Oracle® Argus Safety Service

Administrator's Guide

Release 7.0.2

E35661-01

February 2013

ORACLE®

Oracle Argus Safety Service Administrator's Guide Release 7.0.2

E35661-01

Copyright © 2013, Oracle and/or its affiliates. All rights reserved.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, the following notice is applicable:

U.S. GOVERNMENT RIGHTS Programs, software, databases, and related documentation and technical data delivered to U.S. Government customers are "commercial computer software" or "commercial technical data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, duplication, disclosure, modification, and adaptation shall be subject to the restrictions and license terms set forth in the applicable Government contract, and, to the extent applicable by the terms of the Government contract, the additional rights set forth in FAR 52.227-19, Commercial Computer Software License (December 2007). Oracle America, Inc., 500 Oracle Parkway, Redwood City, CA 94065.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information on content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services.

Contents

Preface v

About This Book v
Documentation Accessibility v
Related Documents v
Checking My Oracle Support vi
Conventions vi

1 Argus Safety Service Overview

Argus Safety Service in a Multi-tenant environment 1-1
Understanding the User Interface 1-2
Argus Process Dialog Box Fields and Field Descriptions 1-3
Understanding Tasks 1-4
Task Descriptions 1-4

2 Argus Safety Service Configuration

Argus Safety Service Processes 2-1
Add an Argus Process 2-2
Modify an existing process 2-2
Enable or Disable a Process 2-3
Remove a Process 2-4
System Resource Usage 2-5
AG Service Processors 2-5
Log File 2-6
Specify Log Directory 2-6

Preface

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

About This Book

This manual contains these chapters:

Chapter 1, "Argus Safety Service Overview"

This section provides a general overview of the Argus Safety Service processes and the user interface.

Chapter 2, "Argus Safety Service Configuration"

This section provides information about configuring Argus Safety Service.

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 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.

Related Documents

This section lists the manuals for Oracle Argus products. You can order printed manuals from the Oracle iStore.

Oracle Argus Documentation

The *documentation set* includes:

- *Oracle Argus Safety User's Guide*
- *Oracle Argus Safety Administrator's Guide*

- *Oracle Argus Safety Database Administrator's Guide*
- *Oracle Argus Dossier User's Guide*
- *Oracle Argus Affiliate User's Guide*
- *Oracle Argus Unblinding User's Guide*
- *Oracle Argus Interchange User's Guide*
- *Oracle Argus Safety Interchange Database Administrator's Guide*
- *Oracle Argus Interchange UICH DTD 2.1 Mapping Reference Guide*

Checking My Oracle Support

The Oracle Argus Safety product suite continues to grow and evolve. To help you use it and stay abreast of updates we provide between releases, it is a good practice to check My Oracle Support for information that enhances our released documentation.

To open the Oracle Argus Safety product page on My Oracle Support, complete the following steps:

1. Open a Web browser to https://support.oracle.com/CSP/ui/flash.html#.
2. Click the Sign In button and log in. The My Oracle Support portal opens, displaying general news from several categories. If you do not yet have an account, click "Register here" and follow the instructions given on the registration page.
3. Click the Knowledge link.
4. In the "Browse any Product, by Name" field, enter "Oracle Argus Safety".
5. Click the Go button to the right of the drop down field. My Oracle Support loads the Oracle Argus Safety Knowledge Browser Product Page.

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1

Argus Safety Service Overview

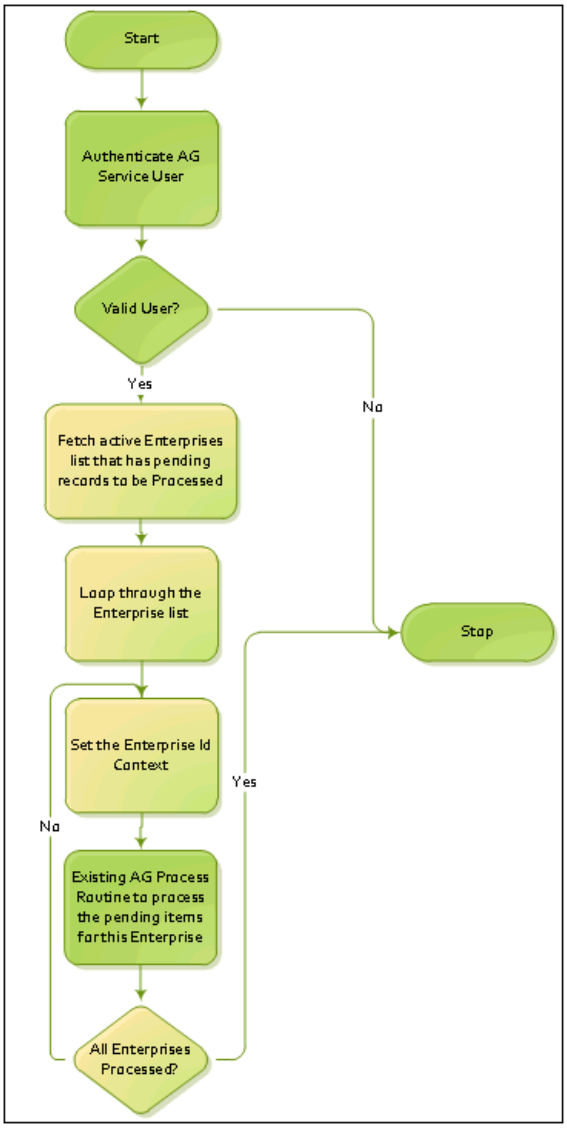
The Argus Safety Services are a suite of processes that run to reduce the load on the front end experienced by perform complex process in the background. These processes that performing several tasks in the background. Argus Safety Service Configuration provides an interface to configure these processes.

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 AG service procesess 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.

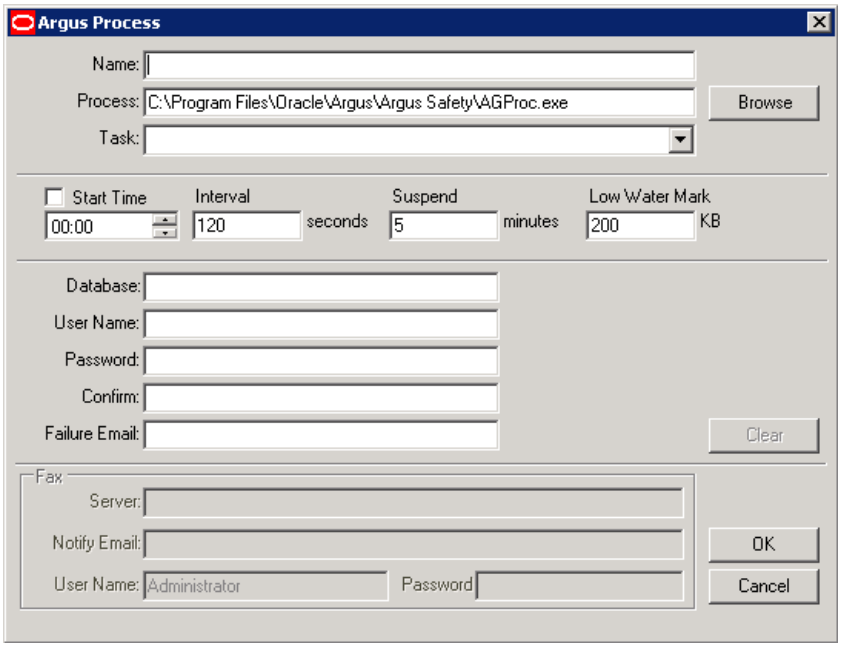


While performing any single task at a time, Argus Safety service will not inter-mix data from multiple enterprises.

The user configured to run any AG 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

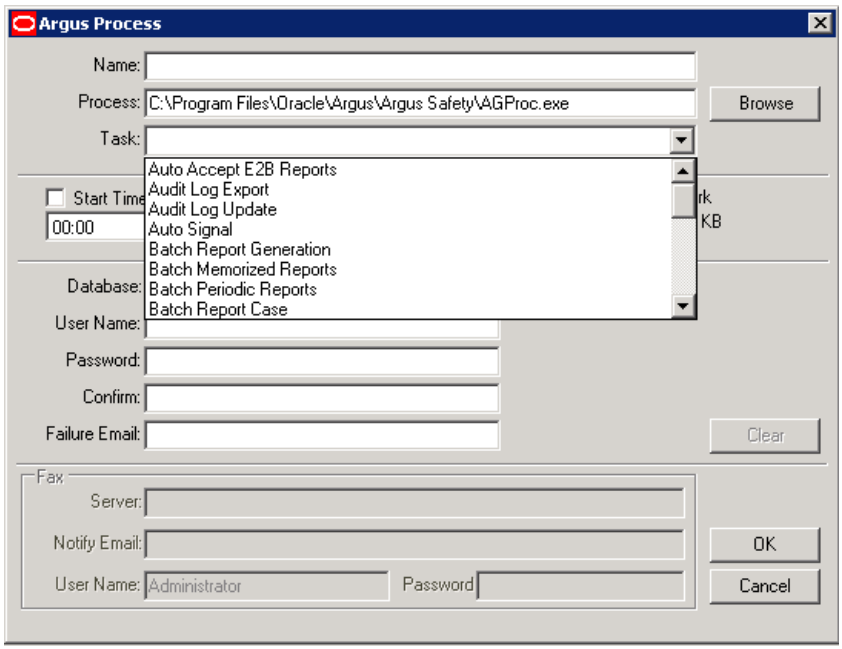
Item	Description
Name	Enter the name of the Argus Safety Process.
Process	Browse to the Argus Safety Service Installation folder and select the AGProc.exe file.
Task	Select the task to run that is associated with the Name entered in the first field.
Start Time	Enter the Initial Start Time for the Process. 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 that 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	Argus Safety Configuration
Auto Accept E2B Reports	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. 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.	

Item	Description	Argus Safety Configuration
Audit Log Export	Argus Safety allows the export of Audit Data to a table in a format that is readable by a user. 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.	
Audit Log Update	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. 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.	
AutoSignal	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.	Utilities \ Configuration \ Auto Signal menu
Batch Report Generation	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. 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. 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.	Utilities \ Configuration \ Batch Reports menu
Batch Memorized Reports	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.	Utilities \ Configuration \ Batch Reports menu
Batch Periodic Reports	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. 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. 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.	Reports \ ICH PSUR Reports menu Reports \ IND Reports menu Reports \ NDA Reports menu
Batch Report Case	Batch Report Case allows users to run reports on a scheduled date.	Run At Options

Item	Description	Argus Safety Configuration
Bulk Report Print	Prints the reports from a particular enterprise to the printer configured for that site in Console for that enterprise.	Bulk Report By Form
Bulk Report Transmit E2B	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.	
Bulk Report Transmit Email	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. 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. This process e-mails up to 100 reports in a row. After 100 e-mails have been sent, the process shuts down and start again at the next scheduled interval. 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.	Bulk Report By Form
Bulk Report Transmit Fax **Note:** If E2B Reports are going to be transmitted, the Bulk Report Transmit Fax process must be running.	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. This process faxes up to 100 reports in a row. After 100 faxes have been completed, the process shuts down and starts again at the next scheduled interval. 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.	Bulk Report By Form
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.	

Item	Description	Argus Safety Configuration
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 AG 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	This process sends all the Workflow Routing emails which can be configured within the Workflow Configuration. It also sends all the Investigator Alert emails which can be configured within the Study Configuration as defined in the Investigator Group configuration.	
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	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. 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.	
Priority	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. 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.	Utilities \ Configuration \ Priority menu Utilities \ Configuration \ Workflow menu

Item	Description	Argus Safety Configuration
Report Scheduling	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. 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.	Utilities \ Configuration \ Reporting Rules menu
Scheduling Check	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.	

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.

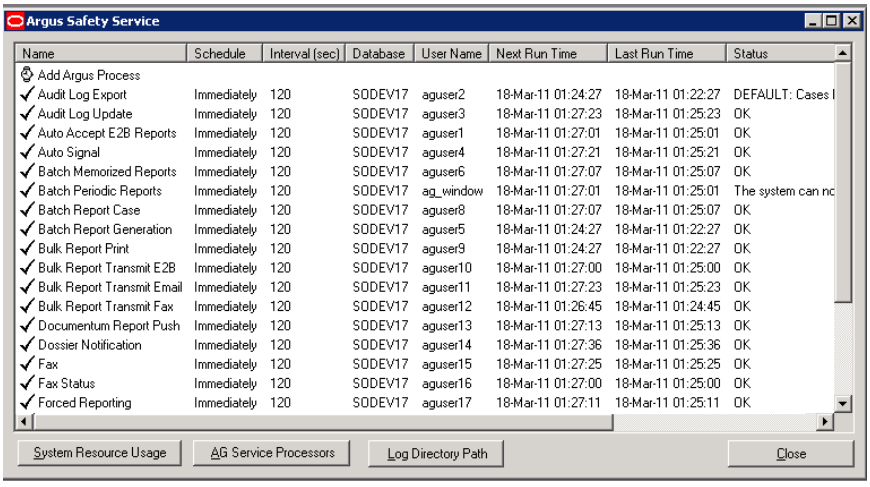
2

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

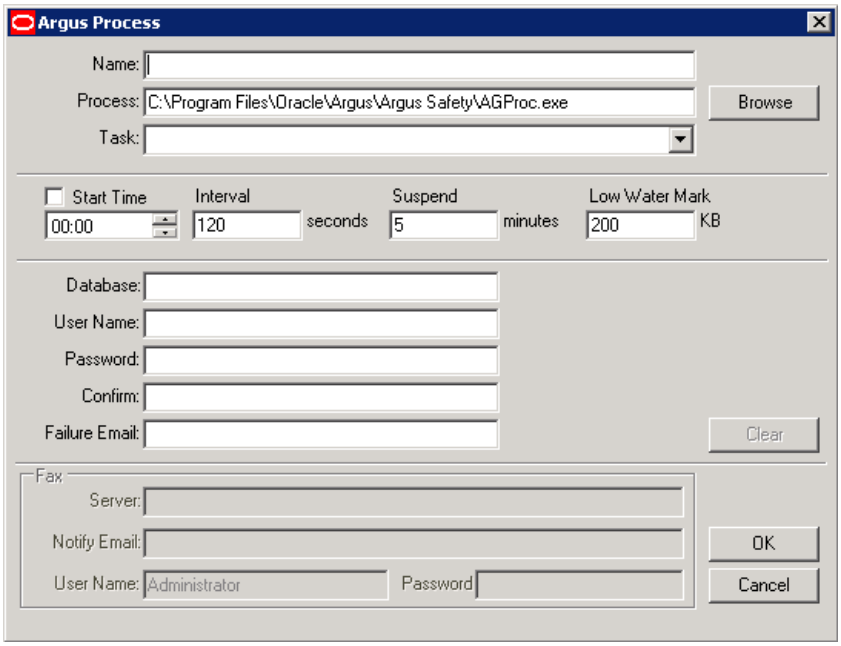
From the Argus Safety Service dialog, you can perform the following :

- 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*.

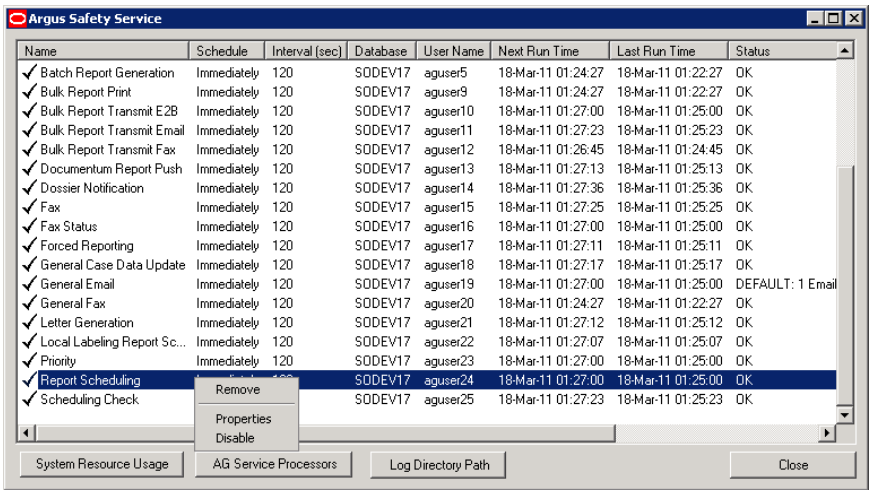
> **Note:** Specify a **Failure Email** address. If a process fails, the system sends an email notifying the person whose mailing address is specified.

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

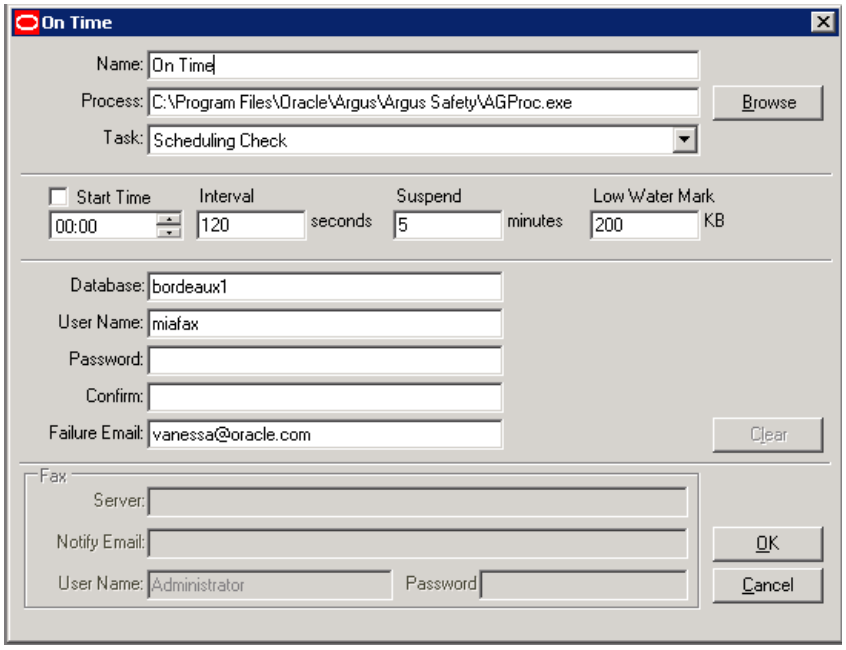
Modify an existing process

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 dispalys.



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

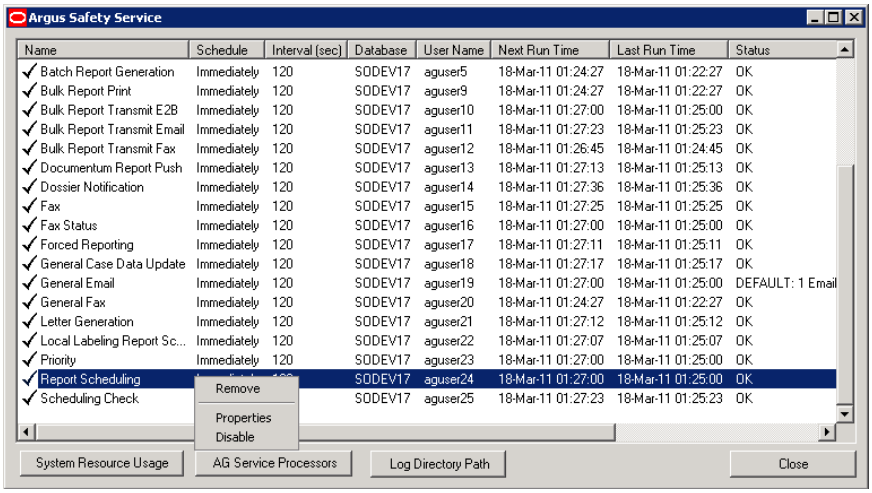


5. Click **OK** to save your changes to the process.

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



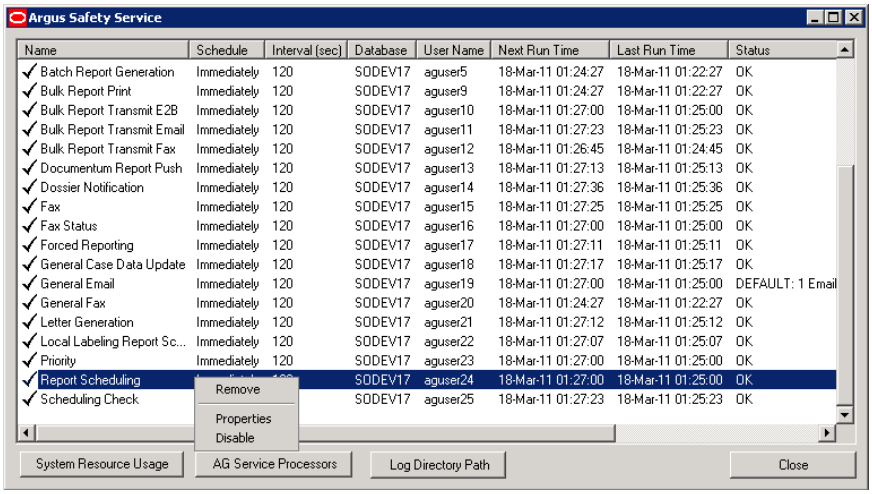
Note: Disabling a process prevents Argus Safety Service from running that process when the service is restarted.

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**.

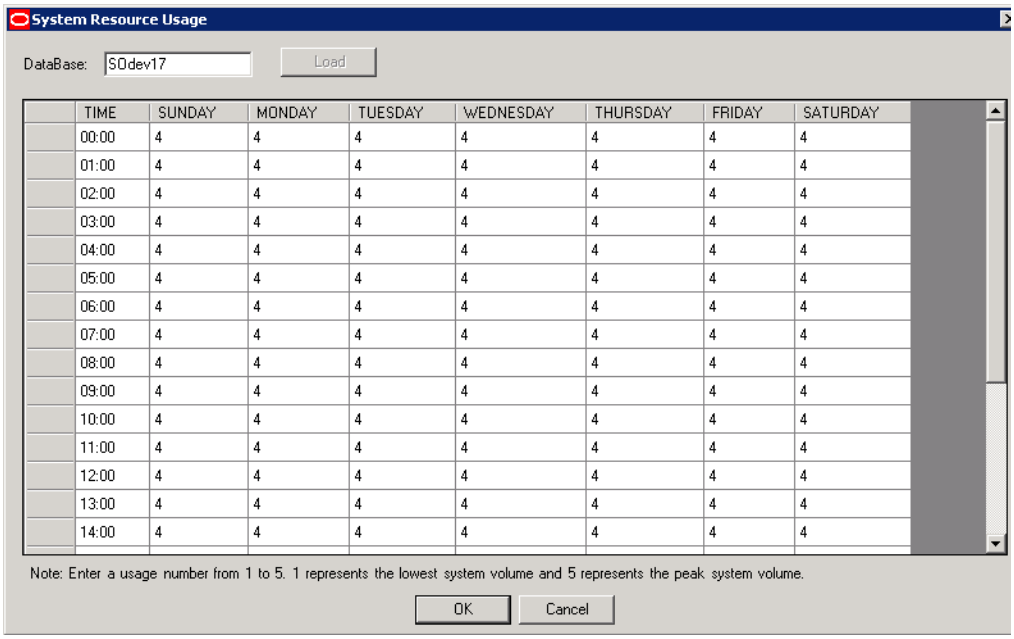
1. Launch the Argus Safety Service Configuration application from **Start>Programs>Oracle>Argus Safety Service Configuration**.
2. The **Argus Safety Service** dialog dispalys.



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.



- 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 less than **1** or greater than **5**.

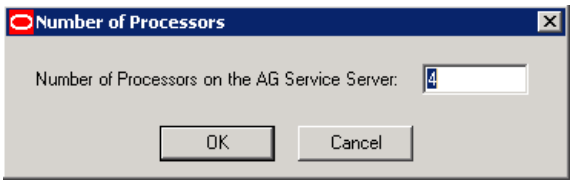
  1 represents the lowest system usage.

  5 represents peak system usage.

  The default value for system usage is **4**.
- Click **OK** or **Cancel**.

AG Service Processors

1. Click **AG Service Processors.**
2. Enter the number of processors you want to run **AG Service** proceses on your server.



- Enter a number less than **1** or greater than **5**.

  The default value for system usage is **4**.

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

3. Click **OK** or **Cancel**.

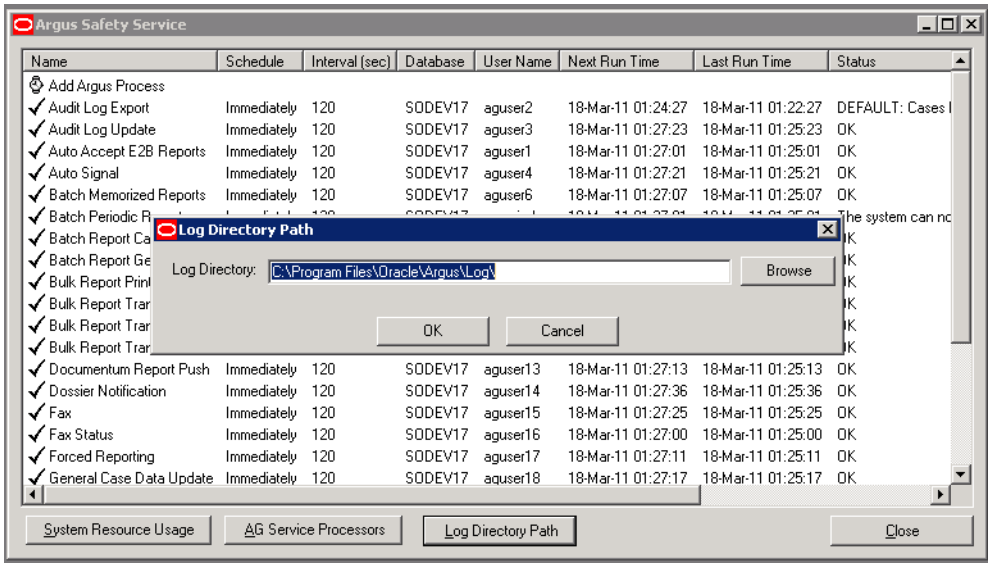
Log File

In case of multi-tenant installations, Argus Safety Service log file identifes 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**.

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



4. Click Browse or enter a path.
5. Click Ok to save your entry.