mode:

1. Navigate to the **ERES Framework Verification** window.
2. Enter required data.
3. Set **Signature Mode** to Online only.
4. Save the record. This sets the signature status to Pending. The signature windows display.
5. Complete the signature process for one user and click **Finish**. If you click Finish or close the browser without completing the signature process, then the window does not save any changes.

To view eRecord and eSignature details from the window:

1. Navigate to the **ERES Framework Verification** window.
2. Query for a record that has completed the signature process.
3. Select **eRecord Details** from the **Actions** menu.

To start the signature process manually:

1. Navigate to the **ERES Framework Verification** window.
2. Query for an existing record and select **Request Signature** from the **Actions** menu.

To verify ERES with attachments:

1. Query for an existing record.
2. Click the attachment icon and attach a file or long text.
3. Set **Category** to either Other or Miscellaneous.
4. Select **Request Signature** from the **Actions** menu. The eRecord displays the attachment along with the eRecord.

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Reporting

The following topics are discussed. Choose one of the following accordingly:

- eRecord Generic Query
- eRecord Details

eRecord Generic Query

The Generic Query provides the functionality of querying the eRecords repository in the following manner:

- The individual product teams determine the XML elements that can be queried upon during creation of the DTDs.
- The Generic Query window displays these elements to the user in a menu. You can select multiple XML elements from multiple menus and provide search criterion for each of them.
- Individual search criteria are OR'ed or AND'ed with each other to create an aggregate search criterion, which is used to query the eRecords repository.
- The search results are presented on the window as multiple rows of eRecords based on the number of hits returned by the query.
- In the backend the query mechanism uses a Intermedia text index to go through each XML document stored in the database to search for individual XML elements. This XML search ability distinguishes the Generic Query from other typical querying applications.

eRecord Generic Query Window

The window is divided into two regions, the top region lets you specify the query criteria and the bottom region shows the results of the query.

There are two options for using the generic query, a Simple option and an Advanced option. The query criteria in the simple option are Event Name, From Date, To Date, and the user id of the eRecord signer. All these are individual columns in the EDR_PSIG_DOCUMENTS table.

The bottom region of the window shows the header level information for the eRecords retrieved from the database. This includes the business event name, the unique identifier of the event, the time of its creation, and the time zone in which it was created.

The Advanced option lets you query eRecords by directly querying the XML element of the eRecord. The Element box on the window takes its values from a LOV and the condition defaults to equals. After selecting a particular element (which corresponds to an XML element), enter a value to be searched.

To view a query using the simple search:

1. Navigate to the **eRecord Generic Query** window.
2. Select an event name using the list of values to search by events.
3. Select the name of the signer to search by a specific signer.
4. Enter the eRecord ID to search by a specific ID.
5. Select a to and from date to view queries within a date range.
6. Click **Search**. The search results and their time zone display. The following information displays for each record:
   - **Event Name** displays the name of each event.
   - **eRecord ID** displays the unique eRecord ID for each event.
   - **Identifier Name** displays the identifiers used to create the event. If there is more than one identifier, then they are all listed and separated by dashes.
   - **Identifier Value** displays the values for the identifiers used in the record. If there is more than one value, then they are all listed and separated by dashes.
   - **Event Date** displays the date the event began.
   - **Status** displays the status of the event. Valid values are error, pending, complete, and rejected.
7. Either click on an event name or select a series of events from the Select box and click **View Selected**. The record displays with all signer information. The following information displays:

- **Event Name** displays the name of the event.
- **eRecord ID** displays the ID for the eRecord.
- **Event Date** displays the date of the event.
- **Time Zone** displays the time zone set in the profile option EDR:Server Timezone.
- **Identifier Name** displays the name of the specific identifier.
- **Identifier Value** display the value for that identifier.
- **Style Sheet** displays the style sheet name.
- **Style Version** displays the style sheet version.
- **Print Count** displays how many times the document has been printed.
- **Attachments** shows if there are any attachments for the eRecord, and lets you navigate to them.

8. Click **Print** to print the record without the viewable headers and with appropriate page breaks.

To view a query using the advanced search:

1. Navigate to the **eRecord Generic Query** window.
2. Click **Advanced Search**.
3. Select an event name using the list of value to search by events.
4. Select the name of the signer to search by a specific signer.
5. Enter the eRecord ID to search by a specific ID.
6. Select a to and from date to view queries within a date range.
7. Select a query element to search by specific elements. The query elements are defined in the DTD.
8. Enter a query value to search on a specific value for a query element. If you do not enter a value in this field, then the search results in no records.
9. If you want to add more criteria, then click **Add** and set the logic operator to AND or OR depending on the type of search you are doing.
10. Click **Search**. The search results and the time zone display. The following information displays for each record:
    - **Event Name** displays the name of each event.

- **eRecord ID** displays the unique eRecord ID for each event.
- **Identifier Name** displays the identifiers used to create the event. If there is more than one identifier, then they are all listed and separated by dashes.
- **Identifier Value** displays the values for the identifiers used in the record. If there is more than one value, then they are all listed and separated by dashes.
- **Event Date** displays the date the event began.
- **Status** displays the status of the event. Valid values are error, pending, complete, and rejected.

  You can sort by any column that has an arrow next to it. Click the column name to sort in ascending or descending order.

11. Either click on an event name or select a series of events from the Select box and click **View Selected**. The record displays with all signer information.
12. Click **Print** to print the record without the viewable headers and with appropriate page breaks.

eRecord Details

On each window that is eRecord / eSignature enabled, there is an option under the Action menu for eRecord Details. This displays the same window as the generic query, but it works in the context of the current transaction.

A

Oracle E-Records Events

The following events are used when you create, update, or delete an input configuration variable for transaction type at the transaction or rule level.

Event Details

Name	Display Name	Description	Status	Owner Name	Ownertag
oracle.apps.edr.file.approvalcompletion	EDR File Approval Complete	This event is raised as a post operation to the oracle.apps.edr.file.approval ERES event. Product teams can subscribe to this event to take specific actions based on whether the file was approved or rejected	ENABLED	Oracle E Records	EDR
oracle.apps.edr.amevar.create	EDR ERES Transaction Variable Creation	eRecords Transaction type variable creations	ENABLED	Oracle E Record	EDR
oracle.apps.edr.file.approve	ERES File Approval Event	This event is raised for each file to be approved using the ERES Framework	ENABLED	Oracle E Records	EDR
oracle.apps.edr.amevar.update	EDR ERES Transaction Variable Update	eRecords Transaction type variable updates	ENABLED	Oracle E Records	EDR
oracle.apps.edr.amevar.delete	EDR ERES Transaction Variable Deletion	eRecords Transaction type variable deletion	ENABLED	Oracle E Records	EDR
oracle.apps.edr.rulevar.delete	EDR ERES Rule Variable Deletion	eRecords Configuration Input Variable Deletion for Rule	ENABLED	Oracle E Records	EDR

Name	Display Name	Description	Status	Owner Name	Ownertag
oracle.apps.edr.framework.test	EDR ERES Framework Verification Event	This event is used to test the eSignature framework	ENABLED	Oracle E Records	EDR
oracle.apps.edr.rulevar.create	EDR ERES Rule Variable Creation	eRecords Configuration Input Variable Creation for Rule	ENABLED	Oracle E Records	EDR
oracle.apps.edr.rulevar.update	EDR ERES Rule Variable Update	eRecords Configuration Input Variable Update for Rule	ENABLED	Oracle E Records	EDR

Event Keys

Name	Event Key	User Key
oracle.apps.edr.file.approve	EDR_FILES_B.FILE_ID	EDR_FILES_B.FILE_NAME
oracle.apps.edr.file.approvalcompletion	EDR_FILES_B.FILE_ID	EDR_FILES_B.FILE_NAME
oracle.apps.edr.amevar.create	EDR_AMETRAN_INPUT_VAR.TRAN_CONFIG_ID	AME_TRAN_NAME,INPUT_NAME
oracle.apps.edr.framework.test	EDR_FWK_TEST_B.TEST_ID	EDR_FWK_TEST_B.TEST_NO
oracle.apps.edr.amevar.delete	EDR_AMETRAN_INPUT_VAR.TRAN_CONFIG_ID	AME_TRAN_NAME,INPUT_NAME
oracle.apps.edr.amevar.update	EDR_AMETRAN_INPUT_VAR.TRAN_CONFIG_ID	AME_TRAN_NAME,INPUT_NAME
oracle.apps.edr.rulevar.create	EDR_AMERULE_INPUT_VAR.RULE_CONFIG_ID	AME_TRAN_NAME,RULE_NAME,INPUT_NAME
oracle.apps.edr.rulevar.delete	EDR_AMERULE_INPUT_VAR.RULE_CONFIG_ID	AME_TRAN_NAME,RULE_NAME,INPUT_NAME
oracle.apps.edr.rulevar.delete	EDR_AMERULE_INPUT_VAR.RULE_CONFIG_ID	AME_TRAN_NAME,RULE_NAME,INPUT_NAME

Subscription Details

Name	Phase	Status	Rule Data	Rule Function	Parameters	Priority
oracle.apps.edr.file.approve	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=oracle.apps.edr.file.approve EDR_AME_TRANSACTION_TYPE=oracle.apps.edr.file.approve	50
oracle.apps.edr.file.approvalcompletion	101	DISABLED	KEY	WF_RULE.DEFAULT_RULE	CORRELATION_ID=UNIQUE	50
oracle.apps.edr.framework.test	101	DISABLED	KEY	WF_RULE.DEFAULT_RULE	CORRELATION_ID=UNIQUE	50
oracle.apps.edr.amevar.create	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edrametranvar	50
oracle.apps.edr.framework.test	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=oracle.apps.edr.framework.test EDR_AME_TRANSACTION_TYPE=oracle.apps.edr.framework.test	50
oracle.apps.edr.rulevar.create	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edramerulevar	50
oracle.apps.edr.rulevar.delete	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edramerulevar	50
oracle.apps.edr.rulevar.update	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edramerulevar	50
oracle.apps.edr.amevar.update	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edrametranvar	50
oracle.apps.edr.amevar.delete	0	DISABLED	KEY	EDR_PSIG_RULE.PSIG_RULE	EDR_XML_MAP_CODE=edrametranvar	50

AME Transactions

Oracle Application	Transaction Type Id	Transaction Type Description	Line Item Query
Oracle E Records	oracle.apps.edr.ametranvar.create	EDR ERES Transaction Variable Creation	N / A
Oracle E Records	oracle.apps.edr.file.approve	EDR ERES File Approval	N / A

Oracle Application	Transaction Type Id	Transaction Type Description	Line Item Query
Oracle E Records	oracle.apps.edr.amevar.create	EDR ERES Transaction Variable Creation	N / A
Oracle E Records	oracle.apps.edr.framework.test	EDR ERES Framework Test	N / A
Oracle E Records	oracle.apps.edr.framework.test	EDR ERES Framework Verification	N / A
Oracle E Records	oracle.apps.edr.amevar.delete	EDR ERES Transaction Variable Deletion	N / A
Oracle E Records	oracle.apps.edr.amevar.update	EDR ERES Transaction Variable Update	N / A
Oracle E Records	oracle.apps.edr.rulevar.delete	EDR ERES Rule Variable Deletion	N / A
Oracle E Records	oracle.apps.edr.rulevar.create	EDR ERES Rule Variable Creation	N / A
Oracle E Records	oracle.apps.edr.rulevar.update	EDR ERES Rule Variable Update	N / A

Glossary

21 CFR Part 11

This rule represents the combined effort of divisions within the US Food and Drug Administration (FDA), along with members of the pharmaceutical industry, to establish a uniform, enforceable, baseline standard by which the FDA will consider electronic records equivalent to paper records and electronic signatures equivalent to traditional handwritten signatures.

Attachment

Any document associated with one or more application entities. You can view attachments as you review and maintain an entity. Examples are operation instructions, purchase order notes, item drawings, or an employee photo.

Batch Journal

A complete history of the all the events that occurred within a batch including the ingredients, lots, steps, activities, processes, and signatures.

Document

Any object that furnishes information to support another object or action. Examples are a purchase order, an invoice, a word processing file listing, receiving instructions, CAD files citing an item's specifications, or video instructions of an assembly operation.

Electronic Record

Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature

A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

ERES

Electronic Records and Electronic Signatures.

Event

An occurrence in an Internet or intranet application or program that is significant to other objects in a system or to external agents.

Event Subscription

A registration indicating that a particular event is significant to a system and specifying the processing to perform when the triggering event occurs. Subscription processing can include calling custom code, sending the event message to a workflow process, or sending the event message to an agent.

Oracle Approval Management Engine (AME)

This component is used to define conditions, rules and, approval hierarchy. We also want to store rule specific attributes such as Electronic recording required or Electronic Signature is required, what type of style sheet need to be applied for this rule, etc. These rules are evaluated runtime based on Transaction ID (this is the primary key for the transaction).

Process Parameter

A process parameter details information such as temperature, pressure, or time that is pertinent to the product but does not fall into the classification of input or output. Process parameters may be used as set points, comparison values, or in conditional logic.

Workflow Business Event System

Workflow Business Event system is used to define an eSignature event and associate a synchronous eSignature subscription to the event.

XML Gateway

XML Gateway is used for mapping definition and generation of XML for an eRecord. Individual product teams define XML maps and DTD for eSignature / eRecord Events (ERES) supported by them. These Maps and DTD are loaded into

the database and source controlled under respective product tops. The eRecord style sheet is also defined as part of XML Gateway.

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