Oracle® Health Sciences Central Coding

Security Guide

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Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Diversity and Inclusion
- Access to Oracle Support
- Additional copyright information

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Oracle Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab if you are hearing impaired.

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1

Security overview

In this chapter:

- Application security overview
- General security principles

Application security overview

To ensure security in the Oracle Central Coding application, carefully configure all system components, including the following third-party components:

- Web browsers
- Firewalls
- Load balancers
- Virtual Private Networks (VPNs)

General security principles

Keep software up to date

Keep all software versions and patches up to date.

Keep up to date on the latest Critical Patch Updates

Oracle continually improves its software and documentation. Critical Patch Updates are the primary means of releasing security fixes for Oracle products to customers with valid support contracts. They are released on the third Tuesday of January, April, July, and October (they were previously published on the Tuesday closest to the 17th day of January, April, July, and October).

Oracle highly recommends that customers apply these patches as soon as they are released.

Require complex and secure passwords

Each password should meet the following requirements:

- Contains a minimum of eight characters.
- Contains at least one upper case character, and at least one number or special character.
- Expires after 90 days.
- Does not contain a common word, name, or any part of the user name.

For information about specific password configuration settings available in Oracle Central Coding, see Password configuration for user security.

Keep passwords private and secure

All users should change their passwords when they log in for the first time.

Tell users never to share passwords, write down passwords, or store passwords in files on their computers. For more information, see Passwords for new users.

Lock computers to protect data

Encourage users to lock computers that are left unattended. For more information, see Log in security.

Provide only the necessary rights to perform an operation

Configure rights, assign roles to users, and assign users to work teams so that they can perform only the tasks necessary for their jobs.

For more information, see:

- Rights assigned to roles
- Users assigned to roles
- Users assigned to work teams

Protect sensitive data

- Collect the minimum amount of sensitive data needed.
- Tell users not to send sensitive information over email.
- Provide access to sensitive data only to users who need it for their jobs.

For more information, see Restricted viewing of sensitive data.

2

Secure installation and configuration

In this chapter:

- Installation overview
- Post-installation configuration

Installation overview

Use the information in this chapter to ensure the Oracle Central Coding application is installed and configured securely. For information about installing and configuring the Oracle Central Coding application, see the *Installation Guide*.

- Secure with HTTPS
- Enable TLS 1.2 and higher on the Oracle Central Coding application server
- Configure strong database passwords
- Close all unused ports
- Disable all unused services
- Install a signing certificate

Secure with HTTPS

Configure your environment so that the Oracle Central Coding application servers are hosted behind a firewall and all communication through the firewall is over HTTPS.

Enable TLS 1.2 and higher on the Oracle Central Coding application server

Oracle recommends that you configure the following security settings on the Oracle Central Coding application server:

- Enable TLS 1.2 and higher.
- Disable SSL 2.0, SSL 3.0, TLS 1.0, and TLS 1.1.

For more information, see the *Installation Guide*.

Configure strong database passwords

During the Oracle Central Coding installation, you are prompted to create a single initial user and to create a password for the user. This user logs into the Oracle Central Coding application and creates all additional users. Ensure all your database passwords are strong passwords.

Close all unused ports

Keep only the minimum number of ports open. Close all ports not in use.
The Oracle Central Coding application always uses the following ports:

- **Port 1521**—Default connection to the Oracle database.
- **One port between 14000-14100**—For connection to the Job Scheduler. When multiple instances of the Oracle Central Coding application are installed on the same server, the port number is incremented for each additional instance.

The Oracle Central Coding application may use the following ports:

- **Port 80**—For the client connection (HTTP).
- **Port 443**—For the client connection (HTTPS).

> **Note:**
>
> The Oracle Central Coding application does not require both Port 80 and Port 443. You can configure the Oracle Central Coding application to use only HTTP or only HTTPS. For more information, see the *Installation Guide*.

Disable all unused services

The Oracle Central Coding application uses the following services:

- Oracle Central Coding Job Scheduler Service.
- COM+ System Application.
- Distributed Transaction Coordinator.
- DNS Client.
- IIS Admin Service.
- Oracle MTS Recovery Service.
- Oracle TNS Listener.
- World Wide Web Publishing Service.
- ASP.NET State Service.

Install a signing certificate

The Oracle Central Coding software uses X.509 digital certificates for securing communications with:

- The Job Scheduler service—You select the certificate in the installation wizard and you can replace it after installation using a utility installed with Oracle Central Coding.
- Oracle InForm Adapter web services—You select the certificate using a utility installed with Oracle Central Coding.

A single certificate can be used for securing communications with both the Job Scheduler and the Oracle InForm Adapter web services. Use a digital certificate issued by a recognized Certificate Authority (CA).

For more information, see the *Installation Guide*.

Post-installation configuration

In this section:

- Restrict access to Oracle Central Coding server machines
- Configure strong user passwords
- Configure roles and rights

Restrict access to Oracle Central Coding server machines

Allow only the necessary user accounts access to the Oracle Central Coding server machine. Limit the number of users with access to the server machine. Disable or delete any unnecessary users.

Configure strong user passwords

Configure password options to require a secure level of complexity.
For more information, see Password configuration for user security.

Configure roles and rights

Configure rights and assign roles to users so that they can perform only the tasks necessary for their jobs. For more information, see Rights assigned to roles and Users assigned to roles.

3
Security features

In this chapter:

- User security features
- Application security features
- Data security features

User security features

In this section:

- Password configuration for user security
- Passwords for new users
- Log in security
- No data loss after a session transaction
- Automatically locked user accounts
- Restricted access to the application

Password configuration for user security

In environments with native authentication, an administrator can define the following formatting, entry, and reuse requirements for passwords directly in the Oracle Central Coding application on the System Configuration page.

- **Password complexity**—Number of the following additional requirements a password must meet. Recommended setting is 3.
  - Password must contain one or more alphabetical (A-Z, a-z) and numeric (0-9) characters.
  - Password must contain at least one non-alphanumeric character.
  - Password must contain one or more upper case [A-Z] and lower case [a-z] characters.
- Minimum length of passwords. Recommended setting is 8.
- Password reuse limit. Recommended setting is 3.
- Number of consecutive failed log in attempts allowed. Recommended setting is 3.
- Number of days before the password expires. Recommended setting is 90 days.

Passwords for new users

For security, in environments with native authentication three types of users can be defined in the Oracle Central Coding application. In all cases, the user profile is stored in the Oracle Central Coding database along with the user ID. The user types differ in where the system stores the passwords and how the system authenticates the user. The user type is set on the User details page in the Oracle Central Coding user interface.

- **Native user**—Password maintained by the Oracle Central Coding application.
  When the user logs in, the authentication module hashes the password entered by the user and compares it to the hashed password stored in the database. The user is granted access to the application only if the hashes match.
- **Windows user**—Does not have a password stored in the database.
  When the user logs in, the authentication module uses the user name and password entered on the Log In page and uses a Windows API to authenticate the user.

  In this mode, the Oracle Central Coding application has no knowledge of what the password is, and it is up to Windows to determine if the user is granted access. This user type requires Oracle Central Coding users to be created as part of a Windows domain. The format of the user ID supports only the user ID, such as **joe** if you want to log in to the current domain, or **EAST\joe** if you want to authenticate the user **joe** in the domain **EAST**.
- **Certificate user**—The system checks a digital certificate for a valid user name and password.

Log in security

Users must enter their user names and passwords to log in. The application does not allow duplicate user names. There are two authentication methods, depending on the type of environment:

- **Environments with native authentication**—User information stored in the Oracle Central Coding application is used for authentication.
- **Oracle SSO environments**—User information stored in Oracle Life Sciences Identity and Access Management Service is used for authentication.

If either a user name or password is incorrect, an error message appears, but does not tell the user the value that is incorrect. Therefore, if someone else is using the account to attempt to log in, the message does not confirm either a user name or password.

No data loss after a session transaction

The Oracle Central Coding application is configured to require users to re-enter their user names and passwords after a defined period of inactivity. The user can log in and continue working without losing data.

In environments with native authentication, this security feature is controlled by the following settings on the System Configuration page:

- **Authentication inactivity timeout**—Period of inactivity after which a user session times out. Default is 20 minutes.
- **Authentication expiration**—Length of time after which a user session times out. Default is 4 hours (240 minutes).
- **Authentication token duration**—Length of time the user login is valid. Default is 10 hours.
- **Authentication token renew duration**—Length of time a previously created security token can be renewed without requiring a user to re-enter the user name and password. Default is one week.
- **Authentication token clock slush**—Number of minutes the server clocks for the Oracle Central Coding and Oracle InForm Adapter application servers can be out of sync. The default is 5 minutes (meaning that a token will be accepted if the server clock is within 5 minutes of the server that issued the token).

Automatically locked user accounts

The Oracle Central Coding application is configured to allow a defined number of attempts to log in correctly. When a user exceeds the number of allowed log in attempts, which is defined on the System Configuration page in environments with native authentication, the user account is locked out for a specified time interval and the user cannot log in. When the time interval elapses, the user can log in again.

This security feature is controlled by the following settings on the System Configuration page:

- **Super user lockout timeout**—Length of consecutive time before an automatically locked super user account is unlocked.
- **Non-Super user lockout timeout**—Length of consecutive time before an automatically locked non-super user account is unlocked.

Restricted access to the application

Access to the application can be restricted in the following ways.

- You can terminate a user.
  Typically, you terminate users who leave the organization. Terminated users cannot log in and cannot be reactivated. All users, including terminated users, remain in the study for audit purposes.
- You can deactivate a user.
  Typically, you manually deactivate users to keep them from accessing the application without removing them from the system. Deactivated accounts can be reactivated.

Application security features

In this section:

- Rights assigned to roles
- Users assigned to roles
- Users assigned to work teams

Rights assigned to roles

The application comes with a predefined set of roles, which are configurable, and rights, which are not configurable.

Rights grant access to different parts of the application. Entire parts of the application are hidden when users do not have the rights to work in those areas.

The predefined roles with selected rights represent typical job responsibilities. You can change the rights that are assigned to each role to suit the needs of your organization.

For example, a user assigned to the coder role has the appropriate rights to code requests. The individual Code Request right is static, but the group of rights assigned to the coder role is configurable.

For more information, see the *User Guide*.

Users assigned to roles

After you review the rights that are assigned to roles and make any necessary changes, you can assign users to roles. A user assigned to a role has the rights that are granted to that role. Changes to a role are immediately applied to all users assigned to the role.

Users assigned to work teams

Work teams provide a high level of control over the Oracle Central Coding request-processing workflow. Users are assigned to work teams. Rules are used to determine which work team or work teams are assigned to a coding request.

The criteria used to organize work teams may be defined by a system administrator to meet the business needs of an organization. Coding requests are assigned to work teams rather than to individual users. Work teams act as a filter for the list of coding requests that are presented to individual users. Users see only those requests that are assigned to the work team or work teams to which they belong.

Data security features

In this section:

- Restricted viewing of sensitive data
- Audit trails for data security

Restricted viewing of sensitive data

You can use roles, rights, and work teams to restrict the data users can view.

Audit trails for data security

Audit trails record updates to the following items:

- Users, roles, rights, and work teams.
- Coding request information.
- Codes, terms, dictionary version, and the reason for change.
- Coding request statuses.
- Approvals.
- Dictionaries.
- Synonym lists associated with the dictionary and changes from impact analysis.
- Synonym lists.
- Stopword lists.
- Algorithms.
- User authentication (available through database queries).

Audit trails are comprehensive records that include the person who made the change, the date and time of the change, the change itself, as well as additional details. You cannot modify data in an audit trail.

For more information, see the *User Guide*.