

# Oracle Argus Safety

## PMDA Device Reporting Best Practices



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# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

## 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>.

## 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.

## Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

## Access to Oracle Support

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- English interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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Oracle customers that have purchased support 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.

# 1

## Revision history

<b>Argus version</b>	<b>Description</b>
8.4	First release

# 2

## Introduction

MHLW has published the revised Paper format and the new XML format for Medical Device reports. Companies should send Medical Device reports in XML format effective from April 1st 2020 and mandatory from April 1st 2021. PMDA has published regulatory guidance for various documents, including Data element check lists, Check rules, and XML references.

**Figure 2-1 Flow diagram for submitting a PMDA device XML and import ACK**





# 3

## PMDA Device support in Oracle Argus Safety

The PMDA Device Form 8 and Form 10 reports in XML format and paper forms as per the revised template are supported from the Argus 8.4 version onwards.

Only Form 8 and Form 10 paper forms were supported prior to Argus 8.4 release.

# 4

## Configuration updates in Argus Console

The following section describes the updates in Argus Console for the PMDA Device Form 8 and Form 10 reports in XML format and paper forms support.

### Device Reporting Category

The old factory data for the Device Reporting Category values are updated to set the Display value to No. It is recommended that you do not modify the display settings since the old values are no longer accepted by PMDA.

Device Reporting Category	Device Reporting Category (J)	Display
Infection Report	感染症報告	No
Malfunction with health damage	副作用報告	No
Malfunction without health damage	不具合報告	No
Measures in Foreign Country Report	外国措置報告	No
Research Report	研究報告	No

### Common Profile Switches

A new common profile switch, **File attachments allowed for PMDA Device Profile**, introduced in System Configuration > Common Profile Switches > Argus J > Reporting > Device Report, has the following types populated by default:

- PDF
- JPEG
- JPG
- BMP
- PNG
- GIF
- TIF
- TIFF
- RTF
- TXT
- XLS
- XLSX
- DOC
- DOCX
- XML

- DICOM
- HTML



### Note:

It is recommended to review the supported attachment formats and remove formats that are not required as per the business need.

However, Argus does not support uploading HTM or HTML file types. It is recommended that you do not upload/attach HTM/HTML files.

## PMDA Device Profile

Listed below you can find the best practices for configuring a PMDA Device Profile:

- The standard device profile, PMDA-DEVICE MESSAGE TEMPLATE, uses a similar framework as the E2B(R3) profile.
- Based on the reporting category selected in case form, either Form 8 or Form 10 XML is generated.
- You can customize the transmit logic for each of the elements by copying the profile and changing the SQL query similar to E2B(R3) profile. Since the profile is common for Form 8 and Form 10 report, the customization logic caters to both report forms.
- For example: If you update the logic for element DOCUMENT for compression logic, the compression logic is applied to both Form 8 and Form 10 reports attachments.
- Since most of the data elements with respect to Form 8 and Form 10 device XML are same, the profile has elements related to both Form 8 and Form 10 XML reports. To distinguish elements specific to Form 8 and Form 10, elements are prefixed with the **F8** and **F10** tags, as shown in the screenshot below:

Figure 4-1 Manage Profile

The screenshot displays the 'Manage Profile' interface for the 'PMDA-DEVICE MESSAGE TEMPLATE' profile. The left pane shows a tree view of the profile structure, with the 'REPORTCLASS [M.2]' element selected. The right pane shows the 'TRANSMIT' logic for this element, which is a complex SQL query. The query includes a CTE for 'LISTEDNESS' and a main query that uses 'CASE' statements to filter data based on 'det\_cas\_cnt' and 'listedness\_cnt'. The query also uses 'F8' and 'F10' prefixes to distinguish between Form 8 and Form 10 reports. The query ends with a 'COUNT()' function.

## Product Configuration

PMDA has published the Medical Device Defect glossary containing the JMDN and JFMDA details. The JFMDA codes are mapped to IMDRF codes. The glossary is loaded as factory data into the Oracle Argus database.

It is recommended that you do not update the glossary from the backend.

To configure a product, go to Console > Business Configuration > Product. Below you can find the recommended best practices:

- The device generic name, along with the corresponding JMDN code and terminology code can be configured in the J Data Entry pop-up window. To access it, select the device from the **Look up** window which lists the JMDN glossary loaded into Argus system.
- You can manually type the device generic name, if the device is not currently part of glossary. Allowing manual entry is implemented based on the feedback from customers. The Oracle Argus system directly transmits whatever is configured in Argus Console. However, PMDA has a validation check for the generic name and JMDN code to be part of glossary. So, if you are manually entering these fields, it is recommended that you work with PMDA to accept the generic name and JMDN code.
- If the terminology code is not assigned for any of the selected or entered device generic name, then you can use the Z01 code for common terms.
- If the product being configured is purely a device product (not a combination product), the device generic name you select in the J Data Entry pop-up window can be configured as a Generic name for the product



# 5

## Setting up reporting destinations

The PMDA device XML has to be submitted to a PMDA device agency through the EDI gateway by using the AS2 protocol or it can be directly uploaded using the PMDA website. To generate device XML files, the reporting destination codelist has to be set up for PMDA device in Oracle Argus.

### PMDA Device XML report

In the **EDI tab**, select the message profile as PMDA-DEVICE MESSAGE TEMPLATE for the new reporting destination created for XML reporting.

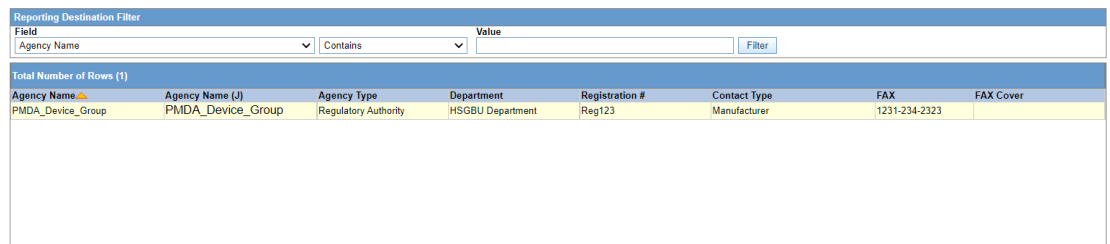
### PMDA Device paper report

In the EDI tab, select the message profile as PMDA-DEVICE MESSAGE TEMPLATE. Since the same profile caters to both XML and paper report, it is recommended that you set the same message profile for the reporting destination for paper format, as well.

#### Note:

If you have already configured the reporting destination for the PMDA device paper format, it is recommended that you create a new reporting destination for the PMDA device XML format. The existing reporting destination for paper report allows you to continue to generate paper report using the updated template.

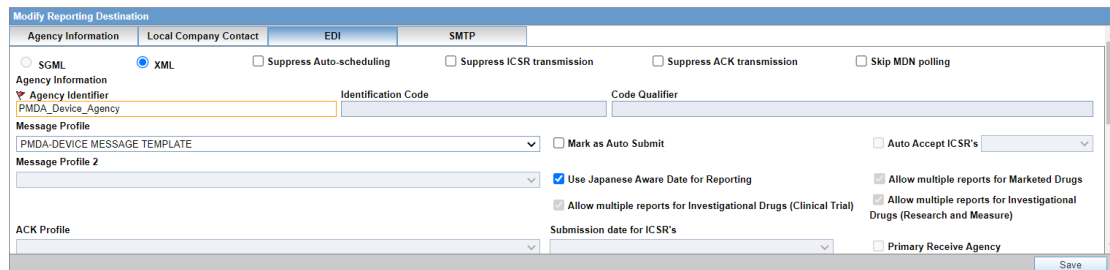
Figure 5-1 Reporting Destination filter



The screenshot shows a 'Reporting Destination Filter' window. At the top, there is a search bar with 'Field' set to 'Agency Name', 'Contains' as the operator, and an empty 'Value' field. Below this is a table with the following data:

Total Number of Rows (1)							
Agency Name	Agency Name (J)	Agency Type	Department	Registration #	Contact Type	FAX	FAX Cover
PMDA_Device_Group	PMDA_Device_Group	Regulatory Authority	HSGBU Department	Reg123	Manufacturer	1231-234-2323	

Figure 5-2 Reporting Destination



The screenshot shows the 'Modify Reporting Destination' window. It has tabs for 'Agency Information', 'Local Company Contact', 'EDI', and 'SMTP'. The 'EDI' tab is active. Under 'Agency Information', 'XML' is selected. The 'Message Profile' is set to 'PMDA-DEVICE MESSAGE TEMPLATE'. There are several checkboxes for reporting options, including 'Use Japanese Aware Date for Reporting' (checked), 'Allow multiple reports for Marketed Drugs', 'Allow multiple reports for Investigational Drugs (Clinical Trial)', and 'Allow multiple reports for Investigational Drugs (Research and Measure)'. A 'Save' button is at the bottom right.

# 6

## Setting up reporting rules

The following table describes the types of auto scheduled reports based on the Device Reporting Category and Form as PMDA Device or Form 8 or Form 10 selected in the reporting rule configuration.

For the existing reporting rules which are configured for paper report Form 8 and Form 10, it is recommended that you review them and update the Device Reporting Category field with corresponding new value.



### Note:

Since **Device Reporting Category** is a common field in reporting rule configuration, please ensure that you select the category only for the PMDA Device Form or Form 8 or Form 10.

Device Reporting Category	Report scheduled
Domestic infection case report	Form 8 XML or Paper
Domestic defect case report	Form 8 XML or Paper
Foreign infection case report	Form 8 XML or Paper
Foreign defect case report	Form 8 XML or Paper
Medical device research /survey report	Form 10 XML or Paper
Survey report of foreign safety measures	Form 10 XML or Paper

# 7

## Medical Device Defect Glossary

The JFMDA coding is enabled in the following case form sections:

- Product > Device > Device Component Information
- Product > Device > Health Impact Information
- Product > Device > Medical Device Problem Coding
- Product > Device > Evaluation / Investigation Code Information section
  - Evaluation Coding – Method / Type
  - Evaluation Coding – Result / Findings
  - Evaluation Coding – Conclusion
- Event > Clinical Sign Coding

Japanese users can select the JFMDA code, and the corresponding IMDRF code is auto populated as shown in the following screenshot for Health Impact as an example. When the global users select the IMDRF code, the corresponding JFMDA code is not auto populated.

After the JFMDA code is added, if the global user accesses the same case and selects a different IMDRF code, the existing JFMDA code is overridden. It is recommended that the global user does not update the IMDRF codes when the JFMDA codes are already available.

After the IMDRF code is added, if the Japanese user accesses the same case in locally unlocked mode and selects a JFMDA code that does not match the IMDRF code, then a message is displayed as: This IMDRF code cannot be updated as the case is globally locked. Please select JFMDA code based on the existing IMDRF code to continue. (症例がグローバルロックされているため、この IMDRF コードを更新することができません。入力された IMDRF コードに紐づいた JFMDA コードを選択してください。)

Figure 7-1 Health Impact

#	IMDRF Code	JFMDA Code	Health Impact	Listedness	Risk or Suspicion	Causality
1.	F2301	E30-e0145	Additional Device Required	Known		100% Certain
2.	F06	H02-e0136	Disruption of Subsequent Medical Procedure	Unknown	Suspicious	Unknown
3.	F12	Z01-f0025	Serious Injury/ Illness/ Impairment		Risk	Probable



Figure 7-2 Health Impact lookup

Health Impact Coding -- Webpage Dialog

Health Impact Coding

Device Generic Name 冠血管向けバルーン拡張式血管形成術用カテーテル JMDN Code 17184024 Terminology code E07

Health Impact Term   JFMDA Code  IMDRF Code

Click on an entry from the list below

IMDRF Code	JFMDA Code	Health Impact Term
F1002	Z01-f0018	Incompatible Blood Transfusion
F0801	Z01-f0014	Intensive Care
F0201	E40-e0097	Intrauterine Fetal Death
F0201	Z01-f0007	Intrauterine Fetal Death
F1203	Z01-f0028	Life Threatening Illness or Injury
F2303	Z01-f0057	Medication Required
F11	Z01-f0024	Minor Injury/ Illness / Impairment
F13	D05-e0068	Misdiagnosis/ Misclassification
F13	D12-e0056	Misdiagnosis/ Misclassification
F13	L01-e0206	Misdiagnosis/ Misclassification

Definition

Receiving incorrect or incompatible whole blood or a blood component.

# 8

## Legacy device case reporting

This topic includes how to handle legacy device case reporting for the following scenarios:

- [Business configuration - License](#)
- [Follow-up for a legacy case](#)
- [PMDA device paper reports for a legacy case](#)
- [Reports submitted in old format and subsequently in XML outside Oracle Argus](#)

### Business configuration - License

The Device classification value, Combination products (Tissue- Engineered Medical Products), is deprecated.

It is recommended that you review the license configuration for the devices and to update the classification if it contains the deprecated value Combination products (Tissue-Engineered medical products). Otherwise, the report would be rejected by PMDA.

### Follow-up for a legacy case

Whenever there is a received follow-up information, which makes the existing legacy device case reportable to PMDA, you must ensure the following data is updated or added before generating the follow-up device report:

1. Device Reporting Category under Case Form > Product > Device > PMDA device information section is updated to select the corresponding new category value.
2. You must ensure that the mandatory fields required for PMDA Device reporting are available. For the list of mandatory fields required for reporting, refer to the Validation sheet in the *PMDA Device Mapping document for Form 8 and Form 10.xlsx* mapping document and filter by the Validation column for the Mandatory value.
3. The PMDA acknowledgment number for old paper form was in the format XXXXX-YY. Oracle Argus Safety supported data entry in this format in Case Form > Product tab > Device sub tab > PMDA Management Information section > Acknowledgment number field. If an XML is generated for the same case having the paper form submissions, then the PREVIOUSREPORTREFERENCENUMBER [M.2.5.3] element is expected to be in the following format: 1-to-6-digit numerical value + 1-to-2-digit alphabet value for the previous acknowledgment number. It is recommended that you accordingly update the acknowledgment number in the PMDA Management Information section.

### PMDA device paper reports for a legacy case

The old Form 8 and Form 10 paper report was generated using editable word template provided by PMDA having form fields. Hence, the labels were not editable, and the data were editable. In Oracle Argus Safety the enhanced report is fully editable.

Any existing report in state generated or above, old layout of Form 8 and Form 10 continue to work. So it is recommended that you do not have any reports in scheduled or new data available state prior an upgrade to avoid errors.

If Form 8 or Form 10 paper report is submitted prior to an upgrade, having the old reporting category and data, after the upgrade AG service auto-schedules the follow-up report. If you try to generate an already auto-scheduled follow-up report after unlocking and selecting new reporting category and data, the application returns an error message since the case had old data when the service was auto-scheduled. This is due to the old reporting category which is no longer an allowed value. It is recommended that you delete the auto-scheduled follow-up report for the paper report after the upgrade and allow the service to auto-schedule again after updating the case data as required for the updated paper reports.

## Reports submitted in old format and subsequently in XML outside Oracle Argus

If you have legacy PMDA Device cases submitted in the old format of Form 8 or Form 10, and subsequent follow-ups have been submitted in XML format using the PMDA free tool, follow the following steps to submit subsequent follow-up device reports once you upgrade to Oracle Argus 8.4:

1. Unlock the case to enter the follow-up information.
2. Update all the data in the case as per the device XML submitted to PMDA using the free tool outside Oracle Argus. This step is required to synchronize up the same data in the case maintained in Oracle Argus.
3. Save and lock the case.

The PMDA device Form 8 XML initial report is scheduled and generated with the same data as the one generated outside Oracle Argus.

4. Transmit and mark the initial report as submitted. Ensure that the physical XML file is not transmitted to the PMDA gateway.
5. Verify that the M.2.5.1 report count tag in the report is set to 1.
6. Import the acknowledgment file obtained from PMDA.

 **Note:**

Before importing the acknowledgment, remember to update the MESSAGENUMBER to match the Device XML generated in Oracle Argus.

7. After the acknowledgment is imported, verify that the PMDA control number is populated with the year and reference number in the PMDA Management Number section on the Product tab.

# 9

## Handling case copy in PMDA Device reportable cases

When you copy an existing device case, it is recommended that you delete the records in the PMDA Device Management section to avoid data inconsistency.

# 10

## Nullification reporting

PMDA accepts nullification reports for Form 8 in XML format, whereas nullification report for Form 10 report is expected in paper format. Argus system supports auto-scheduling or manual initiation of nullification reports.

For more information, see:

- [Nullification reporting – Form 8](#)  
PMDA accepts nullification reports for Form 8 in XML format. Oracle Argus supports auto-scheduling or manual initiation of nullification reports.
- [Nullification reporting – Form 10](#)  
PMDA accepts the Form 10 device report nullification only in paper format.

### Nullification reporting – Form 8

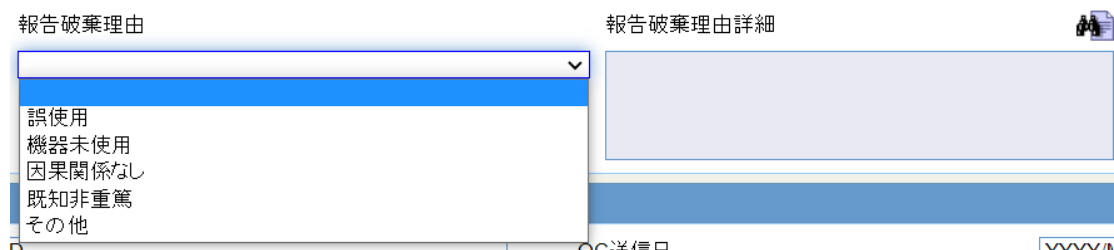
PMDA accepts nullification reports for Form 8 in XML format. Oracle Argus supports auto-scheduling or manual initiation of nullification reports.

#### Auto-scheduling

For a case with a submitted Form 8 device report to PMDA, if you want to nullify the report, the nullification reason has to be selected under Case form > Products > Device sub tab > PMDA Device Information > Nullification Reason (報告破棄理由):

- If the nullification reason is not applicable, select **その他** (Other) and enter the nullification reason detail.
- Once the nullification reason is selected and the report is auto-scheduled, the nullification XML report is auto-scheduled.

**Figure 10-1 Nullification reason**



When a case is deleted, the nullification report is auto-scheduled and generated if the case has submitted the device report similar to the E2B nullification report. If you forget to enter the nullification reason while deleting the case, the application updates **その他** (Other) in ReportWithdrawalReason [M.2.5.4] and populates the justification provided during the case deletion in ReportWithdrawalReasonDetail [M.2.5.5].

#### Manual initiation

You can manually schedule a device nullification report using the below Schedule Nullification option. The manual initiation can be used when you do not want to unlock the case to update the nullification reason. The justification provided while scheduling the nullification is considered as the nullification reason.

**Figure 10-2 Schedule nullification**



### After the nullification report submission

After the nullification report submission, it is recommended that you clear the Nullification Reason field in the case form because until the nullification reason is cleared, the next report is not auto-scheduled even if there are new follow-ups added to the case and system displays validation message.

The next report after the nullification is always Initial report with CaselIdentifier [M.7] generated with the next sequence.

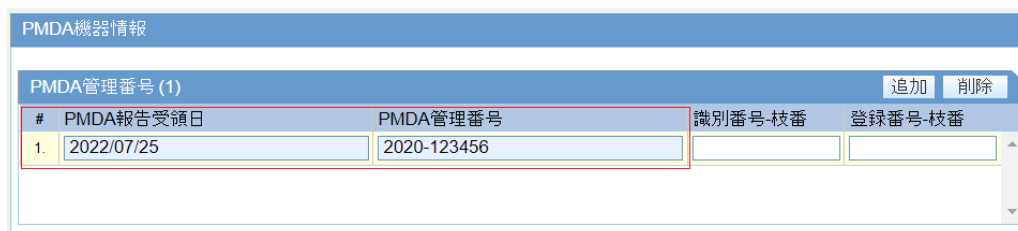
## Nullification reporting – Form 10

PMDA accepts the Form 10 device report nullification only in paper format.

To submit the Form 10 nullification report, it is recommended that once you enter the nullification reason, to manually schedule the paper report by selecting the Form 10 paper form.

Since the Form 10 nullification report is manually submitted, you must manually update the acknowledgment in the PMDA Control Number field under Case Form > Device > PMDA Information section > PMDA Control Number (PMDA 管理番号).

**Figure 10-3 PMDA Management Information section**



You can choose to auto-schedule the Form 10 nullification XML, but the application does not transmit it as it is restricted. Instead, you need to submit the paper view to PMDA based on the process published by PMDA. The Form 10 XML report is

displayed in Bulk reporting only if it is auto-scheduled. If it is manually scheduled, the report is displayed in Bulk reporting and you can choose to transmit. To avoid discrepancy or confusions, the manual generation of the nullification report is suggested for Form 10 report.

# 11

## Acknowledgment handling

Whenever the ACK from PMDA is imported:

- If it is a positive ACK, then a new row is added under Case Form > Product tab > Device sub tab > PMDA Management Information section with the system date and PMDA Control Number populated from M.1.2 (Year) and M.1.3 (Report Reference Number) from the ACK.
- If a negative ACK is imported, then no new row is added.
- If an initial report is submitted to PMDA, M.2.5.1 (report count) is set as 1. If the initial report is rejected by PMDA, then the agency expects the subsequent corrected report to be submitted with the same report count set to 1. If the report is accepted by PMDA, then the agency expects the subsequent report to be submitted with the incremented report count set to 2. Due to this reason, a new row is added in the PMDA Management Information section only for a positive ACK.

The mapping logic calculates the report count value considering the value in the previous positive ACK and increments it by 1. It is recommended that you import the ACK for the submitted report before generating the next follow-up report. Otherwise, the report count might have an incorrect value and the report sequence could be incorrect.



# 12

## Observations during PMDA testing

Oracle has tested the device XMLs generated using the PMDA device profile in Oracle Argus 8.4.

This testing was performed by submitting the XMLs to the PMDA device web portal and by receiving ACKs from PMDA.

The below observations were made during the PMDA testing:

- During testing the attachments, it was observed that the PMDA agency accepts the PMDA device XML reports with the attachments encoded twice in base 64. However, this differs from the way the attachments are encoded in the PMDA E2B(R3) report that are accepted by PMDA. Hence a common profile switch, Attachment encoding method in PMDA Device XML report, is provided with the default value set as Double step encoding. We recommend retaining this default setting.
- The other option, Single step encoding similar to PMDA E2B R3, is provided considering the future versions if the PMDA device updates their system to accept the single step encoding similar to PMDA E2B(R3).

# 13

## Frequently asked questions (FAQs)

This chapter contains the most frequently asked questions about PMDA Device reporting.

- [Can we re-use the existing agency configuration for XML reporting?](#)
- [Can we send a follow-up report in the new XML format for a legacy case having submitted the paper form 8 or paper form 10?](#)
- [Is it required to specify the ACK profile in the Reporting Destination?](#)

### Can we re-use the existing agency configuration for XML reporting?

It is recommended that you create a new Reporting destination for XML reporting instead of modifying the existing reporting destination used for old Form 8 and Form 10 paper reports.

### Can we send a follow-up report in the new XML format for a legacy case having submitted the paper form 8 or paper form 10?

Yes, if a legacy PMDA Device case contains the already submitted paper form 8 or paper form 10, you can add the follow-up information to the case and submit the report in XML format.

### Is it required to specify the ACK profile in the Reporting Destination?

No, the ACK profile field is disabled in the EDI tab. Currently, Oracle Argus supports only the import of the ACKs sent by PMDA.