Oracle® Argus Safety

Service Administrator's Guide

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Oracle Argus Safety Service Administrator's Guide Release 6.0.1

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Contents

Preface

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

About This Book

This manual contains four chapters:

Chapter 1, "Argus Safety Service Process Overview"

This section provides a general overview of the Argus Safety Service process.

Chapter 2, "Argus Safety Service Configuration"

This section provides information about configuring Argus Safety Service.

Chapter 3, "Argus Safety Process Configuration"

This section provides information about configuring Argus Safety Process.

Documentation Accessibility

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Related Documents

This section lists the manuals for all Oracle Life Sciences products. You can order printed manuals from the Oracle iStore. From the iStore, search for the part number in parentheses.

Oracle Argus Documentation

The *Oracle Argus documentation set* includes:

- *Oracle Argus Installation Guide* (E15951)
- *Oracle Argus Interchange User's Guide* (E15946)
- *Oracle Argus Affiliate User's Guide* (E15947)
- *Oracle Argus Safety Console User's Guide* (E15950)
- *Oracle Argus Safety User's Guide* (E15952-01)
- *Oracle Argus Safety End of Study Unblinding User's Guide* (E15956)
- *Oracle Argus Dossier User's Guide* (E15945)

Oracle Clinical Documentation

The *Oracle Clinical documentation set* includes:

- *Oracle Clinical Installation Guide* E15951)
- *Oracle Argus Interchange User's Guide* (E15946)
- *Oracle Argus Affiliate User's Guide* (E15947)
- *Oracle Argus Safety Console User's Guide* (E15950)
- *Oracle Argus Safety User's Guide* (E15952-01)
- *Oracle Argus Safety End of Study Unblinding User's Guide* (E15956)

Oracle Clinical Documentation

The *Oracle Clinical documentation set* (A83790) includes:

- *Oracle Clinical Administrator's Guide* (A83791)
- *Oracle Clinical Getting Started* (B12308)
- *Interfacing from Oracle Clinical* (A83793)
- Oracle Clinical Conducting a Study (A85201)
- Oracle Clinical Creating a Study (A85200)
- *Oracle Clinical Installation Guide* (A83779)

Oracle Clinical NLS Option Documentation

The Oracle Clinical NLS Option documentation includes:

- *Oracle Clinical NLS Option User Guide* (A90473)

Oracle Thesaurus Management System (TMS) Documentation

The TMS documentation includes:

- *Oracle Thesaurus Management System User Guide* (A82842)

- *Oracle Thesaurus Management System Installation Guide* (A83780)

Oracle Adverse Event Reporting System (AERS) Documentation

The Oracle AERS documentation set (B10328) includes:

- *Oracle Adverse Event Reporting System Administrator's Guide* (B10330)

- *Oracle Adverse Event Reporting System Installation Guide* (B10331)

- *Oracle Adverse Event Reporting System User's Guide* (B10329)

- *Oracle Adverse Event Reporting System Quick Guide* (B14419)

Oracle Clinical Remote Data Capture (RDC) Documentation

The Oracle RDC documentation includes:

- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide* (B13921)

- *Oracle Clinical Remote Data Capture PDF Data Entry User's Guide* (B139201)

Oracle Clinical SiteMinder Documentation

The Oracle Clinical SiteMinder documentation includes:

- *Oracle Clinical SiteMinder User Guide* (B15643)

- *Oracle Clinical SiteMinder Installation Guide* (B15645)

Oracle Clinical TrialMinder Documentation

The Oracle Clinical TrialMinder documentation includes:

- *Oracle Clinical TrialMinder User Guide* (B15644)

- *Oracle Clinical TrialMinder Installation Guide* (B15646)

In addition, Oracle Health Science Global Business Unit (HSGBU) publishes PDF-format Technical Reference Manuals (TRMs) containing proprietary information on internal tables and APIs. If you are a licensed customer, contact Oracle Support to obtain a free electronic copy. This is a list of the available TRMs:

- *Oracle Clinical Stable Interface TRM* (A83796)

- *Oracle Thesaurus Management System TRM* (A82841)

- *Oracle Adverse Event Reporting System Saved Queries TRM* (B10353)

- *Oracle Adverse Event Reporting System Reports TRM* (B10352)

- *Oracle Adverse Event Reporting System Edit Checks TRM* (B10355)

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.

Convention	Meaning
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 Process Overview

The flowchart below depicts the sequence of steps that should be followed to configure Argus Safety Service:
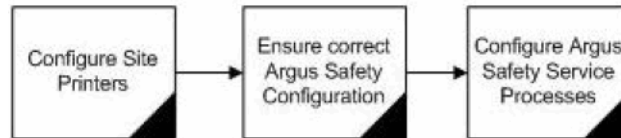
The following table describes each of the steps shown in the flowchart above.

Task	Description
Configuring Site Printers	Specify printers to be used for different sites.
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.

2

Argus Safety Service Configuration

Argus Safety Service configuration is done 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 Solution Components 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.
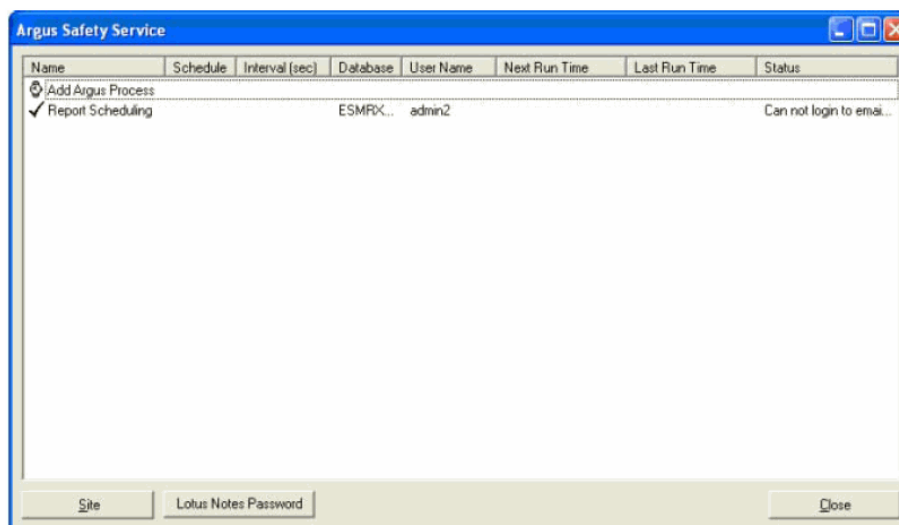
This dialog enables you to configure site printers (refer to Configuring Site Printers), create new Argus Safety Processes and view existing Argus Safety Processes.

Configuring Site Printers

Use the following procedure to configure the site printers.

To configure the site printers

1. Click Site in the Argus Safety Service dialog.

2. The Site Specific dialog opens.
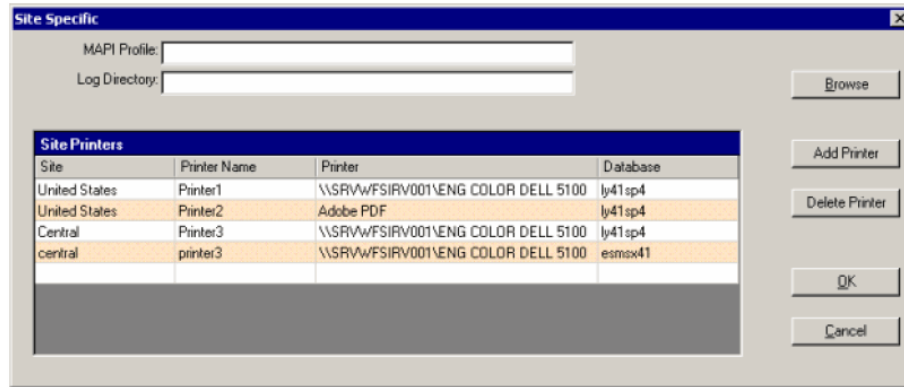
3. Ensure that the **Log Directory** information is correct.

4. Click **Add Printer** to add a printer for the site.

5. Under **Site**, enter the country code of the site. Ensure that the country code is the same as the one in **Argus Safety List Maintenance**.

6. Select a row displaying a printer and click **Delete Printer** to delete it.

To edit an existing site name, select the row corresponding to the site name and after a few seconds, click the site name.

To change the printer assigned to a site, double-click the row corresponding to the site.

7. Click OK to confirm the settings.

Note: You can configure multiple printers for the same site which can be populated within the Bulk Reporting dialog when you print the report to a specific printer.

If a site-based printer is not defined for a particular site, the reports for that site are printed on the default printer on the Argus Safety Service machine.

Site Specific Dialog Box Fields and Field Descriptions

The following table describes the fields in the **Site Specific** dialog.

Field	Description
Log Directory	Enables you to specify the path that will store the AG Service log files through the Browse button.
Site	Displays the full name of the site for which the printer is configured.
Printer Name	Displays the name of the configured printer.
Printer	Displays the full path of the configured printer.
Database	Enables you to select a database instance for the defined site printers.
Browse	Enables you to specify the path in Log Directory to store the AG Service log files.

Field	Description
Add Printer	Enables you to add a printer.
Delete Printer	Enables you to delete a printer selected from the Site Printers grid.

Adding or Modifying an AG Service Process

Use the following procedure to configure an **AG Service Process** for ePSUR notification:

1. Launch the AG Service Configuration application from Start>Programs>Oracle>Argus Safety Service Configuration.

2. The Argus Safety Service dialog appears.
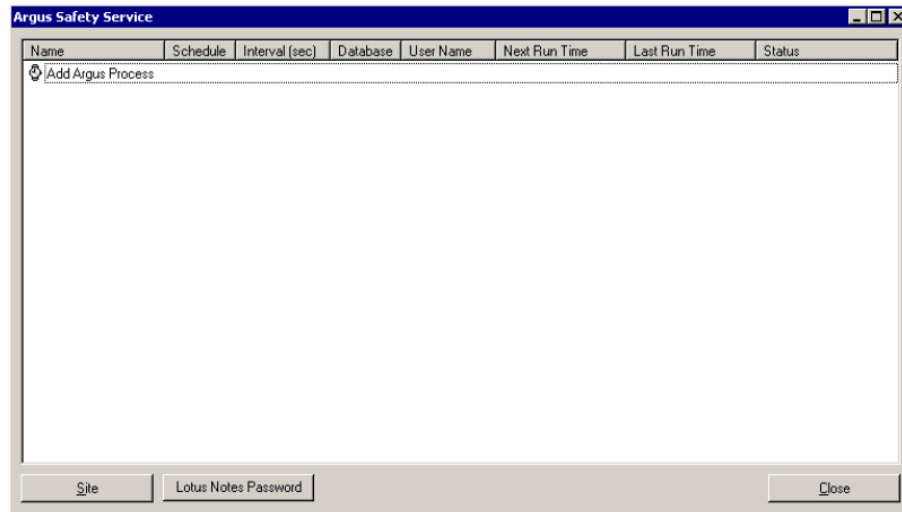
3. Right-click Add Argus Process to enable or disable a process.
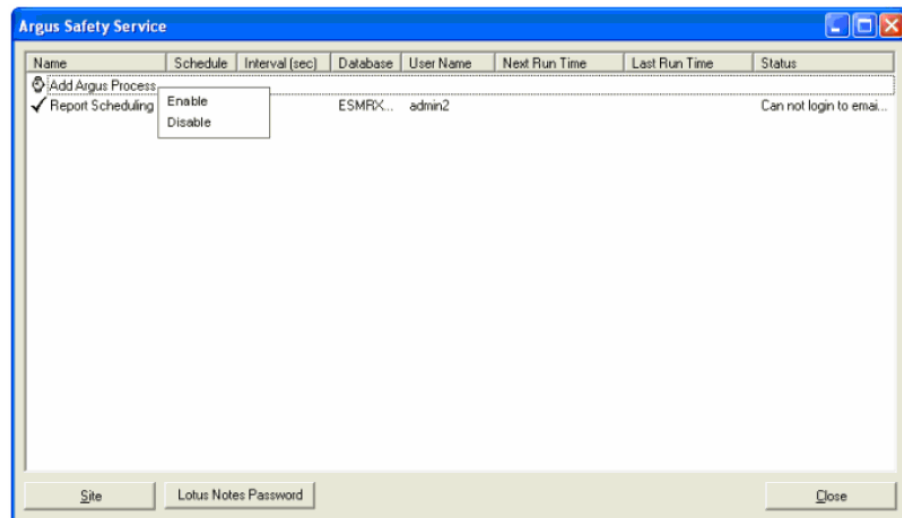
> **Note:** Disabling a process prevents Argus Safety Service from running that process when the service is restarted.
>
> A disabled process is depicted by a red icon before the Process Name.

4. Double click Add Argus Process to open the Argus Process dialog box.

5. Click **Enable** to enable or disable AG Service Processes.

6. If a process fails, the system sends an email notifying the person whose mailing address is specified in Email Address.

7. Click **OK** to save the configuration to the process file.

8. Select **ePSUR Notification** from the Task list box and fill in other necessary information.

3

Argus Safety Process Configuration

Argus Safety Service is a Windows process that automatically performs the tasks related to the Argus Safety Solution Components. The Administrator can configure Argus Safety Service to perform these tasks at specific intervals of time.

Argus Safety processes can be configured using the **Argus Process** dialog shown in the following illustration.

To configure the Argus Safety process:

1. To open the Argus Process dialog for a new process, double-click Add Argus Process in the Argus Safety Service dialog.
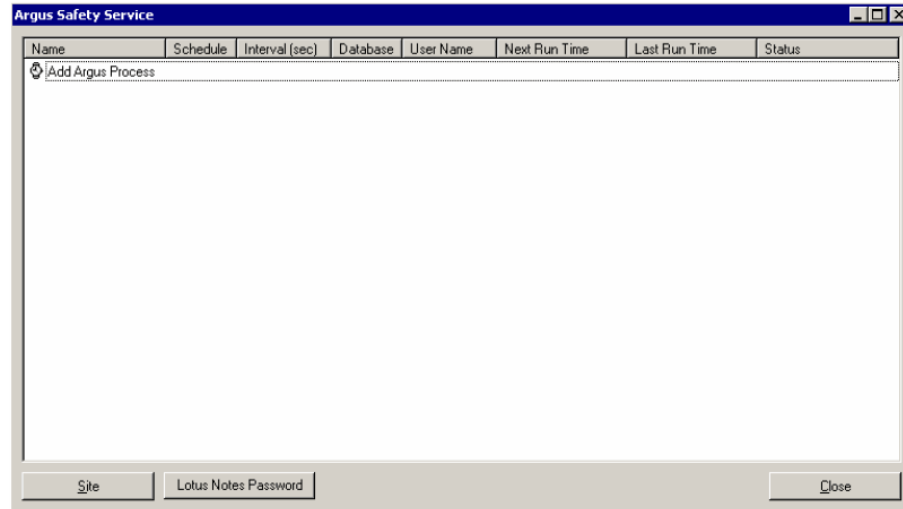
2. To open the Argus Process dialog for an existing process, right-click the process in the Argus Safety Service dialog and select Properties.
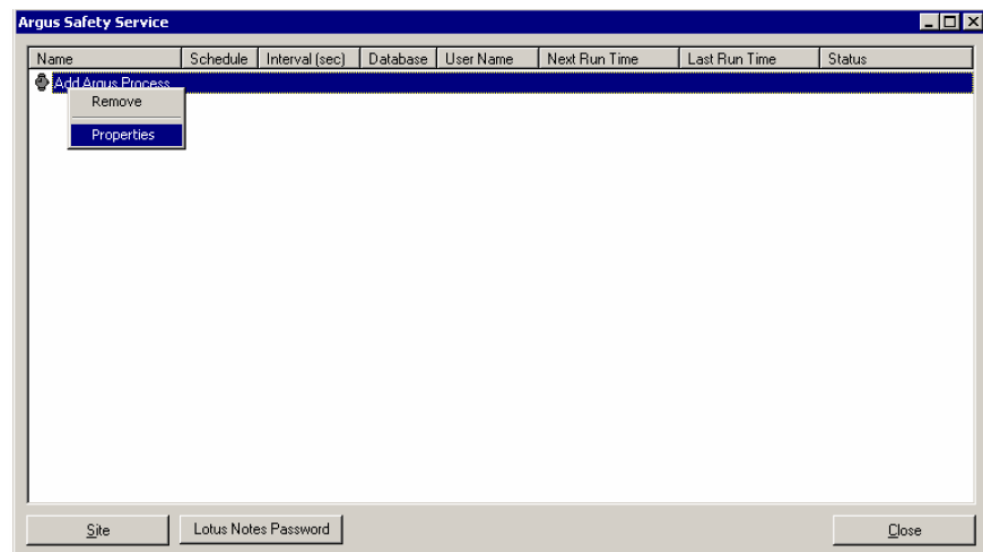
Note:

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.

Item	Description
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.
Enable	Allows you to enter an email address in case a process fails.
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.
Email Address	If a process fails, an email is sent to the address specified in this field.
Documentum	

(**Note:** This section is enabled only if **Document Report Push** is selected in the **Task** list)

Item	Description
User Name	Enter the Documentum user name that AG Service will use to connect to Documentum.
Password	Enter the password for the Documentum user.
Docbase	Enter the Docbase from the Documentum server.
Domain	Enter the domain that the Documentum service is on.
Expedited Reports Cabinet	Enter the cabinet where Expedited Reports will be stored in Documentum.
Periodic Reports Cabinet	Enter the cabinet where Periodic Reports will be stored in Documentum.
Documentum Type to Push	Enter the Documentum table to store the report in.
Fax	

(**Note:** This section is enabled only if **Fax** or **Fax Status** is selected in the **Task** list)

Item	Description
Right Fax	Select Right Fax, if required. Right Fax v9.3 is used and the Right Fax radio button is selected by default.
Fax Senior	Select Fax Senior, if required.
Server	Enter the Fax Senior 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.
Port	Enter the port number of the Fax Senior Server. This port is configured during the installation Fax Senior. If you are unsure what the port is, please see your System Administrator. This field will only be enabled if the task selected is either FAX or FAX STATUS.
Network Dir	Enter the Network Path for the Shared folder created as part of the Argus Safety Service Installation. The path must be entered using the UNC format. Example: \\FAXSENIOR\AGFax.
Local Dir	Enter the Local Path for the same folder as in the Network Dir field above. The Local Path is the full path on the Fax Senior Machine to the same path entered in the Network Dir field. Example: C:\FaxSnr\AGFax.
Notify Email	Enter the Email Address of the Administrator that will receive the e-mails in the event that Argus Safety Service can not access the Fax Server.
RF Login	Enter the Right Fax login name.

Item	Description
Password	Enter the Right Fax password.

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.	
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 loading of data 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 day to day tasks for the end user by moving the Report Generation Load to the Argus Safety Server and off the Local Client or 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.	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

Item	Description	Argus Safety Configuration
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.	Reports \ ICH PSUR Reports menu Reports \ IND Reports menu Reports \ NDA Reports menu
	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.	
Batch Report Case	Batch Report Case allows users to run reports on a scheduled date.	Run At Options
Bulk Report Print	Argus Safety supports Bulk Submission of reports for Printing. The Bulk Report Print Process will automatically generate, submit (if the report has been marked for submission) and print reports based on the printer configured for submission users site.	Bulk Report By Form
	Using this process speeds up day to day tasks for the end user by moving the Report Generation and Printing Load to the Argus Safety Server and off the Web Server.	
	This process prints up to 100 reports in a row. After 100 prints have been completed, 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).The process processes 10,000 reports in a day at a minimum.	
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.	

Item	Description	Argus Safety 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.	Bulk Report By Form
	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 and off the Local Client. 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 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 Senior. Argus Safety Web requires this process to have the ability to fax.	Bulk Report By Form
	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.	
Documentum Report Push	Argus safety will allow the push of Expedited and Periodic Reports into the Documentum system. Expedited Reports are pushed upon marking the report as submitted. Periodic Reports are pushed when they are generated in Argus.	
	Once the Periodic Report has been marked as submitted, the process will update the status of the report within the Documentum database.	
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 to Omtool Fax Senior 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 Case Data Update	This service applies changes to cases based on XML from RPT_CASE_DELTA_MESSAGE. Bulk Report Transmit Email and Bulk Report Transmit Fax use this service to mark the sent date of letters.	
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

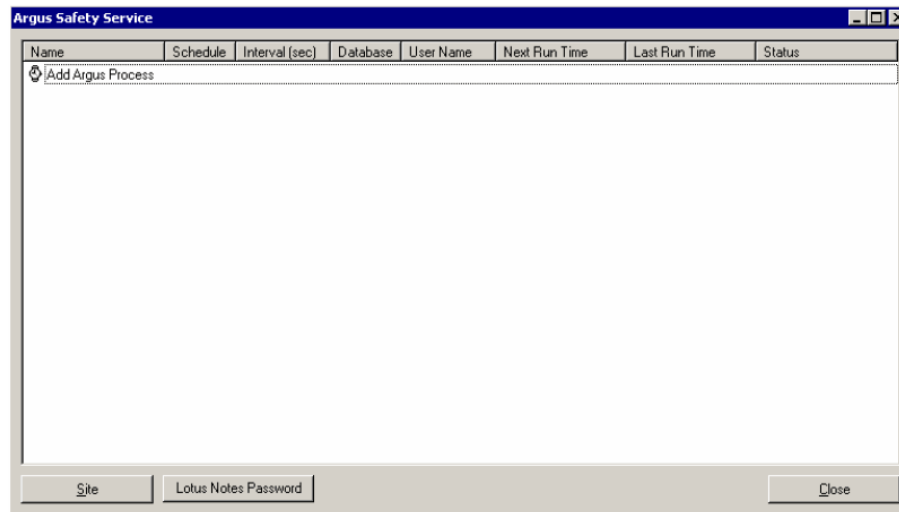| Item	Description	Argus Safety Configuration
Report Scheduling	The Report Scheduling process automatically schedules reports based on Regulatory Rules configured in Argus for new cases. In addition, cases requiring follow-up reports are also evaluated.	Utilities \ Configuration \ Reporting Rules menu
	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.	
	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.	
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.

Configuring Argus Safety Process

Execute the steps below to configure an Argus Safety process:

1. Open the Argus Safety Configuration utility from Start>Programs>Oracle>Argus Safety Service Configuration.

2. The Argus Safety Service dialog opens.

3. Open the Argus Process dialog box.

> **Note:** To remove an existing Argus Safety Service process, right-click the process and select **Remove**.

4. Enter the items in the Argus Process dialog.
5. Click **OK**.