

Oracle Argus Safety

eMDR Best Practices Document

Release 8.0.1

E68590-01

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This document provides information on using eMDR to switch from MedWatch Device reporting, and special considerations about eMDR generated in this release that customers must be aware of. It contains the following sections:

- [Section 1, "Configuration"](#)
- [Section 2, "Special Considerations"](#)
- [Section 3, "Related Documents"](#)
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1 Configuration

This section contains the following topics:

- [Configuring a Reporting Destination for the eMDR Profile](#)
- [Configuring Common Profile Switches for eMDR Reports](#)
- [Configuring Reporting Rules](#)
- [Configuring Codelists](#)

1.1 Configuring a Reporting Destination for the eMDR Profile

Oracle recommends you configure a Reporting Destination with the following settings to enable reports to be sent in the eMDR format:

- Select Message profile as *CDRH eMDR V1.0 MESSAGE TEMPLATE* (standard profile for eMDR).
- Acknowledge the profile is disabled when you select the eMDR profile.
- When eMDR profile is selected, Message type is automatically set to XML and *Maximum # of reports to include in the msg* is set to 1 as report batching in xml is not supported.

When Device reporting is being done using MedWatch Devices for Regulatory reporting and eMDR for pilot testing, Oracle recommends you create a new Reporting Destination for eMDR.

When Device reporting is switched over from the MedWatch Devices to eMDR, Oracle recommends you configure eMDR to the Reporting Destination that was used for sending the MedWatch Devices report.

1.2 Configuring Common Profile Switches for eMDR Reports

The following are the recommended Common Profile Switch settings:

- *Default Reporting Destination for draft eMDR generation* must be set to a Reporting Destination that is configured with the eMDR profile.
- *File attachments allowed for eMDR*, by default, is set to various attachment types supported; you can modify this setting based on the company's requirements.
- *Allowed file size for eMDR* is set to 50 MB; you can modify this setting based on the company's requirements. Oracle recommends retaining the default value or entering a lesser number.
- *Default view for eMDR* is set to the XML view; you can modify this setting based on the company's requirements.

1.3 Configuring Reporting Rules

When Device reporting is being done using MedWatch Devices for Regulatory reporting and eMDR for pilot testing, Oracle recommends you create new Reporting rules for eMDR.

When Device reporting is switched from MedWatch Devices to eMDR, Oracle recommends you configure eMDR to a new Reporting rule and to deactivate the rule for the MedWatch report.

1.4 Configuring Codelists

An Occupation codelist is provided with Factory data along with NCI_Codes. If companies have already entered data in this codelist, and if this data has been used in the Device cases prior to upgrade to 8.x release, Oracle recommends you do the following:

- Update NCI codes for the existing data in the Occupation codelist using the Flexible Data Re-categorization codelist.
- Set *Display* to *No* for the new factory data provided in the Occupation codelist using the Standard codelist.

Note: For more information on Mappings, refer to the eMDR Mapping document.

2 Special Considerations

1. As per eMDR guidelines, attachments sent with previously submitted reports must not be sent with follow-up reports. Since no check to verify that attachments were submitted previously exists, Oracle recommends you select the Attachment classification that does not qualify for eMDR reporting in the follow-up revision of the case to ensure that reports are not sent again. Alternately, you can customize the mapping logic for the data element *includeddocument*.
2. Though eMDR generated in Argus Safety is regulatory compliant, mappings for certain optional data elements are not provided. Customers can make the following configurations to provide custom mappings for user-defined fields for such data elements.

1. Define user-defined field:

User-defined fields can be used as per the following table and users can input data in these fields from the Case Form UI.

eMDR Data element	Description of Data element	UDF in UI	UDF Type	Length as per eMDR specification
mfreemail	Manufacturer Email	Products -> Product Information	Text	50
reprocaddress1	Reprocessor Address Street Line 1	Products -> Product Device	Text	30
reprocaddress2	Reprocessor Address Street Line 2	Products -> Product Device	Text	30
reproccity	Reprocessor City	Products -> Product Device	Text	30
reprocstate	Reprocessor State Code	Products -> Product Device	Text	2
reproccountry	Reprocessor Country Code	Products -> Product Device	Text	3
reprocpostalcode	Reprocessor Postal Code	Products -> Product Device	Text	10
reprocemail	Reprocessor Email	Products -> Product Device	Text	50
reprocfax	Reprocessor Fax Number	Products -> Product Device	Text	26
ufaddress1	User Facility Address Street Line 1	General-> General Information	Text	30
ufaddress2	User Facility Address Street Line 2	General-> General Information	Text	30
ufcity	User Facility City	General-> General Information	Text	30
ufstate	User Facility State Code	General-> General Information	Text	2
ufcountry	User Facility Country Code	General-> General Information	Text	3
ufpostalcode	User Facility Postal Code	General-> General Information	Text	10
ufcontactfirstname	User Facility Contact First Name	General-> General Information	Text	15
ufcontactmiddle name	User Facility Contact Middle Initial	General-> General Information	Text	1
ufcontacttitle	User Facility Contact Title	General-> General Information	Text	4
ufcontactemail	User Facility Contact email address	General-> General Information	Text	50
mfreemail	Manufacturer Email	General-> General Information	Text	50
devicenotevaluatedreasonother	Other Reason for Non Evaluation	Products -> Product Device	Text	40

2. Provide custom export logic for the required data element:

The eMDR standard profile can be used to create a copy of the custom profile, and the SQL statement for the required data element can be modified to map the data element to the corresponding user-defined field.

3. Configure a Reporting Destination with the custom eMDR profile:

Specify the custom eMDR profile created in step 2 in the Reporting Destination identified for sending eMDR reports.

4. Modify the eMDR XSL file:

Modify eMDR XSL files present in the following locations:

Web Server:

```
{ArgusInstallPath(FromArgus.ini)} \ Argus.NET\CommonWebUIComponent
\HL7\XSLT\AS\eMDR
```

AGServer:

```
{ArgusInstallPath(From Argus.ini)}\
Argus.NET\CommonWebUIComponent\HL7\XSLT\AS\eMDR
```

3 Related Documents

For more information, see the following documents for this release:

- *Oracle Argus Safety Installation Guide*
- *Oracle Argus Interchange User's Guide*

4 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

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