

# Oracle Life Sciences Safety One Intake Cloud Service Release Notes



Release 23.3

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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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# Preface

This preface contains the following sections:

## 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>.

## Access to Oracle Support

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 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 <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

## 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.

# 1

## Introducing Oracle Safety One Intake

Oracle Life Sciences Safety One Intake Cloud Service is a cloud-based solution for automatically processing structured and unstructured source documents to extract adverse event data and convert it to safety cases.

The system is powered by artificial intelligence, machine learning, and natural language processing and significantly reduces manual data entry, allowing users to focus on high-value activities. It is built on Oracle Cloud Infrastructure (OCI), which supports high-performance workloads using modern architectures with high-capacity compute, including graphics processing units. It has a modern, intuitive, browser- and device-independent user interface with dashboards and metrics for reviewing operational performance.

Oracle Safety One Intake architecture follows the Oracle Argus Safety model for user management and data security. Common configurations are shared, allowing seamless behavior across the entire system and reducing operational overhead. Oracle Safety One Intake uses Argus Console for all intake configuration, and the applications use single sign-on (SSO) for authentication.

Oracle Safety One Intake 23.3 supports English for all intake processing.

## Compatibility and browser requirements

### Oracle Argus Safety compatibility

Oracle Safety One Intake 23.3 is a companion release for Oracle Argus Safety 8.4.1.

### Browser requirements

Browser	Resolution
<ul style="list-style-type: none"><li>Google Chrome version 116.0.5845.97</li><li>Microsoft Edge version 116.0.1938.54</li></ul>	Make sure the resolution display of your computer is above 1280 x 1024.

## Why do you need Oracle Safety One Intake?

Oracle Safety One Intake is designed to help you get all adverse event (AE) documents into Oracle Argus Safety as quickly and accurately as possible.

Here's how the application can help you work faster and more efficiently:

- You collect all your AE documents and upload them to Oracle Safety One Intake for processing.
- The application classifies your AE documents and extracts their data.
- If documents include free text, machine learning reads and extracts the information.
- The machine learning model can decipher how different pieces of information in the narrative are connected.

- Multiple specialized machine learning models can be used simultaneously to predict specific attributes of adverse events more accurately.
- You can review and correct the machine's extractions and predictions regarding AE data. The application uses the corrections you provide to generate training data for supervised machine learning.
- Oracle Safety One Intake sends the validated AE data to Oracle Argus Safety.

## What can you do in Oracle Safety One Intake?

Oracle Safety One Intake provides some key features you can use to extract AE data and convert it for use as Oracle Argus Safety cases.

Activities you can perform with Oracle Safety One Intake:

- [Upload AE documents manually](#)
- [Upload automatically via REST APIs](#)
- [Your to-do list, created automatically](#)
- [Validate and group documents](#)
- [Review and update your AE](#)
- [Create a new record](#)
- [Monitor the workload](#)
- [Track changes through an audit log](#)

## Manual upload of an AE document

Oracle Safety One Intake streamlines the processing of AE documents and converts raw data into meaningful information.

You can specify the originating site to which the source document belongs.

When you upload a new AE document, Oracle Safety One Intake determines the document type and uses artificial intelligence to extract structured and unstructured data.

The application runs basic checks on uploaded documents, including for malware, file size, and file type.

The default permissible file types for document upload are XLS, XLSX, DOC, DOCX, TXT, VSD, TIF, TIFF, RTF, PSD, PS, PNG, PDF, MDB, JPG, BMP, XML, SGML, SGM, MSG, GIF, JPEG, WPD, ZIP, DICOM, DCM, CSV, and PPT. You can customize the file types in Oracle Argus Safety: `Console > Common Profile Switch: Case Processing > Valid Attachment File Types`.

The default permissible maximum file size for document upload is 30 MB. You can adjust this setting in Oracle Argus Safety: `Console > Common Profile Switch > Case Form Configuration > Attachment File Size Limit (in Megabytes)`.



**Note:**

OCR extraction is supported exclusively for image-based documents, such as faxes or scanned documents, and applies only to DOC, DOCX, and PDF files.

## Automatic upload via REST APIs

Oracle Safety One Intake provides a set of REST APIs you can use to ingest documents automatically from third-party systems and applications.

When you upload documents through the REST APIs, you can set various parameters in the call that specify how the documents are handled:

- You can specify the originating site and the source of the document.
- You can indicate whether the document requires manual validation.
- For multiple documents, you can specify whether the documents are intended for a single potential case or whether each one represents a separate potential case.
- For multiple documents intended for a single potential case, you can specify which document requires OCR processing.

Documents uploaded through REST APIs adhere to the same rules and processing mechanism as documents you upload manually.

## Your to-do list, created automatically

Oracle Safety One Intake provides an Intake Worklist view that offers you a structured display of AE documents flagged for manual intervention. You can use this worklist as your to-do list.

You can apply filters and sorting options to your worklist to effectively manage your tasks, and you can easily determine the required action that needs to be performed on an intake item or record. In addition, you can personalize your worklist by choosing the columns you want to display.

The worklist inherits the site security configured in Argus Console for the logged-in user.

As a workflow manager, you can view an aggregate list of intake records and assign them to the right users or groups.

## Validate and group documents

You can review and validate incoming records and manage any that consist of multiple documents by grouping them into potential cases.

Records that the system flags for validation appear in the intake worklist with their task set to **Check Validity**.

In cases where a record has multiple documents, you can group the documents into one or more potential cases. You can also designate a document for OCR extraction.





**Note:**

For multiple documents within one potential case, only the document you designate will undergo the OCR extraction process.

## Review and update your AE

If Oracle Safety One Intake has a low level of confidence in data extraction, or required data is missing, it flags the document for manual review.

The records that the system flags for manual review appear in the intake worklist with their task set to **Review Record**.

During manual review, you can verify the extracted data and view the source document indicating the location of the extraction.

You can view the confidence score of the extracted data, confirm or correct it, and provide any missing information before submitting it to Oracle Argus Safety. Additionally, you can annotate AE data elements that the system has not identified.

## Create new records

If the system cannot automatically identify a document for extraction, it sets the task for the corresponding files to **Create New Record** in the intake worklist.

You can view the source document and the AE form side by side, allowing you to complete the AE form efficiently. You can then submit the AE document to Oracle Argus Safety.

## Monitor the workload

As a workflow manager, you can monitor the workload in Oracle Safety One Intake through an aggregate view of end-to-end intake processing.

You can see system metrics representing the most important key performance indicators (KPIs) as charts and drilldown views.

You can ensure that any record that comes into the system has been processed to conclusion within the system-defined SLA (24 hours, including holidays and weekends). You can easily identify if any records in the system are in danger of exceeding the SLA.

You can trace any record that enters the system, get real-time status updates on it, and track any user activity to do with the record. At any stage, you can take action to ensure the record is processed successfully.

## Audit log

Oracle Safety One Intake tracks all operations performed on AE data.

All Oracle Safety One Intake activities related to an ingested record, including user changes and system events, are captured in an audit log. You can download and view the audit information for any record in the system.

## How does Oracle Safety One Intake work with Oracle Argus Safety?

Oracle Safety One Intake transmits intake records as XML to Oracle Argus Safety for processing.

Oracle Safety One Intake submits files to Oracle Argus Safety in one of the following formats:

- **Converted XML reports:** The E2B R3+ XML transformed by Oracle Safety One Intake from documents uploaded as PDF, DOC, DOCX, and other file types.
- **Enriched XML reports:** E2B R2 or R3 XML files uploaded into Oracle Safety One Intake.

XML files are submitted through the Oracle Argus Safety REST API. These XML files are processed in a similar way to E2B Intake in Oracle Argus Safety. Oracle Argus Safety processes these incoming reports through the existing Auto-Accept mechanism or ICSR Pending screen.

A new ICSR profile, SAFETY ONE ARGUS TEMPLATE E2B R3+, has been introduced to process converted XML reports. For more information on the attributes of this profile, refer to the following Oracle Argus Safety 8.4.1 eTRM document:

*ArgusInterchange841\_SAFETY\_ONE\_ARGUS\_E2B (R3+) Mapping.xlsx*. See also [How to obtain eTRM documents](#).

Enriched XML reports are processed according to the existing ICSR import logic for the respective profiles.

If the reports are not auto-accepted by Oracle Argus Safety, they are displayed in the ICSR Pending screen and are available to be accepted as a case. The site displayed for these reports is the one specified in Oracle Safety One Intake.

You can review the incoming files, search for duplicates, and view differences as you can for any E2B report in Oracle Argus Safety.

After the ICSR reports from Oracle Safety One Intake are accepted or rejected, an acknowledgment is sent to Oracle Safety One Intake. It includes the case number if the report is accepted or the justification if the report is rejected.

The original documents ingested into Oracle Safety One Intake are provided as attachments under `Case > Additional Information > Notes and Attachments` with relevant notes added for various document types. The intake ID specified in Oracle Safety One Intake is available under `Case > Additional Information > References` for tracing the corresponding intake record.

### How to obtain eTRM documents

Oracle provides some documents as Electronic Technical Reference Manuals (eTRMs). eTRMs are available as downloads from My Oracle Support, and they require a password, which you can get by opening a service request. For links to the appropriate My Oracle Support page, see <https://docs.oracle.com/en/industries/life-sciences/argus-safety/8.4.1/astrmee.html>.

## System monitoring

The Product Verification Pack (PVP) is a collection of product release documents designed to help our customers with their validation efforts.

Oracle Safety One Intake administrators have access to Oracle Identity Cloud Service reports, which provide comprehensive information related to application access and users, for example the number of successful or failed logins. Reports on system diagnostics are also available. For more information, see <https://docs.oracle.com/en/cloud/paas/identity-cloud/uaid/run-oracle-identity-cloud-service-reports1.html>.

# 2

## Enhancements to Oracle Argus Safety

The following enhancements have been made to Oracle Argus Safety 8.4.1 to support Oracle Safety One Intake 23.3:

[Intake module](#)

[Intake numbering](#)

[User roles for Oracle Safety One Intake](#)

[Code list updates](#)

### Intake module

Oracle Argus Safety 8.4.1 includes an Intake module to support Oracle Safety One Intake.

This module is enabled during the onboarding process. You can view the list of modules enabled in your environment through [Argus Safety > Console > System Configuration > Enabled Modules](#).



#### Caution:

Oracle recommends not changing the default settings of the Intake module.

### Intake numbering

In Oracle Argus Safety 8.4.1, you can define the format of the unique identifier assigned to the intake records in Oracle Safety One Intake.

You can configure the settings on the Intake Numbering screen from the [Argus Safety Console > System Numbering > Intake](#) menu.

Make sure the System Numbering menu and its child menu, Intake, are enabled from [Argus Safety Console > User Group](#).

#### Intake numbering format

The following attributes can be used to define the intake numbering format so it corresponds with the system numbering format:

Placeholder Code	Placeholder	Recommended characters for each placeholder
SSS	Site	3
DD	Day	2
MM	Month	2
YY	Year	2

Placeholder Code	Placeholder	Recommended characters for each placeholder
#####	Numeric sequence*	Numeric sequence

### Understanding the intake numbering format

- Each placeholder must be defined within square brackets, for example [SSS].
- The default numbering format is [SSS][YY][MM]-[#####].
- Only automatic numbering is possible.
- You can start a new sequence for the following attributes in the numbering format:
  - Separate sequence for each site
  - Separate sequence for each month
  - Separate sequence for each year

 **Note:**

If a separate sequence for Month is selected, a separate sequence for Year is auto-selected.

## User roles for Oracle Safety One Intake

New roles have been introduced in Oracle Argus Safety to support Oracle Safety One Intake.

- Intake Processor - Enables the user to access and process ingested documents in Oracle Safety One Intake. This role is required for accessing the Oracle Safety One Intake UI. In combination with the Workflow Manager role, it exposes additional features in the UI.
- Intake Designer - Enables the user to push the document processing recipes into the Oracle Safety One Intake system.

The existing Workflow Manager role has been enhanced to allow the user to assign intake records, monitor their progress in Oracle Safety One Intake, and make sure they are completed within the defined SLA.

## Code list updates

Oracle Safety One Intake and Oracle Argus Safety share the Oracle Argus Safety Console. Oracle Safety One Intake uses the code lists from Oracle Argus Safety where applicable.

The following changes have been made to the Oracle Argus Safety Console code lists. For more information, refer to the eTRM document *Argus\_Safety8.4.1-S1A23.3\_CaseForm\_Console\_Updates\_Summary.xls*. See [How to obtain eTRM documents](#).

### Attachment classification

New values have been added to the Attachment Classification code list to support Oracle Safety One Intake.

- Source File
- Supporting
- Other Document Imported

You can access this code list from `Argus Safety > Console > Code Lists > Argus > Attachment Classification`.

### Media Type

The following attachment types have been added to the Media Type standard code list to support additional media types accepted in Oracle Safety One Intake.

Attachment Type	Media Type
PD	application/pdf
ZIP	application/zip
DCM	application/dicom
CSV	text/csv

The mapping of these values with agencies is NULL as these will not be used for outgoing AE reports to the agencies.

You can view the MIME type from `Argus Safety > Console > Code Lists > Flexible Data Re-Categorization > Flexible Data Re-Categorization > MEDIATYPE > en` (column).

### Justification

When an invalid document is rejected, a justification must be provided. To support this behavior, the following values have been introduced for type Intake Rejection Justification in the Justifications codelist:

- No Company Product
- Non-AE Document
- Other

### Intake Source

A new flexible code list named `INTAKE_SOURCE` has been introduced to add external third-party systems and applications as sources. Additionally, this code list facilitates the configuration of processing rules for AE documents received from these sources.. You can view this code list and its values in `Argus Safety > Console > Code Lists > Flexible Data Re-Categorization > Flexible Data Re-Categorization`.

 **Note:**

Safety One Intake accepts AE documents for automatic ingestion only from the sources that have been added to the Intake Source code list.

Source name	Source type
User Upload	0

The attributes Triage Required and Multi-Case are used to configure processing rules.

- When Triage Required is set for a source, the processing skips the Check Validity step.
- If Multi-Case is set for a source, each document is treated as a separate potential case; otherwise, all documents correspond to one potential case.

# 3

## Known issues in Oracle Safety One Intake

This section lists known issues in this release of Oracle Safety One Intake and provides workarounds where available.

### **Issue 35097191**

In the Intake Workload screen, the list of selectable search values loads slowly for filter categories that have a large number of choices, for example **country**.

Workaround: Wait a few seconds for the list to load.

### **Issue 35096651**

In the Check Validity screen, if you search in the **Move to Group** dropdown list but then close and reopen the dropdown list with the ESC key, the filter no longer functions as expected. Instead of presenting the filtered results you searched for, the system shows all available groups.

Workaround: None.

### **Issue 35297584**

On the Intake Monitor screen, if you select multiple sections from different graphs, the selections are not cleared correctly. For example, if you select a section from the **24h by Site** chart and then click a section in the **24h by Type** chart, the application does not remove the first selection.

Workaround: Click on the area outside a chart to clear your selection.

### **Issue 35420718**

Updates made to code list values are not reflected in the Intake Worklist and Intake Monitor screens. Similarly, when a user's configuration is modified to remove them from a group, the records assigned to that user continue to appear in the worklist of the users of their previous group. The behavior persists until the records are reassigned.

Workaround: There is no workaround for the code list update issue on the Intake Worklist and Intake Monitor screens. To avoid the issue with removing a user from a group, it is recommended that you unassign or reassign records before changing user group settings. If you skip this step, the solution is to filter the records associated with the removed user and reassign them.



# 4

## Oracle Safety One Intake Product Verification Pack (PVP)

The Product Verification Pack (PVP) is a collection of product release documents designed to help with your validation efforts.

The PVP is used by Oracle for certification purposes, and Oracle makes the pack available to customers with every release (except patches). You can use the PVP as a blueprint for acceptance testing.

The PVP for Oracle Safety One Intake is available on [My Oracle Support](#). For information on how to download a PVP, follow the instructions in [Oracle Argus Product Verification Pack](#). The patch containing the PVP for Oracle Safety One Intake is **35790103**.