



Oracle Life Sciences

# Safety One Intake Cloud Service

## Service Descriptions and Metrics



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## METRIC DEFINITIONS

### **Safety Source Document – Pooled Capacity**

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Safety Source Document is defined as a document processed by the Oracle Life Sciences Safety One Intake Cloud Service including but not limited to an email, fax, E2B report, regulatory report, call center and/or customer complaint report, case series, literature review, signal analysis, clinical trial report, and/or social media post. “Pooled Capacity” means the quantity purchased is a pool of Safety Source Documents that may be processed over the duration of the Services Period.

## GLOSSARY

### **Production Environment**

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Production Environment is defined as an environment provided to You as part of the Oracle Cloud Service that is designed for daily commercial use and production operations of live data. Unless otherwise specified, a single Production Environment is provided for an Oracle Cloud Service.

## SERVICE DESCRIPTIONS

### Oracle Life Sciences Safety One Intake Cloud Service – Safety Source Document – Pooled Capacity

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**Part #: B92051**

#### Modules and Features

Users of the Cloud Service are authorized to access the following modules:

- Oracle Life Sciences Safety One Intake

#### Pre-Requisites

This Cloud Service is intended for use with Oracle Life Sciences Argus licensed software on version 8.4.2 or higher.

You are responsible for deploying and maintaining Oracle Cloud Infrastructure (OCI) GoldenGate (for source system only) in order to replicate essential data from Argus to Oracle Life Sciences Safety One Intake.

#### Environments

The Cloud Service includes one (1) Production Environment and (2) Non-Production Environments.

#### Usage Limits

This Cloud Service is subject to usage limits based on:

- The quantity of Safety Source Documents specified in Your order.
- If all Safety Source Documents purchased are used prior to the end of the Services Period, You may purchase additional quantity. Safety Source Documents which have not been used by the end of the Services Period will expire and may not be rolled over.
- A Safety Source Document has maximum size limit of 100 pages. Any pages in a Safety Source Document in excess of 100 pages count as additional Safety Source Document(s) in increments of 100 pages. For example, 300 pages will count as three Safety Source Documents. One page is equivalent to one side of a single sheet of paper.

#### Disaster Recovery and Service Availability

As described in the Oracle Cloud Policies, this Oracle Cloud Service has the following Recovery Time and Recovery Point Objectives and Target Service Availability Level for the Production Environment:

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SYSTEM AVAILABILITY
12 hours	1 hour	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third-party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

## **System Access**

For single sign-on (SSO) functionality the Cloud Services are deployed with Oracle Identity Cloud Service (IDCS). You are responsible for performing user management for Your Users using IDCS.

## **Oracle Cloud Policies**

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at [www.oracle.com/contracts/cloud-services/](http://www.oracle.com/contracts/cloud-services/).

## **Retrieval of Your Content and Information**

Oracle will make Your Content from the Cloud Service available for the purpose of data retrieval by You as provided below, in accordance with Your Agreement and the Oracle Cloud Policies.

- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies.

Oracle will make the information below for the Cloud Service available for retrieval by You as provided below, in accordance with Your Agreement and the Oracle Cloud Policies.

- Support service request information is available via the Oracle Life Sciences Support Cloud. You are responsible for requesting and retrieving such information as needed to address your record retention purposes.
- Where required You may request a listing of user logon activity to the Cloud Service via a Service Request through the Oracle Life Sciences Support Cloud.