Oracle® Argus Standard Edition Cloud Service

Administrator's Guide

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Contents

3   Dictionaries

4   Utilities

5   Extensibility

Preface

This preface contains the following sections:

- Intended Audience
- Documentation accessibility
- Related resources
- Access to Oracle Support
  To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Intended Audience

This document contains information intended for Oracle Argus Cloud Service customer-delegated administrators (CDA) to understand roles and responsibilities around administration tasks.

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.

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

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

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

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

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

On-premises customers receive support assistance through My Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

1

User Administration

In this chapter:

- Get Your Administrator Credentials
- Manage Oracle Argus User Access
- Manage sFTP User Access

Get Your Administrator Credentials

Before you can manage users in Oracle Argus Safety Cloud Service, Oracle must provision your customer-delegated administrator account. There are two scenarios for this process.

Your company is a new Oracle Argus Cloud customer—during onboarding, Oracle emails your company and requests all the information necessary to provision your administrator account. After your company has provided the necessary information, Oracle emails you the account credentials.

Your company is an existing Oracle Argus Cloud customer—your company must raise a change request with Oracle, as follows:

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **Application User Access** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change > Cloud Environment > Application > User > Add**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select Oracle Argus Safety, and then click **OK**.

10. In the **Business Service** drop-down, select the appropriate server name, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the appropriate environment, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: Create CDA user <user name> in IDM.

15. In the **Description** field, enter a detailed description of your request, including the following information about the user you want to create:

    - first name

    - last name

    - user ID

    - user email address

    - Oracle Identity Self Service URL of your company

16. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

17. In the **Date Required By** field, select a value from the calendar.

18. Click **Submit**.

Manage Oracle Argus User Access

Site, group, and user configuration takes place in the **Access Management** section of Oracle Argus Safety Console. Here you can add, copy or delete users, groups or sites.

Each user must be assigned to at least one group to determine their security level. Each group is assigned a specific security level. This security level enables members of the group to view, modify, or restrict access rights to various sections of the Case Form.

The first set of steps in configuring Oracle Argus Safety is to create the following:

- Sites

- Groups

- Users

For more information, see:

- Configure User Sites

- Configure Groups

- Provision Users

Configure User Sites

Addition of sites is necessary for user creation, because every user must be assigned to exactly one site. Site information can also be used in automatic numbering of case IDs.

To configure sites, use the **Access Management > Argus > Sites** section.

For more information, see:

- Field Descriptions

- Add User Sites

- About Filtering Criterion

Field Descriptions

The following table describes the fields on the screen.

Field or Control Name	Description
Description	Enter a description of the site.
Abbreviation	Enter an abbreviation of the site name. A one to four character abbreviation is required for each site.
Site Type	Select the Site Type—Argus or LAM (Local Affiliate Module).
Protect Patient Confidentiality - Default	Protects or reveals Patient Confidentiality for the specific site.
Protect Reporter Confidentiality - Default	Protects or reveals Reporter Confidentiality for the specific site.
Bulk report By form (Approved reports) - Default	Allows or protects availability of the Bulk Reports by Form for the specific site.
LAM Sites	Select and add previously created LAM sites.
Site Printers	The Site Printers section is used to configure site printers.

Add User Sites

Use the following procedure to add a user site.

1. Navigate to **Access Management > Argus > Sites**.

2. In the left pane, select **User Sites**. The user sites are listed in the right panel.

    > 💡 **Tip:**
    >
    > You can alternatively click **Modify** to modify an existing site.
    >
    > Use **Copy** to make an editable copy of an existing user site.
    >
    > Use **Delete** to delete a user site.

3. Select a **User Site** and click **Add New**.

4. Enter the user site **Description**.

5. Enter the user site **Abbreviation**.

    > ✏️ **Note:**
    >
    > A maximum four-character abbreviation is required for each user site.

6. Select a **Site Type**.

> **✐ Note:**
>
> Each Oracle Argus Safety user must be assigned to exactly one user site.
>
> You cannot change the site type from LAM to Central if the current central site has an association with a LAM site, the current site is associated with any user, or the current LAM site has any events assigned to it.

7. Select the following options as required:

    - Select the **Protect Patient Confidentiality - Default** to protect or reveal *Patient Confidentiality* for this specific user site.

    - Select the **Protect Reporter Confidentiality - Default** to protect or reveal *Reporter Confidentiality* for this specific user site.

    - Select the **Bulk Report by Form (Approved Reports) - Default** to enable availability of the *Bulk Reports By Form* for this specific site.

8. Add or remove any **LAM Sites** information.

> **💡 Tip:**
>
> To add more **LAM Sites** to the LAM Sites list, use the **Add>/Add All** options.
>
> To delete the **LAM Sites** from the Lam Sites list, use the **Remove>/ Remove All** options.

9. In the **Site Printers** section, click **Add** to add a site printer.

10. Enter the **Name** of the printer that will be displayed in the application when referring to the printer. The name can have up to 20 characters.

11. To delete a site printer, select the printer and click **Delete**.

12. Click **Print** to print the site information.

13. In the **Path** text field, enter the full path of the printer on the network. This path name can have up to 256 characters. The specified path should be accessible from the system where Argus Safety Service is installed.

14. To save the information and return to the **Code List Maintenance** dialog, click **Save**.

About Filtering Criterion

The filtering criterion is essential, as it helps you search for specific items. The Oracle Argus Safety Console provides this option for the **Access Management** section. The filtering browser is displayed as the **Code Filter List**.

Argus Console helps you filter information further for the **Access Management** section. Using the **Code Filter List**, you can specify whether your search should contain or start with specific characters.

Configure Groups

Each user of Oracle Argus Safety can be a member of one or more user groups. The access rights of each user group to the menus in the user interface and specific sections of the Case Form can be configured when the group is created.

You configure groups using the **Access Management > Argus > Groups** section.

For more information, see:

- Field Descriptions
- Add User Groups
- Groups Included with the Factory Data
- Use Organized By
- Print a User Group
- Group Configuration Printout

Field Descriptions

The following table describes the fields in the **Modify Group Information** section.

Field or Control Name	Description
Group Name	Enter a unique name for the group.
Email	Add the group email, used for case priority notifications and workflow routing notifications.
Supervisor Email	Add the group supervisor's email, as applicable. This email address is used to send notifications when the maximum time of a case for a particular workflow state is exceeded.
Menus	Lists the menus and submenus within a Case Form and allows you to enable or disable each of them.
Case Form	Lists the sections and subsections within a Case Form and enables you to assign the group Modify; View (Read Only); or No Access (not visible) to each area.
Advanced Condition	Allows you to configure advanced condition settings, as applicable. The options are: No Access to Create Advanced Conditions, No Access to Share Advanced Conditions, No Access to View and Edit SQL.
Listedness Determination - Countries	Assigns Argus users to the group that has rights to change the listedness determination for licenses originating in the selected countries.
Restrictions - Products	Limits the number of products that can be viewed in the trade name lookup and non-study cases.
Restrictions - Studies	Limits the number of studies available for selection and the study cases that can be viewed. 1. Click the **Studies** checkbox to enable the **Select** button 2. Click this button to view a security configuration containing a tree view list of available items 3. Select a study family to select all its constituents

Field or Control Name	Description
Default report (LAM only)	Lists the expedited report forms in the drop-down list.

Add User Groups

This section enables the administrator to configure the security levels for each work group.

Radio buttons enable you to view the group and assign access rights for several specific sections of the case form, menu, case workflow, and report workflow.

If a user belongs to multiple groups, the access rights for the user will be a combination of the highest access level permissions for each individual group. Consider the following example:

John Smith is an Oracle Argus Safety user and his profile has been added to two user groups with different access level permissions for each group.

- John has access rights to the **Patient** tab in one group and access rights to the **General** tab in another group.

- In this case, John will be able to access both the **Patient** and the **General** tabs of Oracle Argus Safety.

Use the following procedure to create a user group

1. Click **Access Management > Argus > Groups**.

2. Select the filtering criterion to display the list of Groups or Users in the left pane.

3. Select a **Group** and click to view the group details in the right panel.

> **Tip:**
>
> - You can alternatively click **Add Group** to create a new group.
> - Use **Copy** to make an editable copy of an existing group.
> - Use **Delete** to delete a group.

4. Enter the **Group Name**. This should be a unique name associated with this Group.

5. Enter the **Email** address, if applicable.

6. Enter the **Supervisor Email** address, if applicable.

7. In the **Case Form** section, select the desired access right option (**Modify**, **View**, or **No Access**) for the group's access to each of the listed items of the Case Form.

> **✎ Note:**
>
> To save a case, the following fields must be populated: **Initial Receipt Date**, **Country of Incidence**, **Report Type**, **Suspect Product**, and **Event Description as Reported**. Therefore, the group responsible for initial case entry must have access to these fields to save new cases.

8. In the **Menus** section, enable or disable access of the group to particular items in the Oracle Argus Safety menu.

> **💡 Tip:**
>
> Refer to the *Oracle Argus Safety User's Guide* for information about the functions of the Case Form sections and the menu items in the Oracle Argus Safety user interface.

9. In the **Listedness Determination** section, select a list of countries. This enables the end user to override the listedness determination in the **Event Assessment** section of the Case Form for product licenses that match the countries selected in this step.

10. In the **Advanced Conditions** section, select **No Access to Create Advanced Condition**, **No Access to Share Advanced Conditions**, and/or **No Access to View** and **Edit SQL**.

> **✎ Note:**
>
> Only trusted users should be given access to Advanced Conditions, because users who have this access will have complete access to the information in the Oracle Argus Safety Schema.

> **💡 Tip:**
>
> • If you select **No Access to Create Advanced Condition**, **Advanced Conditions** does not appear as an option for that user group.
>
> • If you select **No Access to Share Advanced Conditions**, the user group does not have access to share advanced conditions.
>
> • If you select **No Access to View and Edit SQL**, the **SQL...** button does not appear as an option for that user group.

11. In the **Restrictions** section, select **Products**.

12. To open the **Available Products** dialog box, click **Add Product**.

13. Select each product you want to add and click **OK**.

14. In the **Restrictions** section, select **Study**.

15. To open the **Available Studies** dialog box, click **Add Study**.

16. Click the appropriate checkboxes to select the required studies and click **OK**.

17. Click **OK** to save the group.

> **Note:**
>
> If you haven't selected any products or studies, the group will have access to all products or studies.

Groups Included with the Factory Data

The following table describes the groups included with the factory data.

Group	Description
Administrator	This group has access rights to all areas and all the functionality of Oracle Argus Safety.
Investigator	Receives an e-mail alert that can be set up during Clinical Study Configuration.

Use Organized By

The system displays the filtering browser in the top-left corner of the left pane. You can filter based on either of the two options in the drop-down list, **Groups** and **Users**.

Consider the following.

- If you enable **Organized by Groups**, the generated output displays in a tree format in the left pane. The structure is based on the entire categorization of groups and users.

- If you enable the **Organized by Users**, only the User list is available in the tree view in the left pane.

Use **Contains** or **Starts with** to specify whether your search should contain or start with specific characters. For example, if you select **Contains** and type **administrator** in the text box, the system searches for all the groups that contain the word "administrator".

Print a User Group

1. Select **Access Management > Argus > Groups**.

2. Select the filtering criterion to display the list of groups or users (based on the filtering criterion) in the left pane.

3. Select a **Group** and click to view the group details in the right panel.

4. To display a **Print** dialog that enables you to print either the entire window or only the text covered by the current selection, click **Print**.

5. Select the appropriate option and click **OK**.

6. The system opens the **Print Groups** to enable you to select the sections to be printed in the **Group Configuration** printout.

By default, the **Group Information** check box is selected and disabled so that this information always gets printed.

7. Select the appropriate check boxes and click **OK**.

Group Configuration Printout

The **Group Configuration** printout lists the users configured to the groups. Users are sorted alphabetically by user full name in the report section.

Provision Users

Before you can manage users in Oracle Argus Safety Cloud Service, you must provision users in Oracle Health Sciences Identity Self Service.

1. Open a browser and navigate to your company's Oracle Identity Self Service URL. Log in using your Oracle Argus Cloud Service administrator credentials.

2. Click **Administration > Users** in the left pane.

3. Click **Create**.

4. Enter the user attributes listed below (the values in the table are provided only as examples) to create the user.

Item	Value
Last name	Doe
Organization	example
User Type	Full-Time Employee
User Login	johndoe
Password	Enter a password.
Confirm Password	Confirm the password.

5. When you are done entering the user information, click **Submit**.

Once you have created a user in Oracle Identity Self Service, follow the steps below to create the user in Oracle Argus Safety.

1. Open a browser and navigate to your company's Oracle Argus Cloud Service URL. Log in with your Oracle Argus Cloud Service administrator credentials.

2. Click **Argus Console > Access Management > Argus > Users**.

3. In the left pane, select **Add Users**.

4. Enter the user attributes listed below to create the user.

Field or Control Name	Description
User Name	Enter the full name.
User ID	Enter a unique user identification (ID).
Reset Password	Reset the password of a user to a default value specified in the common profile section.
Email Address	Enter the user's e-mail address.

Field or Control Name	Description
Site	Assign the user to a site. The values in this field are populated from the codelist item **User Sites**.
User Group - Select	Attach the user to pre-configured user groups.
User Type	Select the type of user, such as an Oracle Argus Safety Japan user, from the drop-down list.
User Roles - Select	Attach the user to pre-configured user roles. The following user roles are available: • **Enterprise User**—This privilege allows you to configure a workflow manager user as an enterprise user. If the enterprise role is assigned, the user can view cases of any site outside their own site. • **ESM Admin**—This privilege allows the user to access the Interchange Mapping utility in the Argus Console. • **Copy Configuration**—This privilege lets a user copy all the configuration data from the enterprise where they have this role to any new enterprise that they create through Global Enterprise Management. The factory data administrator user has this role enabled by default. • **Global Admin**—This privilege lets you allow users to be designated as Global Users for selected enterprises, and not necessarily all enterprises. By default, a Global Admin role is granted to only one administrator, who can grant/revoke this role to other Argus users. • **AC Library Admin**—This privilege lets you allow users to perform specific operations on ACs, such as re-assigning the ownership, and granting access to various user groups using Permission, Modification, and Deletion. • **Workflow Manager**—This privilege allows users to perform specific workflow operations such as routing cases to any workflow state, routing cases to users, viewing all open cases and all action items present in the system, changing the priority of a case and changing the assignee of an action item or a case.
Application Access	Configure user access settings for Argus Console and Oracle Argus Safety. You can select the default application access for the user from the list.
Worklist to display at login	Configure users to see their worklists immediately upon login. The options are: • None (default) - Does not open any worklist when the user logs into Oracle Argus Safety. Displays personal Oracle Argus status on login. • Action Items - Opens Worklist - Action Items screen for the user on login. • New - Opens Worklist - New screen for the user on login. • Open - Opens Worklist - Open screen for the user on login. • Reports - Opens Worklist - Reports screen for the user on login.
Enable site security	If **Enable Security** is checked, the site-based data security will be enabled for the user. If the box is not checked, the user will have full access to data from all sites.
Enable LDAP Login	Authenticates users against the active directory server. When **Enable LDAP Login** is selected, all fields inside the **Access** section are disabled, excluding the **Account Disabled** option.

Field or Control Name	Description
Account Disabled	When this option is selected, the user account is temporarily disabled to prevent users from logging in. This option is different from deleting a user, as it enables you to re-activate the account at a later date. Before you disable a user account in Oracle Argus Safety Cloud Service, you must disable the account in Oracle Identity Self Service. For more information, see *Disable a User Account* below.
Security Disabled Account	• When **unchecked**, the login procedure keeps track of the number of consecutive unsuccessful attempts at logging into the system. If the count reaches three, the user is locked out. Administrators with rights to user maintenance can reset the login attempts for the user to unlock the account. • When **checked**, the login procedure that tracks the consecutive unsuccessful attempts at logging in to the system does not apply.
Force password change at login	If this check box is selected, the user must change the password the first time they log in to the system.
Force password to expire every	Enables you to force the user's password to expire in the specified number of days.
Days	Enables you to enter the number of days after which the password should expire.
Allow unblinding of cases	Enables the user to unblind a study case. For example, a user without unblinding rights does not see the Study Drug field. A user with unblinding rights sees a yellow **Unblind** tag next to concentration of product field and the **Broken by Sponsor** option in the **Blinding Status** drop-down if enabled. The user will have to enter their password when they select the Broken by Sponsor option.
Protect from unblinded information	When checked, the user cannot view any unblinded information.
Protect from printing unblinded information	When checked, the user cannot print any unblinded information.
Allow locking of cases	Enables the user to lock/unlock cases.
Allow local locking	Enables the user to locally lock/unlock a case for which local Japan data entry/assessment is complete, triggering the scheduling and/or generation of the applicable local reports.
Allow Global Unlock on Pending Local Lock	Allows users to be set up with the privilege to forcibly unlock a case that is still pending a local lock. This option is enabled only if the **Allow locking of cases** check box (above) is checked.
Allow closing of cases	Allows the user to close cases.
Route on close case	Opens a routing dialog when the user closes the case.
Enable Checklist on Route	By default, this check box is selected. If this check box is not selected, the checklist for the workflow is not displayed to the user while routing cases, even if the rule that is being used has a checklist.

> **Note:**
>
> 1. When you create a user in Oracle Argus Safety Cloud Service, you must use the same user name and email address that you used when you created the user in Oracle Identity Self Service.
>
> 2. When you use Oracle Identity Self Service authentication, you must select **Enable LDAP Login** in the Oracle Argus Safety user creation pane.

For more information, see:

- Reset a User Password
- Disable a User

Reset a User Password

1. Open a browser and navigate to your company's Oracle Identity Self Service URL. Log in using your Oracle Argus Safety Cloud Service credentials.

2. In the left pane, click **Administration > Users**.

3. In the right pane, enter one of the following for the user whose password you want to reset: user login, first name, last name or email address, then click **Search**.

4. In the results list, click the user whose password you want to reset.

5. In the right pane, click **Reset Password**.

6. Select **Manually change the Password**.

7. Enter and confirm the new password, then click **Reset Password**.

> **Note:**
>
> For cloud environments, the password reset option in Oracle Argus Safety is disabled, as this feature is managed from Oracle Identity Self Service.

Disable a User

Before you can disable a user in Oracle Argus Safety Cloud Service, you must disable the user in Oracle Identity Self Service.

1. Open a browser and navigate to your company's Oracle Identity Self Service URL. Log in using your Oracle Argus Safety Cloud Service credentials.

2. In the left pane, click **Administration > Users**.

3. In the right pane, enter one of the following for the user whose account you want to disable: user login, first name, last name or email address, then click **Search**.

4. In the results list, click the user login of the user whose account you want to disable.

5. In the right pane, click **Disable User**.

6. Click **Submit**.

Manage sFTP User Access

In this section:

- Add an sFTP User
- Reset an sFTP User Password
- Remove an sFTP User Account

Add an sFTP User

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **SFTP User Access** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change - Cloud Infrastructure > Infrastructure Services > SFTP > User > Add**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the relevant server name, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want to create the sFTP user, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Create sFTP user <user name> in <environment>.`

15. In the **Description** field, enter a detailed description of your request.

16. In the **sFTP path** field, enter the relevant sFTP path.

17. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

18. In the **Date Required By** field, select a value from the calendar.

19. To load the public key for the user you want to create, under **Attach Documents**, click **Browse**, and then navigate to the key file.

> **✎ Note:**
>
> For information on how to generate a public key for sFTP user authentication, navigate to My Oracle Support, at `https://support.oracle.com/`, and search for Doc ID 2467980.1. To access this article, you must be logged in to My Oracle Support.

20. Click **Submit**.

Reset an sFTP User Password

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **SFTP User Access** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change - Cloud Infrastructure > Infrastructure Services > SFTP > User > Change**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the relevant server name, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the relevant environment, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Reset sFTP user password for <user name> in <environment>.`

15. In the **Description** field, enter a detailed description of your request.

16. In the **sFTP path** field, enter the relevant sFTP path.

17. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

18. In the **Date Required By** field, select a value from the calendar.

19. Click **Submit**.

Remove an sFTP User Account

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **SFTP User Access** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change - Cloud Infrastructure > Infrastructure Services > SFTP > User > Remove**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the relevant server name, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the relevant environment, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Remove sFTP user <user name> from <environment>.`

15. In the **Description** field, enter a detailed description of your request.

16. In the **sFTP path** field, enter the relevant sFTP path.

17. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

18. In the **Date Required By** field, select a value from the calendar.

19. Click **Submit**.

2
Oracle Argus Cloud Service Enterprise Edition

In this chapter:

Create a New Enterprise in Oracle Argus Mart

1. Navigate to Oracle Health Sciences Support, at https://hsgbu.custhelp.com/.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **General Information/Action** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Service Request > Application > General > Action**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the name of the server where you want to create the enterprise, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want to create the new enterprise, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: Create enterprise <enterprise name> in the <environment name> environment.

15. In the **Description** field, enter a detailed description of your request, including the enterprise to use as a source for the configuration of the new enterprise.

    Example: Please create a new enterprise named <enterprise name> in the <environment name> environment, using <source enterprise name> as a source to copy the configuration.

16. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

17. In the **Date Required By** field, select a value from the calendar.

18. Click **Submit**.

Extract, Transform and Load Data

The change request examples included below for Extract, Transform and Load (ETL) tasks can be used for Oracle Argus Mart, Oracle Argus Analytics, and Oracle Argus Insight. Make sure you include the applicable product name in your change request, instead of the <product name> placeholder.

For more information, see:

- Run the Initial ETL
- Schedule Incremental ETLs
- Re-initialize the ETL Process

Run the Initial ETL

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.
2. Click **Login**, and then enter your user credentials.
3. Click **My Requests**.
4. In the upper left side of the screen, click **Change Requests**.
5. In the upper right side of the screen, click **Create a new Change Request**.
6. In the **General Information/Action** tile, click **Create a Request**.
7. From the **Category** drop-down, select `Service Request > Application > General > Action`, and then click **OK**.
8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.
9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.
10. In the **Business Service** drop-down, select the name of the server where you want to run the initial ETL, and then click **OK**.
11. In the **Action** drop-down, select **Other**, and then click **OK**.
12. From the **Oracle Internal** radio buttons, select **No**.
13. In the **Environment** drop-down, select the environment where you want to run the initial ETL, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.
14. In the **Summary** field, enter a short description of your request.

    Example: `Run <product name> initial ETL in the <environment name> environment.`

15. In the **Description** field, enter a detailed description of your request.
16. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.
17. In the **Date Required By** field, select a value from the calendar.
18. Click **Submit**.

Schedule Incremental ETLs

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request.**

6. In the **General Information/Action** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Service Request > Application > General > Action**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the name of the server where you want to schedule the incremental ETLs, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want to schedule the incremental ETLs, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Schedule <product name> incremental ETLs in the <environment name> environment.`

15. In the **Description** field, enter a detailed description of your request.

    Example: Please schedule <product name> incremental ETLs to run every <number> hours in the <environment name> environment.

16. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

17. In the **Date Required By** field, select a value from the calendar.

18. Click **Submit**.

Re-initialize the ETL Process

Once an initial ETL process has been successfully executed on a database, it cannot be executed again until the mart environment is reset. To request this:

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **General Information/Action** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Service Request > Application > General > Action**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and then click **OK**.

10. In the **Business Service** drop-down, select the name of the server where you want to re-initialize the ETL process, and then click **OK**.

11. In the **Action** drop-down, select **Other**, and then click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want to re-initialize the ETL process, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Run re-initial <product name> ETL in the <environment name> environment.`

15. In the **Description** field, enter a detailed description of your request.

    Example: `Please run a re-initial <product name> ETL in the <environment name> environment.`

16. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

17. In the **Date Required By** field, select a value from the calendar.

18. Click **Submit**.

3

Dictionaries

In this chapter:

- Load Dictionaries
- Recode Dictionaries
  Recoding does not take place automatically following a dictionary upgrade. To recode your cases with the latest dictionary, you need to create a change request ticket in the Oracle Health Sciences Support.
- Use Dictionaries

Load Dictionaries

In this section:

- Before You Load Dictionaries
- How to Load Dictionaries
  To upload a dictionary file to Argus, you need to create a change request ticket in Oracle Health Sciences Support.

Before You Load Dictionaries

Your company must purchase a subscription license for the third-party dictionary software, as well as all the consents, permits, and authorizations necessary for Oracle to access and use the software on your company's behalf. Before Oracle can install the optional software, your company must provide evidence of such licenses, as well as a copy of the licensed software, if applicable. Your company is responsible for supporting third-party software, including the purchase of support contracts from third-party vendors, as applicable.

Third-party software includes:

- MedDRA dictionary subscriptions
- MedDRA J and J Drug dictionary subscriptions
- WHO Drug dictionary subscriptions

Oracle applies regular updates to third-party dictionary software, as follows:

Dictionary	Update interval
MedDRA and MedDRA J	6 months
J Drug	6 months
WHO Drug	12 months

How to Load Dictionaries

To upload a dictionary file to Argus, you need to create a change request ticket in Oracle Health Sciences Support.

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and then enter your user credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **Application Install/Change/Re-setup/Uninstall** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change - Cloud Environment > Application > Setup**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and click **OK**.

10. In the **Business Service** drop-down, select the name of the server where you want to load the dictionary files, and click **OK**.

11. In the **Action** drop-down, select **Other**, and click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want to load the dictionary files, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

    Example: `Load <WHO DRUG|MEDDRA|MedDRA J> dictionary in <environment>.`

15. In the **Description** field, enter a detailed description of your request. Make sure you specify whether the dictionary files are located on an sFTP server or attached to the change request.

16. If you have uploaded the dictionary files to an sFTP server, enter the location in the **sFTP path** field.

17. Select appropriate values from the **Severity** and **Implementation Window** drop-downs.

18. In the **Date Required By** field, select a value from the calendar.

19. If you want to attach the dictionary files to the change request, under **Attach Documents**, click **Browse**, and then navigate to your files.

20. Click **Submit**.

The Oracle team will upload the provided dictionary files to Argus.

> **Note:**
>
> • After the dictionary is uploaded, you need to select it in the Argus Console, so that it is available for coding.
>
> • You need to create one change request ticket per environment, for one dictionary. Therefore, to upload a dictionary file to the Production, Development, and Validation environments, you need to create three change requests tickets in total.

Recode Dictionaries

Recoding does not take place automatically following a dictionary upgrade. To recode your cases with the latest dictionary, you need to create a change request ticket in the Oracle Health Sciences Support.

> **Note:**
>
> • Recoding applies only to MedDRA and MedDRA J dictionaries.
>
> • Ensure that you have selected the latest dictionary from the Argus Console, after the Oracle team uploaded it in your environment.

1. Navigate to Oracle Health Sciences Support, at `https://hsgbu.custhelp.com/`.

2. Click **Login**, and enter your credentials.

3. Click **My Requests**.

4. In the upper left side of the screen, click **Change Requests**.

5. In the upper right side of the screen, click **Create a new Change Request**.

6. In the **Application Install/Change/Re-setup/Uninstall** tile, click **Create a Request**.

7. From the **Category** drop-down, select **Change - Cloud Environment > Application > Setup**, and then click **OK**.

8. In the **Select Customer** drop-down, either type the name of your company in the search field or select it from the list, and then click **OK**.

9. In the **Select Product** drop-down, select **Argus Safety**, and click **OK**.

10. In the **Business Service** drop-down, select the name of the server where you want the dictionary recode to be performed, and click **OK**.

11. In the **Action** drop-down, select **Other**, and click **OK**.

12. From the **Oracle Internal** radio buttons, select **No**.

13. In the **Environment** drop-down, select the environment where you want the dictionary recode to be performed, and make sure your selection is consistent with the value you selected in the **Business Service** drop-down above.

14. In the **Summary** field, enter a short description of your request.

Example: `Recode <MEDDRA|MEDDRA J> dictionary in <environment> in <view-only|update> mode.`

15. In the **Description** field, enter a detailed description of your request, including any MedDRA recoding tool parameters, if applicable.

    You can also instruct Oracle to provide you with a log of the recode process.

16. Select the appropriate values from the **Severity** and **Implementation Window** drop-downs.

> ✎ **Note:**
>
> - All users are expected to close the opened cases before recoding starts, to avoid any errors.
>
> - Usually, view-only recoding does not require downtime. However, if you don't want users to open cases while the recoding is in progress, specify that you want the Argus application to be inaccessible during the view-only recoding process and provide the downtime information.
>
> - Take into account that the process of update-mode recoding requires at least four hours of downtime. For this case, plan the downtime during weekdays for the Validation and Development environments, and during weekend for the Production environment.
>
> - The downtime duration may vary depending on the data volume in your environment.

17. In the **Date Required By** field, select a value from the calendar.

18. Click **Submit**.

The cases will be updated based on the uploaded dictionary in the specified environment.

To recode your cases based on a dictionary, you need to create two change request tickets for each available environment, one for the view-only mode and one for the update mode. Therefore, for the Production, Development, and Validation environments you need to create six change request tickets in total:

1. One change request ticket for the view-only mode recoding, where you ask Oracle to generate a file with the existing cases that will include the new coding. As a result, you will obtain a file with all the cases that will be changed. You can review the changes and make sure that the cases are properly updated.

2. One change request for update mode recoding, where you ask Oracle to recode the cases based of the new dictionary for the specified environment. As a result, the cases will be updated based on the new dictionary in the environment.

Use Dictionaries

For information on how to use dictionaries, see the *Oracle Argus Safety Administrator's Guide* on the Oracle Argus Safety Documentation page, at `https://docs.oracle.com/en/industries/health-sciences/argus-safety/index.html`.

4

Utilities

In this chapter:

Check Your License Compliance

The Argus Cloud Utilities - Usage Billing is an utility to add license usage counting capability.

You can generate the following reports:

- Case Perpetual Report (Whole Month Report) - This report counts the total number of new cases created over a specified period rolled down by each calendar month / year for the specified period.
- Case Subscription Report - This report counts the total number of new cases created over a specified period from the Subscription Start Date rolled down by quarter and pseudo month.
- User Perpetual Report (Whole Month Report) - This report counts the total number of new human users (that is, excluding system users) created in user tables over a specified period rolled down by each calendar month / year for the specified period.
- User Subscription Report - This report counts the total number of new human users (that is, excluding system users) created in user tables over a specified period from the Subscription Start Date rolled down by quarter and pseudo month.

For more information, see article 2584665.1 on My Oracle Support, at https://support.oracle.com/.

> **✎ Note:**
>
> To access knowledge base articles, you need to be logged in to My Oracle Support.

Refresh Your Data

The Argus Cloud Utilities - Data Refresh is an utility for automated Data Refresh and Restoration capabilities. This utility is to refresh the customer test environments (like DEV and VAL), in an automated way, to be in sync with Production data in the cloud, with little or no downtime and little or no manual intervention.

For information about data refresh and restoration from Argus Cloud production to non-production environments, see article 2394884.1 on My Oracle Support, at https://support.oracle.com/.

5
Extensibility

The Oracle Argus Cloud Utilities - Extensibility Framework is an utility that allows you to deploy and utilize custom database objects through a special customized schema, by leveraging the reporting and extensibility without impacting the out-of-the-box database objects supplied by Oracle Argus Safety.

For information on the Oracle Argus Cloud Service Extensibility and Integrations Framework, and the deployment process, see article *2399180.1* on My Oracle Support, at https://support.oracle.com/.

> **Note:**
>
> To access knowledge base articles, you need to be logged in to My Oracle Support.