

Oracle® Argus Safety Service

Administrator's Guide

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Oracle Argus Safety Service Administrator's Guide Release 8.1.1

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Preface

This book describes the Argus Service process, including Safety Service configuration and Safety Process configuration.

Where to Find More Information

Oracle Help Center

The latest user documentation for Oracle Health Sciences products is available at <http://docs.oracle.com/en/industries/health-sciences/>.

My Oracle Support

The latest release notes, patches and white papers are on My Oracle Support (MOS) at <https://support.oracle.com>. For help with using MOS, see https://docs.oracle.com/cd/E74665_01/MOSHPTOC/toc.htm.

Revision History

September 2017: Updated format for OHC. No content change.

Documentation Accessibility

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Argus Safety Service Overview

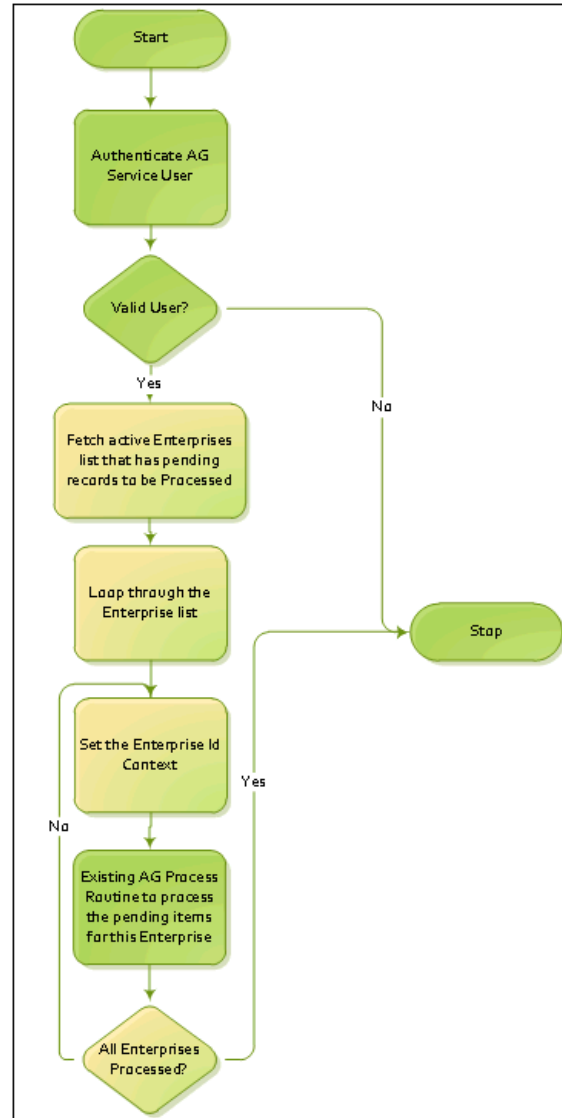
The Argus Safety Services are a suite of processes that run to reduce the load on the front end experienced by perform complex process in the background. These processes that performing several tasks in the background. Argus Safety Service Configuration provides an interface to configure these processes.

The following table describes each of the major steps that should be followed to configure Argus Safety Service:

Task	Description
Understanding Tasks	Ensure that Argus Safety has been configured so that the Argus Safety Service processes can be configured. Refer to the Argus Console User Guide for details on configuring Argus Safety.
Configuring Argus Safety Process	Specify details for scheduling Argus Safety Service processes.

Argus Safety Service in a Multi-tenant environment

Each Argus Safety Service processes the data for all enterprises. It does not need to be segregated by enterprises as it is not meant for the end users and is maintained by the CRO Administrator or Hosting provider.



While performing any single task at a time, Argus Safety service will not inter-mix data from multiple enterprises.

The user configured to run any Argus Safety Service task must belong to all enterprises as these tasks have to process records for all the enterprises.

Understanding the User Interface

You can create Argus Safety processes configure existing processes from the **Argus Process** dialog box.

Argus Process Dialog Box Fields and Field Descriptions

Item	Description
Name	Enter the name of the Argus Safety Process.
Process	Browse to the Argus Safety Service Installation folder and select the AGProc.exe file.
Task	Select the task to run that is associated with the Name entered in the first field.
Start Time	Enter the Initial Start Time for the Process. After the initial starting, the process will follow the Interval set in the next field. If Start Time is not selected, the process will begin immediately after starting the service.
Interval	Enter the frequency at which the process will be executed.
Suspend	If a process is running for a period that is longer than what is specified in this field and the memory consumption of the process is below the Low Water Mark specified in the next field, then the process will be terminated. Default for 5 Minutes is the ideal setting and should not be changed.
Low Water Mark	The Low Water Mark setting works with the Suspend field above. The Default setting of 200 is ideal and should not be changed.
Database	Enter the database name.
User Name	Enter in the Argus Safety Service User name that the process will connect to the system as. These users should be configured before using this utility. Each Process requires its own user configured to run.
Password	Enter the password that has been configured for the user entered above.
Confirm	Re-enter the password that has been configured for the user.
Failure Email	If a process fails, an email is sent to the address specified in this field.
Fax	
(Note: This section is enabled only if Fax or Fax Status is selected in the Task list)	

Item	Description
Server	Enter the Fax Server name that the Fax Process will be using to submit faxes with. This field will only be enabled if the Task selected is either FAX or FAX STATUS.
Notify Email	Enter the Email Address of the Administrator that will receive the email in the event that Argus Safety Service can not access the Fax Server.
User Name	Enter in User name that the fax will connect to the system as.
Password	Enter the password that has been configured for the user entered above.

Understanding Tasks

The **Task** list in the **Argus Process** dialog lists the different items for which processes can be created.

Task Descriptions

Item	Description
Auto Accept E2B Reports	<p>When ESM Service receives incoming E2B reports and the Argus Console for the electronic recipient is configured to auto accept in Reporting Destination with the AGService Process, then AGService auto accepts the E2B reports.</p> <p>The process creates a case for Initial reports or updates the case for follow-up reports received in a Queue. After auto accept, the system moves the reports to "E2B Processed" screen and ESM Service generates an Acknowledgment.</p>
Audit Log Export	<p>Argus Safety allows the export of Audit Data to a table in a format that is readable by a user.</p> <p>This process exports up to 2000 cases at a time. After 2000 cases have been exported, the process shuts down and starts again at the next scheduled interval.</p>

Item	Description
Audit Log Update	<p>Argus Safety allows auditing of data which are updated through database scripts. The Audit Log Update process updates the Audit Log, based on the item stored in the queue.</p> <p>This process audits up to 500 audits in a row. After 500 Audits have been completed, the process shuts down and starts again at the next scheduled interval.</p>
AutoSignal	<p>Argus Safety allows the configuration of Signals. Signals can be used to detect events that can be configured using Advanced Conditions. Argus Safety Service will automatically check for triggered events and notify a selected user of the event.</p>
Batch Report Generation	<p>The Batch Report Generation process eliminates the process of a user having to manually generate a report during a case workflow. Rules can be setup in Argus to have reports automatically generated on a scheduled basis.</p> <p>Using this process speeds up the day-to-day tasks for the end user by moving the Report Generation Load to the Argus Safety Server.</p> <p>This process executes batch jobs in the ascending order of Due Date of the report (Earliest Due First). It processes 10,000 reports in a day at a minimum.</p> <p>For details about the Batch Report Generation process, see Batch Report Generation Process.</p>
Batch Memorized Reports	<p>The Batch Memorized Reports process allows users to have System Reports such as Case Listing Reports and Case Data Analysis Reports automatically-generated, based on a pre-configured report.</p>
Batch Aggregate Reports	<p>The Batch Aggregate Reports process executes the CDA, Case Listing and CIOMS II Line Listing Aggregate Reports in the background thereby reducing the load on the Web server and avoiding unnecessary user wait time for report generation.</p> <p>Only standard PDF and CSV output formats use this AG Service. The CDA chart output continues to run in the synchronous mode only.</p>
Batch Periodic Reports	<p>The Batch Periodic Reports process removes the need to remember to schedule, generate and submit IND, NDA and PSUR Reports. Periodic Reports can be automatically scheduled and generated on a schedule configured based on the License Award Date.</p> <p>Using this process also speeds up day to day tasks for the end user by moving the Report Generation Load to the Argus Safety Server and off the Web Server.</p> <p>This process executes batch jobs in the ascending order of Due Date of the report (Earliest Due First). It processes 10,000 reports in a day at a minimum.</p>
Batch Report Case	<p>Batch Report Case allows users to run reports on a scheduled date.</p>
Bulk Report Print	<p>Prints the reports from a particular enterprise to the printer configured for that site in Console for that enterprise.</p>
Bulk Report Transmit E2B	<p>When a user transmits an E2B Report from "Bulk Reporting" screen, this AGService generates the E2B Report, if not previously generated, and transmits the report to ESM Service. The ESM Service creates a report in the outgoing folder, depending on the configuration.</p>

Item	Description
Bulk Report Transmit Email	<p>Argus Safety supports Bulk Submission of reports for e-mailing. The Bulk Report Transmit Email Process will automatically generate, submit (if the report has been marked for submission) and e-mail reports based on the e-mail address configured for the Report Submission Authority.</p> <p>Using this process speeds up day-to-day tasks for the end user by moving the Report Generation and Emailing Load to the Argus Safety Server. Argus Safety Web requires this to process Emails.</p> <p>This process e-mails up to 1000 reports in a row. After 1000 e-mails have been sent, the process shuts down and start again at the next scheduled interval.</p> <p>This process executes batch jobs in the ascending order of Due Date of the report (Earliest Due First). It processes 10,000 reports in a day at a minimum.</p>
Bulk Report Transmit Fax	<p>Argus Safety supports Bulk Submission of reports for faxing. The Bulk Report Transmit Fax Process will automatically generate reports for Fax Submission via Fax. Argus Safety Web requires this process to have the ability to fax.</p> <p>This process faxes up to 1000 reports in a row. After 1000 faxes have been completed, the process shuts down and starts again at the next scheduled interval.</p> <p>This process executes batch jobs in the ascending order of Due Date of the report (Earliest Due First).The process processes 10,000 reports in a day at a minimum.</p>
Documentum Report Push	Refer to Argus Console for storing submitted expedited and periodic reports into Documentum.
Dossier Notification	After a PSUR report is generated and if Dossier is enabled, this process sends e-mails to all users who are members of groups with assigned roles for periodic reports.
Fax	The Fax Process will automatically transmit fax reports processed by the Bulk Report Transmit Fax Process for Submission.
Fax Status	The Fax Status Process will continuously check for the status of the Fax Submission to update Argus Information. This process is required to be running if the Bulk Report Transmit Fax Process is enabled.
Forced Report	When forced reporting is configured, this Argus Safety Service sends out forced expedited reports, based on configured reporting rules. This task has a dependency on the Scheduling Check task, so both must be configured.
General Email	<p>This process sends all the Workflow Routing emails which can be configured within the Workflow Configuration.</p> <p>It also sends all the Investigator Alert emails which can be configured within the Study Configuration as defined in the Investigator Group configuration.</p>
General Fax	This service is used when a fax service is configured to transmit faxes. It transmits pending faxes in the queue of faxes that are waiting to be sent.
Letter Generation	When letters are configured to be sent based on the case data and configured criteria, this service auto generates letters from cases where the Contact Date has been reached.
Local Labeling Report Scheduling	<p>The Local Labeling Report Scheduling process automatically schedules reports based on the Regulatory Rules configured in Argus for licenses that are marked as processed from the Local Labeling dialog.</p> <p>Report Scheduling occurs in the order of the Case Master Follow up Date or the Initial Receipt Date if Follow up is null. This is in ascending order of the Aware Date of the case.</p>

Item	Description
Priority	<p>The Priority Process re-assesses all case priorities based on the Priority rule configuration in Argus. Using this process prevents cases from being reported on late by escalating the priority of the case which is visible by the users on the Argus Worklist, Case Form and other areas.</p> <p>In addition to raising priority, an escalation email will be sent to the supervisor of the group if a case is not routed to the next workflow state within a specified amount of time configured in the Workflow Rules.</p>
Report Scheduling	<p>The Report Scheduling process automatically schedules reports based on Regulatory Rules configured in Argus for new cases. In addition, cases requiring follow-up reports are also evaluated.</p> <p>Priority for new cases entered into the system is assessed from the Report Scheduling Process. After the Initial Assessment, the PRIORITY process will reassess the priority based on changes made to the case if the process is running.</p>
Scheduling Check	<p>Argus Safety will allow forecasting of reports that may be due within a specified amount of time for cases that have not been locked and do not have reports scheduled.</p>

Note: When Argus Safety Service sends an email to the local email client or print job to Adobe Acrobat, it marks the report as "Success". If the email client fails to send the email to the Server or the OS fails to print the report to the printer due to network issues or configuration issues outside of Argus, the status will not be changed to "FAILED".

It is prudent to add a manual process to confirm that the email client and print queue outside Argus Safety Service are functioning on an on-going basis.

Batch Report Generation Process

Parallel processing has been introduced into the Batch Report Generation AG Process to enable its improved performance.

This has been made possible by introducing a new AG process called BATCH REPORT GENERATION WORKER.

The Batch Generation Argus Safety Service process has been split into two separate processes:

1. BATCH REPORT GENERATION
2. BATCH REPORT GENERATION WORKER

Both the above processes need to be configured to generate Batch Reports.

Note: The configuration for BATCH REPORT GENERATION remains the same as is.

In addition to the above process, you need to now configure the new BATCH REPORT GENERATION WORKER process as well.

Multiple instances of the new BATCH REPORT GENERATION WORKER process must be configured either on the same AGService box, or on multiple Argus Safety Service boxes, to achieve better performance.

If multiple instances are configured, each process of type "BATCH REPORT GENERATION WORKER" should be configured with a different Argus Safety Service user.

Details

The The BATCH REPORT GENERATION process will populate the reports (Expedited Reports only) that need to be processed by the BATCH REPORT GENERATION WORKER in a new table BATCH_GENERATION_QUEUE.

The Report IDs from CMN_REG_REPORTS are used to populate this new table. The status column in this table indicates to the batch report generation and worker processes about how to process the corresponding reports.

It will have one of the following values:

Value: Status	Denotes that..
0: Pending	The record has been populated by the Batch Report Generation process but has not yet been picked up by the Worker process.
1: Processing	The record has been picked up by a worker process for generation.
2: Completed	The report has been successfully generated.
3: Failed	The report generation failed.

If the report generation fails, another record for the same Report ID is inserted in the queue table during the next run of the BATCH REPORT GENERATION process so that the Report generation is tried again.

At any point of time, there will not be more than two records in the queue table with the same REG_REPORT_ID.

If a record in the queue table remains in Status "1" for more than 2 hours, then the Status is marked as "3" during the next run of BATCH REPORT GENERATION process.

The records with Status "2" get removed in the next run of the BATCH REPORT GENERATION process.

The records with Status "3" get retried once by the process.

After that, the report is not retried for 8 hours and will get removed after the 8 hour window.

Note that the failed records are kept for 8 hours in order to prevent the same record, which may have failed due to configuration or data issues, being retried continuously.

Once the failed records are cleared after 8 hours, the report will be retried for generation. The 8 hour cycle will repeat indefinitely until the report generates successfully or until the report is deleted.

For expedited reports that are set to generate on DLP, when the BATCH REPORT GENERATION process runs and sees that there are still DLP Reports yet to be picked by a worker process or is still being generated, it will exit without adding any more DLP reports to the queue.

Once all the DLP reports (RUN_ON_DLP = 1) are processed (i.e., have STATUS = 2 or 3), the BATCH REPORT GENERATION process will insert more DLP reports to the queue table.

Note: The logs of Success/Failed count for the Batch Generation process are now distributed across multiple processes. Getting a cumulative count is not possible. Customers need to check the BATCH_GENERATION_QUEUE table to see if there are failed records which have failed consistently.

The following table lists the structure of the queue table:

Batch_Generation_Queue				
Column Name	Data Type	Nullable	Primary Key	Comments
ID	NUMBER	No	1	This is the Primary Key of the table, and the values come from the sequence S_BATCH_GENERATION_QUEUE.
BATCH_ID	NUMBER	No		This column holds the value of BATCH_ID which comes from CFG_REPORT_SCHEDULE.ID
PROCESSING_USER_ID	NUMBER	No		This column holds the value of the AGService User ID of the process which picks up this record for processing.
STATUS	NUMBER	Yes		This column can hold the following values: 0:Pending, 1: Processing, 2: Completed, 3: Failed.
REG_REPORT_ID	NUMBER	No		The data for this column comes from CMN_REG_REPORTS.REG_REPORT_ID
REPORT_FORM_ID	NUMBER	Yes		The data for this column comes from CMN_REG_REPORTS.REPORT_FORM_ID
SESSION_USER_ID	NUMBER	Yes		For Non-DLP Reports, the value for this column is the AGService User ID. For DLP Reports, it is the Lot User ID.
STATE_ID	NUMBER	Yes		The data for this column comes from CMN_REG_REPORTS.STATE_ID
LAST_PROCESSING_TIME	DATE	Yes		The time at which the record was last picked up for processing.
RUN_ON_DLP	NUMBER	Yes		The value of 1 means the report generation should run on DLP. If not, the value should be 0.

Batch_Generation_Queue				
Column Name	Data Type	Nullable	Primary Key	Comments
ERROR_TEXT	VARCHAR2 (4000 CHAR)	Yes		<p>The worker process generates the reports and if it fails, it updates the error text (if any).</p> <p>However, for E2B reports, the worker process just delegates to PDP for generation.</p> <p>The PDP generates the reports asynchronously. The worker process does not know whether the report generation has been successful. Hence, it sets the error_text as "Success value not available", and leaves the record there itself.</p>

Configuration

Some of the parameters described above (such as the 8 hour cycle, the number of times the failed reports get retried, etc.) can be controlled through settings in agservice.ini.

More information can be found in the Default values that have been listed below:

[Batch Generation Configuration]

Max Retry Attempts = 1

This is the number of times that a given reg_report_id gets added in the queue in a given 8 hour slot. It gets added only if the first attempt results in a failure (status = 3).

The above setting indicates that if a report fails during generation, another record for the same report id is added to the queue table for the same reg_report_id, in spite of the failed record still being there in the queue (with status = 3).

This enables the report generation to be retried. If the second attempt also fails, then that report is not added to the queue again, until the queue is cleared (which happens once in 8 hours).

[Batch Generation Configuration]

Max Failed After Minutes = 120

This value is used to identify crashed reports. If a report in the queue is still in status 1 (which means "in processing") even after so many minutes, it means that the EXE would have crashed.

Configure this value to the maximum number of minutes that a report generation would take in your environment, plus 1.

[Batch Generation Configuration]

Clear Failed Records After Hours = 8

Failed reports are not inserted multiple times (for more than the configured number of retries) as long as they remain in the queue table (with status 3).

However, these records are automatically deleted after 8 hours. This is done to enable retrying the failed records again.

In the duration of 8 hours, there is a possibility that users would have corrected the case data and the reports might succeed now.

Set this value to a realistic number, as applicable.

If you set the value to an unrealistic number, in case of any report failures because of data problem, the Argus Safety Service Process continues attempting the generation of the same report again and again, thus blocking other newer reports from getting generated.

[Batch Generation Configuration]

Max Iterations = 10

This is the number of reports that a worker process tries to generate in a single run. When the worker process gets instantiated, it locks one record at a time from the queue table, and starts processing it.

Some of the reports may fail, while the others may succeed. After processing the configured number of reports (default 10), the process exits.

The next instance of the worker process comes up after the time interval that has been configured in the AGConfig utility.

Configure the above value to a higher number if the process has enough speed to generate more number of reports in the time duration before the next instance of the process starts.

You must also ensure that you verify when the agproc.exe is using maximum memory and becoming slow.

If you find that the EXE would consume a lot of memory and might slow down by the time it generates 20 reports, then configure the number to something smaller.

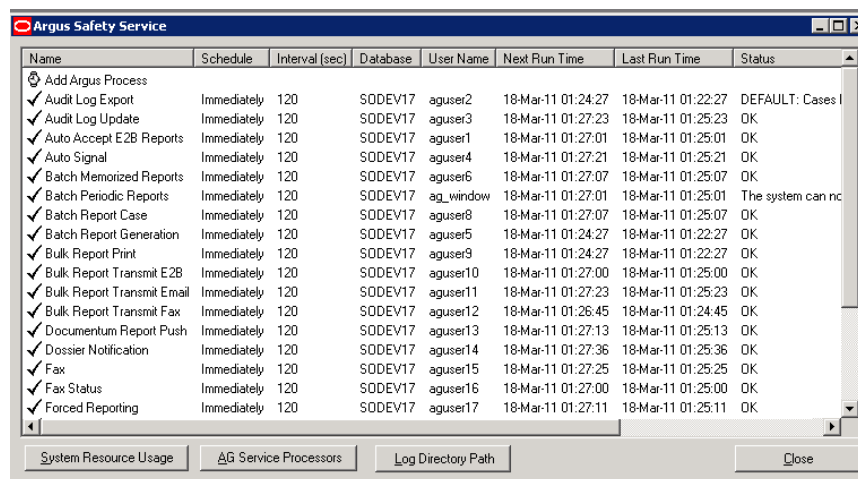
Whatever the configured number is, note down how much time it is taking to process so many records, and configure the frequency of that process to start another instance soon, after those many seconds/minutes.

Argus Safety Service Configuration

Argus Safety Service configuration is performed from the Argus Safety Service configuration utility.

Note: Before starting Argus Safety Service, ensure that the service has been installed and at least one process has been configured. Refer to the **Argus Safety Installation Guide** for information on starting Argus Safety Service.

1. To open this configuration utility, go to **Start > Programs > Oracle > Argus Safety Service Configuration**.
2. The **Argus Safety Service** dialog opens.



Argus Safety Service Processes

From the Argus Safety Service dialog, you can perform the following :

- Add a process
- Modify a process
- Enable or disable a process
- Remove a process

Add an Argus Process

Use the following procedure to add an **Argus Safety Service Process**.

1. Double-click **Add Argus Process** to open the Argus Process dialog box.

2. Fill in the process details to create your Argus Process. See [Understanding the User Interface](#).

Note: Specify a **Failure Email** address. If a process fails, the system sends an email notifying the person whose mailing address is specified.

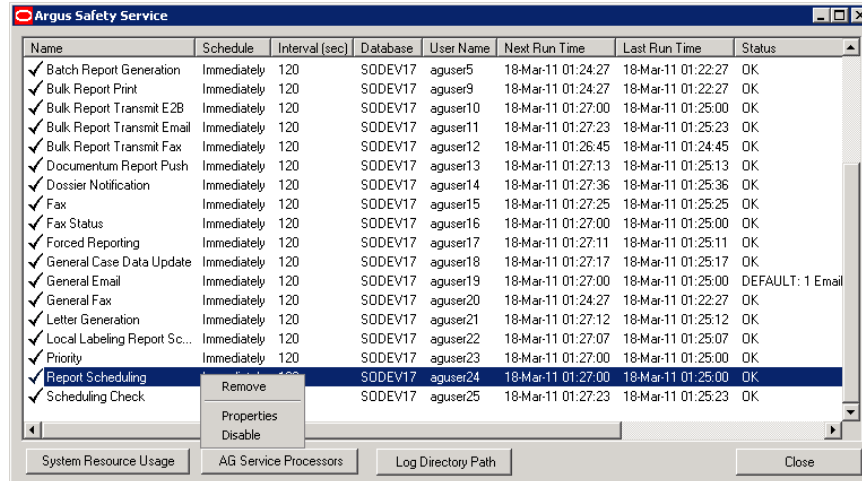
3. Click **OK** to save the configuration to the process.

Note: Restart the Argus Safety Service after adding the AG Service.

Modify an Existing Process

Use the following procedure to modify an existing **Argus Safety Service Process**.

1. Launch the Argus Safety Service Configuration application from **Start>Programs>Oracle>Argus Safety Service Configuration**.
2. The **Argus Safety Service** dialog displays.



3. Right-click the process and select **Properties** to view the Argus Processes dialog.
4. Modify the process details. See [Understanding the User Interface](#).

On Time

Name:

Process:

Task:

Start Time Interval: seconds Suspend: minutes Low Water Mark: KB

Database:

User Name:

Password:

Confirm:

Failure Email:

Fax:

Server:

Notify Email:

User Name: Password:

5. Click **OK** to save your changes to the process.

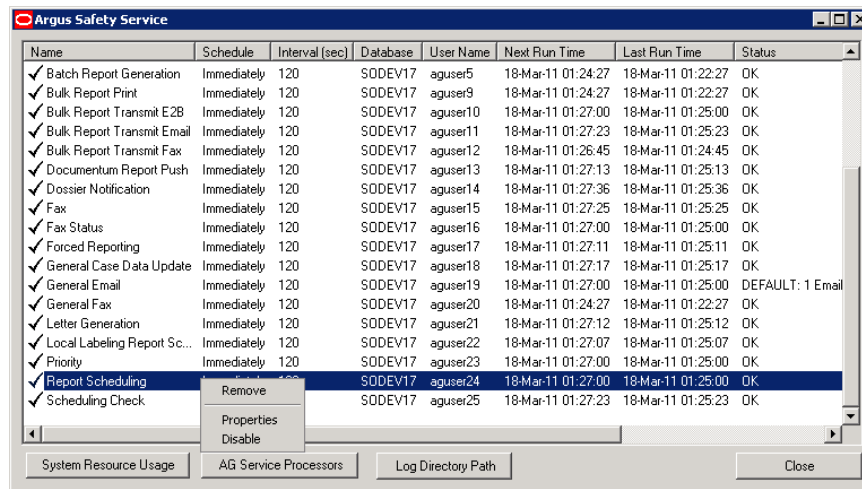
Note: Restart the Argus Safety Service after adding the AG Service.

Enable or Disable a Process

Use the following procedure to enable or disable an **Argus Safety Service Process**.

1. Launch the Argus Safety Service Configuration application from **Start>Programs>Oracle>Argus Safety Service Configuration**.
2. The **Argus Safety Service** dialog displays.

3. Right-click any process to **Enable** or **Disable** it.



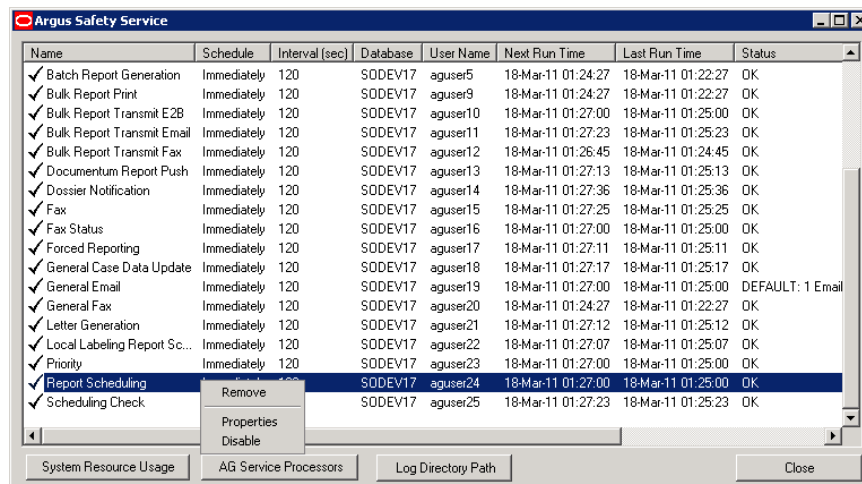
Note: Disabling a process prevents Argus Safety Service from running that process when the service is restarted.

A disabled process is depicted by a red icon before the Process Name.

Remove a Process

Use the following procedure to remove an **Argus Safety Service Process**.

1. Launch the Argus Safety Service Configuration application from **Start>Programs>Oracle>Argus Safety Service Configuration**.
2. The **Argus Safety Service** dialog displays.



3. Right-click any process and select **Remove**.

System Resource Usage

- Enter a valid **Database** name and click **Load** for the current settings to be displayed.

TIME	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
00:00	4	4	4	4	4	4	4
01:00	4	4	4	4	4	4	4
02:00	4	4	4	4	4	4	4
03:00	4	4	4	4	4	4	4
04:00	4	4	4	4	4	4	4
05:00	4	4	4	4	4	4	4
06:00	4	4	4	4	4	4	4
07:00	4	4	4	4	4	4	4
08:00	4	4	4	4	4	4	4
09:00	4	4	4	4	4	4	4
10:00	4	4	4	4	4	4	4
11:00	4	4	4	4	4	4	4
12:00	4	4	4	4	4	4	4
13:00	4	4	4	4	4	4	4
14:00	4	4	4	4	4	4	4

Note: Enter a usage number from 1 to 5. 1 represents the lowest system volume and 5 represents the peak system volume.

- If an invalid database name is entered you will receive this error message: "Database name not valid, please enter a valid database name."
- Enter a number between **1** and **5**.
 - 1** represents the lowest system usage.
 - 5** represents peak system usage.
 - The default value for system usage is **4**.
 - Some of the Argus Safety Service processes perform multi-thread processing, based on the value of this parameter. For example:
 - Audit Log Update
 - Batch Report Generation to attach Expedited Reports
- Click **OK** or **Cancel**.

Argus Safety Service Processors

- Click **Argus Safety Service Processors**.
- Enter the number of processors you want to run **Argus Safety Service** processes on your server.

- Enter a number between 1 and 5.

1 represents the lowest system usage.

5 represents peak system usage.

The default value for system usage is 4.

Some of the Argus Safety Service processes perform multi-thread processing, based on the value of this parameter. For example:

Audit Log Update

Batch Report Generation to attach Expedited Reports

- Once set, subsequent visits to this screen displays the entered number of processors.

- Click **OK** or **Cancel**.

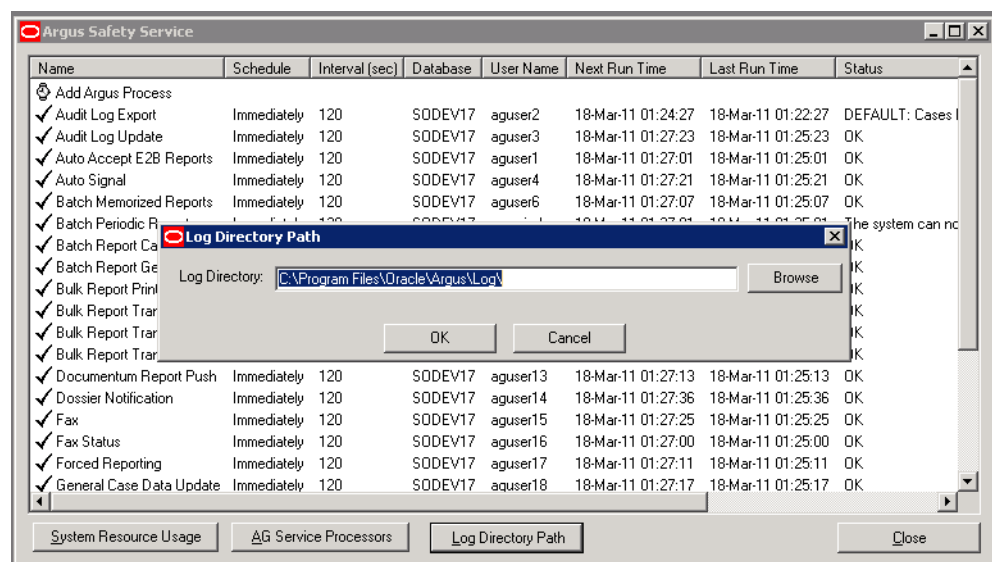
Log File

In case of multi-tenant installations, Argus Safety Service log file identifies all the log items which are related to processing of data specific to a particular enterprise by specifying Enterprise Short Name in the log record. The generic log records which are not related to any enterprise specific data will not append Enterprise Short Name.

Specify Log Directory

Use the following procedure to specify the **Log Directory Path**.

- Launch the Argus Safety Service Configuration application from **Start>Programs>Oracle>Argus Safety Service Configuration**.
- The **Argus Safety Service** dialog displays.
- Click **Log Directory Path**. The Log Directory Path dialog displays.



- Click **Browse** or enter a path.
- Click **OK** to save your entry.

Configuring Background Periodic Reports

This section describes the configuration of Background Periodic Reports.

You must ensure that you adhere to the following points while configuring Background Periodic Reports:

1. No new AG task is required. You can simply use the existing Batch Periodic Reports. You need to create one iteration of the task for every periodic report you want to run in parallel. For example, if you'd like Argus to generate only 1 periodic report at a time then configure 1 Argus Safety Service process for Batch Periodic Reports, but if you'd like Argus to generate up to 5 periodic reports in parallel then configure 5 Argus Safety Service processes for Batch Periodic Reports, each one using a unique Argus Safety Service named account.
2. You must also consider the average duration of a report and the number of reports when deciding on the number of Batch Periodic Reports processes that need to be configured. If one process does not suffice, multiple processes can be created on the same server. However, if multiple processes cause consistently high CPU and memory utilization, a new server may be required to support the additional processes.
3. The Interval setting for the Batch Periodic Reports process should be based on the average time taken to generate a report and the number of reports generated on a day. Ideally, all reports for a day should be generated on the same day itself.

