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Draft Guidance for Industry, User Facilities and FDA Staff eMDR - Electronic Medical Device Reporting

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Comments and suggestions regarding this draft document should be submitted within **[insert]** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Howard Press 301-796-6087.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Division of Postmarket Surveillance
Information Analysis Branch

Preface

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1679 to identify the guidance you are requesting.

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Draft Guidance for Industry, User Facilities and FDA Staff

eMDR - Electronic Medical Device Reporting

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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This draft guidance is intended to address general issues related to FDA's proposed rule to require the submission of medical device reports in an electronic format that FDA can process, review, and archive.[1] This draft guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the Center for Devices and Radiological Health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 draft guidance also indicates 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, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply

[1] The proposal to amend 21 CFR Part 803 can be found in 73 FR XXXXX, DATE).

[2] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127932.htm

with those requirements. However, if you believe an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to Howard Press (e-mail Howard.Press@FDA.HHS.GOV) or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOmbudsman/default.htm.

2. General Issues

Specific requirements for the submission of postmarket medical device reports (MDRs) to FDA are in 21 CFR Part 803. This draft guidance document addresses some general issues related to the electronic submission of postmarket medical device reports and provides links to more detailed information on the preparation of an electronic MDR submission. This draft guidance does not apply to adverse event reports associated with devices subject to an approved investigational device exemption or reports submitted for post approval studies.

A. Electronic MDR Submissions

What is an electronic MDR submission?

For the purposes of this draft guidance, an electronic MDR 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 a medical device report. An electronic MDR contains the same data elements. User facilities must include the information specified in 21 CFR 803.32. Importers must include the information specified in 21 CFR 803.42. Manufacturers must include the information specified in 21 CFR 803.52.[3]

What is the format of an electronic MDR ?

[3] You may find the current regulations at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a42f0070e5a1a4e3a0b03e3ed2f36cae&rgn=div5&view=text&node=21:8.0.1.1.3&idno=21. The proposed amendments providing for the submission of medical device reports in electronic format may be found at 73 FR XXXXX, DATE.

FDA's current systems are configured to process, review, and archive MDRs configured according to the Health Level Seven Individual Case Safety Report (HL7 ICSR) message format. The report 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, irrespective of the reporting option (discussed below), see the *Health Level Seven (HL7) Individual Case Safety Report (ICSR) Release 1: Implementation Guide for FDA Medical Device Reporting* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127948.htm) .

B. Preparing and transmitting electronic MDR submissions

What do I need to do to submit an MDR in electronic format?

To submit an MDR in electronic format, you will need to do the following:

1. Obtain a digital certificate for use with FDA's Electronic Submission Gateway (ESG). For more information see http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm .
2. Prepare the electronic file containing the information specified in the appropriate section of 21 CFR Part 803.
3. Send the electronic file to FDA through the ESG.

How do I prepare an electronic MDR submission ?

There are two available options that can be used to prepare an electronic MDR submission.

1. Low-volume reporting (few or infrequent reports) can be carried out using the CDRH eSubmitter (CeSub) software, to submit one report at a time. With CeSub, you manually enter all the pertinent MDR report information into the CeSub program. The program produces the XML message, in HL7 ICSR format, needed to transmit the report via the ESG. The CeSub program permits you to print a copy of the submitted report. The CeSub software and instructions for installation are free and available at: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm:
2. High-volume reporting (numerous or frequent reports) can be carried out by developing an application using the Health Level Seven (HL7) ICSR to create an electronic MDR submission directly from adverse event information in the reporter's computer system. An HL7 ICSR submission may contain multiple reports in a single submission. HL7 ICSR is a message format, not a specific software application, and has no inherent print capability, but reporters

developing applications using this standard may build functions for saving or printing the resultant reports.

Where can I find more detailed information on these two methods of preparing an electronic MDR ?

More detailed information on these methods can be accessed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127932.htm

What do I need to do to send to the submission through the ESG?

As explained in more detail on FDA's ESG website (see next question), you need to do the following:

1. Request a test account.
2. Obtain a digital certificate for use with the FDA ESG if you do not already have one.
3. Send test submissions to FDA through the ESG.
4. Upon successful testing, set up a production account.

Where can I find more information concerning the ESG?

Specific information on using the ESG is available at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htmhttp://www.fda.gov/esg .

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

FDA's computer system will send you three acknowledgments.

Acknowledgment 1– confirms that the submission was received by the ESG.

Acknowledgment 2 – indicates that the submission reached CDRH.

Acknowledgment 3 –indicates which reports in your submission successfully loaded to CDRH's adverse event database and describes the errors for any reports that failed during the validation and loading process

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

If you do not receive Acknowledgment 1 or 2, check the ESG status at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/ucm161883.htm. If the ESG Status Page indicates the Gateway is operating normally, contact the ESG Staff as indicated on their Web site.

If you do not receive Acknowledgment 3, check the eMDR Status Page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127932.htm. If the status page indicates that eMDR is operating normally, contact eMDR@FDA.HHS.GOV. If you do not understand one of the error messages in Acknowledgment 3, you may send an e-mail to eMDR@FDA.HHS.GOV.

What should I do if Acknowledgment 3 notifies me of errors in validating and loading my electronic MDR submission?

If you submit an electronic MDR individually (not as part of a batch), and you get an error message in Acknowledgment 3, correct the errors and resend the submission. When you resubmit the MDR, you will get another set of three acknowledgments.

If you submit an electronic MDR as part of a batch, Acknowledgment 3 will list all the reports in the batch and indicate the status of each report as loaded successfully or failed to load. Correct the errors for the failed reports and resubmit the FAILED reports ONLY. Do not resubmit the entire original batch. When you resubmit, you will get another set of three acknowledgments.

Should I keep a copy of the reports that are in my electronic submission and the acknowledgments?

Yes, you are already required to keep copies of all MDR forms and other information that you submitted to us or to importers, distributors, or manufacturers (21 CFR 803.18(b)(1(ii)). If FDA's proposed rule is finalized, this requirement will be amended to refer specifically to copies of all reports submitted, whether paper or electronic. In addition, under the proposed rule, you will be required to keep copies of all electronic acknowledgments that FDA sends you in response to electronic submissions. .

C. Follow-up and additional information submissions

If the proposed regulation is finalized, supplemental or follow-up reports submitted by manufacturers in accordance with 21 CFR 803.56 will be required to be submitted in electronic format. Other reporters who choose to update an initial report may also submit the update in electronic format. FDA may also request additional information in follow up to a specific report, under 21 CFR 803.15. The following provides information on submitting both of these types of reports in electronic format.

How do I update my report?

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, 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 submission. If you are updating the Model Number, provide the new information. The electronic MDR format that FDA can process, review, and archive contains discrete data fields, such as Brand Name or Model Number and narrative fields such as the event description. Updates to the narrative fields add additional narrative to the event record. Changes to discrete fields replace the previous entry in the field.

Can a manufacturer respond to an FDA Request for Additional Information electronically?

Yes, manufacturers responding to a request for additional information made under 21 CFR 803.15 can submit the response electronically. (FDA is not presently prepared to accept electronic responses to requests for additional information from other types of reporters.) Note that this process is different from the process manufacturers use for supplemental or follow-up reports under 21 CFR 803.56 (refer to the question above). For a response to an FDA request for additional information, enter the initial report number, indicate that the type of follow up is a Response to FDA Request and provide the additional information requested as Additional Manufacturer Narrative. All discrete data elements should be reported as Additional Manufacturer Narrative. You may submit the letter you received as an attachment to the message.

D. Additional Sources of Information

Where can I find technical information concerning the CeSub system?

Technical information, e.g., information on downloading the software, on the CeSub 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 electronic medical device report 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.

3. References

1. Medical Device Part Reporting 21 CFR 803: see also the proposed rule on electronic Medical Device Reporting, 73 FR XXXXX, DATE.
2. Electronic Medical Device Reporting http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127932.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