*Contains Nonbinding Recommendations*

# Questions and Answers about eMDR - Electronic Medical Device Reporting

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# Guidance for Industry, User Facilities and FDA Staff

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# Preface

## Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFZ-305), Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1679 to identify the guidance you are requesting.

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# Guidance for Industry, User Facilities and FDA Staff

***This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.***

## 1. Introduction

This guidance is intended to answer questions related to FDA's final rule requiring device manufacturers and importers to submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs), to the Agency in an electronic format that FDA can process, review, and archive (hereinafter referred to as the eMDR Final Rule).[1] Electronic reporting is also available to user facilities, however, the eMDR Final Rule permits user facilities to continue to submit only written reports to FDA. The requirements of this final rule will take effect on August 14, 2015. This guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the Center for Devices and Radiological Health (CDRH) in FDA. The guidance also identifies where you can find more detailed information on the preparation and transmission of the reports.[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

[1] The eMDR Final Rule, which amends 21 CFR Part 803, can be found in 79 FR DOC 2014-03279, February 13, 2014.

[2] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm.

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## 2. Background

For over 20 years, FDA received postmarket MDRs in a paper format through the mail. The eMDR Final Rule requiring the electronic submission to FDA of manufacturer and importer MDRs is an important step toward improving the Agency's systems for collecting and analyzing postmarket MDRs. When FDA receives data elements in a paper format, the information must be manually entered into our internal electronic database before it can be effectively reviewed and analyzed. This process is extremely time consuming, costly, and susceptible to data entry errors. Electronic submission of MDRs will have the following benefits:

- Reducing industry's time and costs associated with transcribing data from internal data management systems to paper and mailing the paper reports to the Agency;
- Reducing the Agency's transcription errors, time, and costs associated with receiving paper reports and transcribing data to electronic format for review and analysis;
- Expediting the Agency's access to safety information in a format that supports efficient and comprehensive data analysis and reviews; and
- Enhancing the Agency's ability to rapidly communicate information about suspected problems to the medical device industry, health care providers, consumers, and other government Agencies.

## 3. General Issues

Specific requirements for the submission of postmarket MDRs to FDA are in 21 CFR Part 803. This guidance document addresses general issues related to the electronic submission of postmarket MDRs and provides links to more detailed information on the preparation of an electronic MDR (eMDR) submission.

### A. Electronic MDR Submissions

**What is an electronic MDR submission?**

For the purposes of this guidance, an eMDR submission is a file containing one or more medical device reports in an electronic format that FDA can process, review, and archive.

**What information do I need to include in my electronic MDR?**

The MDR regulation (21 CFR Part 803) specifies the types of reports and the data elements required in an MDR. An eMDR contains the same data elements. Importers must include the information specified in 21 CFR 803.42. Manufacturers must include the information specified in 21 CFR 803.52. User facilities must include the information specified in 21 CFR 803.32. Although the eMDR Final Rule permits user facilities to continue to submit MDRs on paper, user facilities may instead choose to submit MDRs in an electronic format.

**What is the format of an electronic MDR?**

FDA's current data system was developed to process, review, and archive MDRs configured according to the Health Level Seven Individual Case Safety Report (HL7 ICSR) message format. An MDR is made up of data element identifiers and the associated data element value in a machine-readable format. For specific information on data element identifiers used by both of the reporting options discussed below, see the *Health Level Seven (HL7) Individual Case Safety Report (ICSR) Release 1: Implementation Guide for FDA Medical Device Reporting* at http://www.fda.gov/ForIndustry/DataStandards/IndividualCaseSafetyReports/default.htm.

## B. Sending an Electronic MDR Submission via FDA's Electronic Submissions Gateway (ESG)

**What do I need to do to start submitting MDRs electronically to FDA?**

To submit MDRs electronically, you will need to set up a Web Trader Account and then submit test data that is successfully processed through the ESG before you receive a production account to use for your MDR submissions. Here is the process for beginning to file eMDRs:

1. Request a Web Trader Account from the ESG.
2. Submit a Letter of Non-Repudiation to FDA.[3]
3. Obtain a personal digital certificate.[4]
4. Submit test data. Prepare a test eMDR (a mock report and not an actual adverse event report) containing the information specified in the appropriate section of

[3] The non-repudiation agreement allows the FDA to receive electronically signed submissions in compliance with 21 Code of Federal Regulations (CFR) 11.100. You can find sample letters of non-repudiation agreement at http://www.accessdata.fda.gov/esg/userguide/webhelp/Sample_Letters_of_Non-Repudiation_Agreement.htm

[4] A digital certificate is an attachment to an electronic message that allows the recipient to authenticate the identity of the sender via third- party verification from an independent certificate authority. Digital certificates are used to identify encryption and decryption codes between message senders and recipients. Information on the FDA ESG and digital certificates is available at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113223.htm

21 CFR Part 803: 803.32 for user facilities, 803.42 for importers, or 803.52 for manufacturers.

5. Receive a production account from the ESG. CDRH will notify ESG to provide you with the production account once you have completed successful testing.
6. Use the production account to send your actual eMDRs to FDA.

Detailed instructions can be found at:
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm

Additional information about the ESG is available at:
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

**How do I prepare an electronic MDR submission?**

You can choose from two options to create your eMDR submission. More information on the two options for filing eMDRs is available at:
http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm .

1. FDA eSubmitter (formerly referred to as CDRH eSubmitter or CeSub) Software

The eSubmitter program is a free, downloadable application that allows users to create one report at a time. With eSubmitter, the user manually enters the required MDR information into the eSubmitter program. The program contains data elements that correspond with 21 CFR 803.32, 803.42, and 803.52, and generates the .xml message, in HL7 ICSR format, needed to successfully transmit the report via the ESG.

The eSubmitter program allows the user to print a copy of the submitted report(s) and allows the attachment of labeling or other documents to the initial report or to a supplemental or follow-up report.

The eSubmitter program and installation instructions are free and available at:
http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.

2. Health Level Seven (HL7) Individual Case Safety Reporting

This option provides the capability to create and submit eMDRs either individually or in batches (containing multiple individual reports in a single submission). Entities who choose this option are encouraged to develop systems that can save or print the resultant report and that can encode attachments into their eMDRs.

You can find more detailed information on these two methods of preparing an eMDR at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm.

**How should I complete a data field (a field where a user can type information) if I do not have information for the field?**

For Health Level Seven (HL7) Individual Case Safety Reporting users, the HL7 ICSR schema provides for several values that may be used when there is no information to enter in an optional field:

ASKU - asked but unavailable

NI - no information

NA - not applicable

These "null values" are added to the code of the HL7 ICSR message to further clarify why data is not being provided. Information on how to properly implement null values is found at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127951.htm.

(At that site, click the link for "Complete Packet: eMDRHL7files.zip" and select the ICSR Implementation Technical Specification document, which answers the question "How do I address null values?").

For eSubmitter users, if you have no information to provide for a given data field, and eSubmitter does not allow the selection of a null value for that field, you should leave the field blank.

**How do I know if my submission of an electronic MDR was successful?**

FDA's system will automatically route three separate electronic acknowledgments to the user's ESG account. These acknowledgements indicate the stage of processing that the eMDR has reached:

Acknowledgment 1, also known as the Receipt or MDN (Message Disposition Notification) acknowledgment, indicates that the ESG received the eMDR(s).

Acknowledgment 2 indicates that CDRH received the eMDR(s).

Acknowledgment 3 indicates the pass or failure status of the eMDR(s) into CDRH's adverse event database--that is, whether the eMDR was successfully loaded into the database.

If there are no errors, we anticipate that the three acknowledgement letters will be generated the same day or within 24 hours of the submission.

**What date does FDA consider the receipt date for an electronic MDR?**

FDA considers the receipt date for an eMDR to be the date the eMDR arrived at the ESG (Acknowledgment 1), but only if the eMDR is successfully loaded in the CDRH database

(a passing Acknowledgment 3). If a failure occurs during the validation or loading process, the error is described in Acknowledgment 3. The reporting entity should correct the error(s) and resubmit the eMDR. If the resubmitted eMDR is successfully loaded, (a passing Acknowledgment 3), the receipt date will be the date that the resubmitted eMDR arrived at the ESG, as documented in the Acknowledgment 1 issued for the resubmitted eMDR.

The time zone should not be a concern for timely reporting under MDR. Although Acknowledgment 1 displays both the date and time according to the Eastern Standard Time (EST)/Eastern Daylight Time (EDT) zone, MDR considers only the date for the purposes of calculating timely reporting. If the report is successfully loaded, this processing should take no more than an hour. Although Acknowledgment 1 displays EST/EDT, FDA will consider the local time of the submitter when determining the submission date, just as a postmark date is used for mailed paper reports.

**What should I do if Acknowledgment 3 notifies me of validation and loading error(s) in my electronic MDR?**

If you submit an eMDR individually (not as part of a batch), and receive an Acknowledgment 3 that states that your report has failed to load, the Acknowledgment 3 will describe the error(s). You should correct the error(s) and resubmit the eMDR, at which time you will receive another set of three acknowledgments.

If you submit an eMDR as part of a batch, Acknowledgment 3 will list all the reports in the batch and indicate whether each report has passed or failed to load. You should correct the error(s) for the failed reports and resubmit the FAILED reports ONLY. You should not resubmit the entire original batch. When you resubmit the report(s) that contained errors, you will get another set of three acknowledgments for the resubmitted eMDR(s).

Errors that will prevent successful loading in the CDRH database of an eMDR include:

- Failure to provide data in a required data field, such as the report number,
- Failure to use the appropriate format for a data field, such as an incorrect date format,
- Invalid report number error: Use of an invalid report number (i.e., not following the correct format for the number or using an incorrect number for the reporting entity),
- Character max error: Too many characters entered, exceeding the character limitations for a given data field,
- Duplicate report error: Caused when a reporting entity submits a report that was previously loaded successfully into the CDRH database, and

- Initial report not found for this supplemental error: Caused when a user submits a supplemental report to an initial report that has not been accepted in the CDRH database.

If you need help interpreting error messages in Acknowledgment 3, send an e-mail to eMDR@fda.hhs.gov.

**What should I do if I send my eMDRs and do not receive one or more of the acknowledgments?**

If you do not receive Acknowledgment 1 or 2, check the status of the ESG at:http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm367545.htm . If the ESG system status website indicates the ESG is operating normally, contact the ESG Staff at ESGHelpDesk@fda.hhs.gov.

If you do not receive Acknowledgment 3, check the eMDR Status Page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/ucm179299.htm. If the eMDR system status website indicates that eMDR is operating normally, contact eMDR@fda.hhs.gov.

**Should I keep a copy of the eMDRs that are in my electronic MDR submission? Should I keep the acknowledgments?**

Yes, under 21 CFR 803.18(b)(1)(ii) of the eMDR Final Rule, an entity is required to keep paper or electronic copies of all reports submitted to us or to importers, distributors, or manufacturers. In addition, under 21 CFR 803.18(b)(1)(iii) of the eMDR Final Rule, an entity must keep copies of all electronic acknowledgments sent by FDA in response to the entity's eMDRs.

## C. Supplemental, Follow-up, and Additional Information Submissions

**How do I update a report?**

Under 21 CFR 803.12 of the eMDR Final Rule, manufacturers and importers must submit supplemental or follow-up reports to FDA in an electronic format that FDA can process, review and archive. User facilities may submit follow-up reports to FDA in an electronic format, but are still allowed to report only on paper in accordance with 21 CFR 803.12(b).

The options for preparing and transmitting a supplement or follow-up report are the same as those for initial reports, discussed above. For all updates, you should include the initial report number and state that the type of submission is a follow-up report. Limit your additional entries to those where you need to update previously provided information. For example, if patient age and sex are unchanged, do not include them in your supplement or follow-up report. If you are updating or correcting the model number, provide the

corrected information only. A submitter should use electronic submissions for supplemental or follow-up reports even for MDRs that were initially filed on paper.

**Can a reporting entity respond to an FDA Request for Additional Information (AI) electronically?**

If FDA requests additional information for an MDR under 21 CFR 803.15, you are encouraged to submit the response electronically.

A manufacturer responding to an FDA request for additional information, using the 3500A format, should enter the initial report number, indicate in Block H2 that the type of follow-up is a "Response to FDA Request," and provide the requested information in Block H10/11, Additional Manufacturer Narrative. Any discrete data elements should also be reported in Block H10/11. You may submit the letter you received as an attachment to the submission.

The FDA request for AI may give the manufacturer the option to respond using email to the FDA sender. The manufacturer's email response should include the identifying information specified in the AI request.

A communication from FDA to a user facility or importer that requests additional information will provide instructions for responding to the sender. That response should include the identifying information specified in the AI request.

## D. Communication about Software Changes and System Outages

**How will I learn of future changes to software, data fields and code lists?**

FDA is committed to providing industry with adequate notice of any specification changes and, when possible, will ensure previous versions of such specifications can still be utilized to submit adverse events electronically. We will utilize our websites for MDR, eMDR, and FDA ESG as well as Federal Register notices and updates to this guidance (when appropriate) to provide sufficient advance notification of changes to all stakeholders. We will work with stakeholders on implementation of the changes and expect to support previous specifications long enough to ensure that HL7 and eSubmitter users are able to make the necessary changes.

**What should I do if a System Outage prevents me from filing an electronic MDR on time?**

The FDA ESG website provides notification of scheduled maintenance and maintains a status history that documents unscheduled down time for the FDA ESG. The CDRH eMDR website provides notification of scheduled maintenance for the CDRH eMDR processing system. Typically, an ESG or CDRH eMDR processing system outage will not last more than 24 hours and should not require an extension of time. However, if a manufacturer or importer is unable to submit a report on time due to an outage affecting the ESG or the CDRH eMDR processing system, it may document its attempts at timely

filing in Block H10 for the affected reports and submit reports electronically as soon as the ESG or CDRH eMDR processing system is operational.

A reporting entity using an HL7 reporting option should plan for a backup method of reporting for an outage affecting its own system. If a reporting entity experiences an outage within its own system that will affect timely reporting, it should contact FDA at the eMDR email address, eMDR@fda.hhs.gov. The email should provide FDA with information on the problem, the number of reports affected, and an estimate of how long it will take to resolve. We will respond to provide instructions on alternatives for submission of the adverse event reports. A description of the problem with the electronic submission should be documented in Block H10 for the affected reports before they are submitted.

When an alternative method is used during a system outage, FDA will respond with an Acknowledgment 3 that documents that the report has been successfully loaded in the CDRH database or failed to load due to specified errors. In these instances, the reporting entity will not receive an Acknowledgment 1 or 2.

## E. Additional Sources of Information

**Where can I find technical information concerning the eSubmitter software?**

Technical information, e.g., information on downloading the software, on the eSubmitter system is accessible at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.

**Where can I find technical information concerning the HL7 ICSR?**

Technical information, including technical specifications, on the HL7 ICSR is accessible at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127948.htm

**Who do I contact if I cannot find the answer to my question?**

For general questions on eMDR submissions, e-mail eMDR@fda.hhs.gov. For questions concerning the FDA Electronic Submissions Gateway (ESG), please contact the ESG staff as indicated on their Web site: http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

For questions about the MDR regulation and reporting, you may call 301-796-6670 or send an email to MDRPolicy@fda.hhs.gov

# 4. References

1. Medical Device Part Reporting 21 CFR 803: see the final rule, Medical Device Reporting: Electronic Submission Requirements,79 FR DOC 2014-03279, February 13, 2014.
2. Electronic Medical Device Reporting

   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm
3. HL7 Individual Case Safety Report - technical files
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127951.htm
4. FDA Electronic Submissions Gateway (ESG)
   http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm