Electronic Medical Device Reporting (eMDR)

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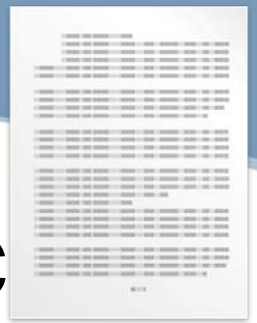
Existing Regulation

- **§ 803.12 Where and how do I submit reports and additional information?**
- (a) You must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002.

Proposed Regulation

- **§ 803.12 How do I submit reports and supplements?**
- (a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an *electronic format that FDA can process, review, and archive*. FDA will provide and update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission).



MDR, ASR, PSR, RAE, etc

- The electronic submission process starting at the ESG and ending in MAUDE is currently only for 3500A MDRs.

- Not currently submitted via the ESG:
  - Alternative Summary Reporting
  - Postmarket Spreadsheet Reports
  - Remedial Action Exemptions
  - Other Exemptions

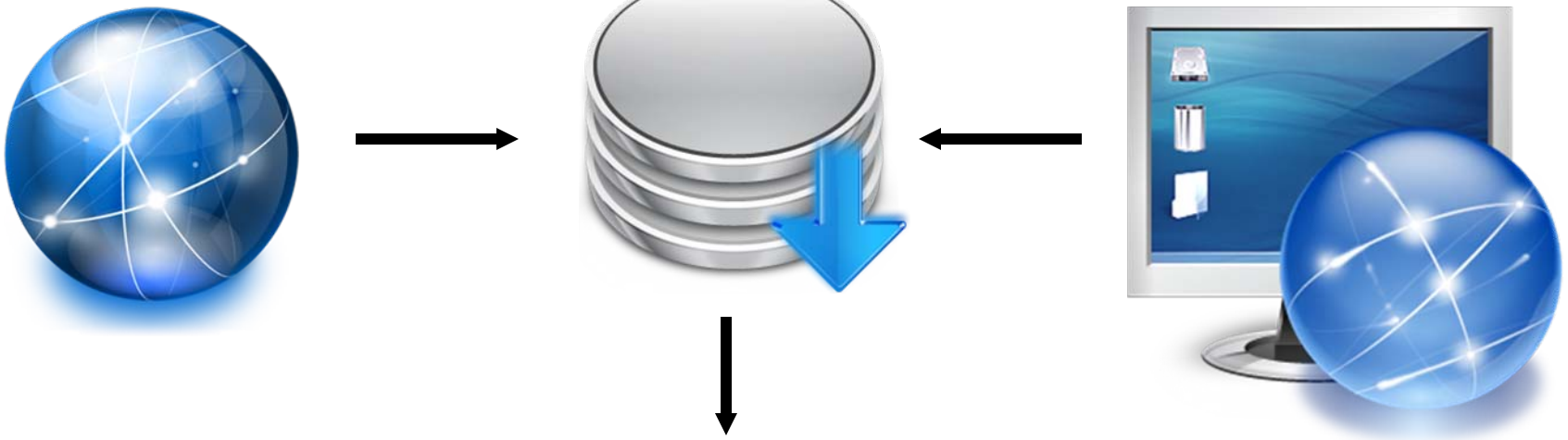
High Volume Reporting (AUTOMATED)

Single Or Batch Reporting

Electronic Submissions Gateway (ESG)

Low Volume Reporting (MANUAL)

Single Report



eMDR System

MDRs

Attachments

MAUDE

IMAGE 2000

Getting Onboard

1. Get a test account with the ESG.

2. Get a digital certificate.

3. Send a letter on non-repudiation (authenticating your digital identity).

4 Contact CDRH (eMDR@fda hhs gov)

5. Test sending MDRs with CDRH.

6. CDRH approves production account with the ESG.

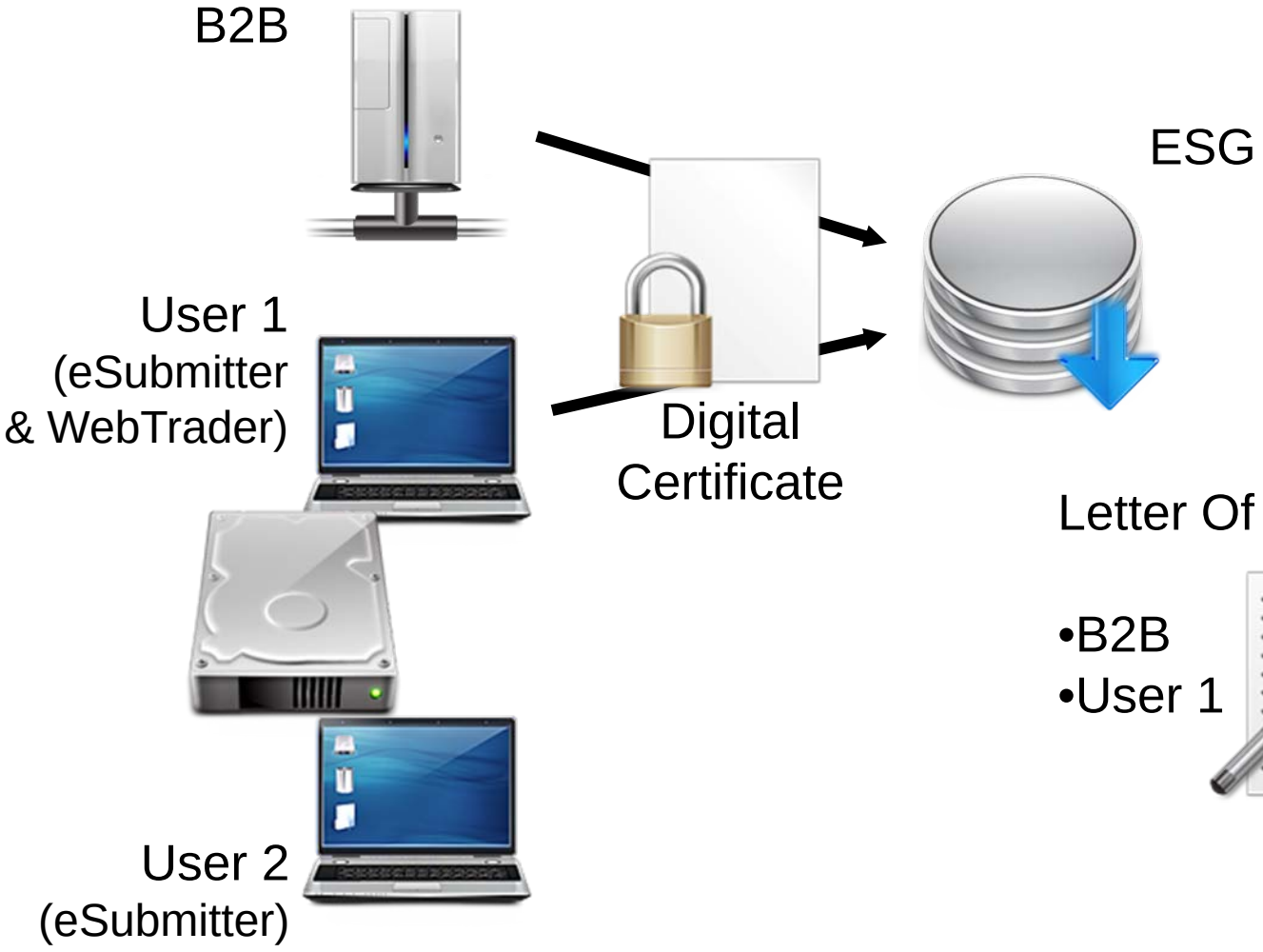
Electronic Submissions Gateway (ESG)

- The ESG is at the Agency level and not under CDRH control.
- Single point of entry for all electronic submissions into FDA.
- Two options for submission
  - B2B (Automated/High Volume/Batch Reporting)
  - WebTrader (Manual/Low Volume/Single Reports)
- Acknowledgments for each stage of report transmission.

ESG website:

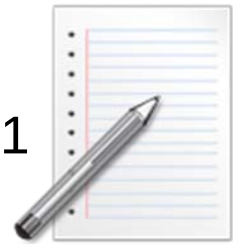
- – http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm
- – « FDA ESG » in Google or Bing

Digital Certificates And the ESG



Letter Of Non-repudiation:

- B2B
- User 1



Acknowledgements

Acknowledgment 1

```
This MDN (Message Disposition Notification) was
automatically built on Tue, 31 Jul 2007 22:15:56 GMT in
response to a message with id
<8180602.1185920139411.JavaMail.qdn@DR2MM5102150> received
from ZZFDATST on Tue, 31 Jul 2007 22:15:51 GMT.
Unless stated otherwise, the message to which this MDN
applies was successfully processed.
```

Ack1: Regulatory Date Using Reporter Time Zone *IF* Ack3 Passes.

Acknowledgment 2

```
MessageId: <8180602.1185920139411.JavaMail.qdn@DR2MM5102150>

CoreId: 1185920151277.11322@llntap02

DateTime Receipt Generated: 07-31-2007, 18:17:27

CDRH has received your submission
```

Acknowledgment 3

Submission Summary	
Core ID:	1185920151277.11322@llntap02
Batch ID:	[redacted]-20070731181208
Date Entered:	Tue Jul 31 18:18:17 EDT 2007
Summary:	passed: 1, Failed: 0

Report List:	
Report Number:	[redacted]-2007-06009, passed.

Gateway Acknowledgements

Reporters

ESG

CDRH

eMDR/MAUDE

Failed Ack Scenarios

- No Ack1/Ack2/Ack3
- – Customer or FDA ESG server down.
- – *Contact ESG (esgreg@gnsi.com)*

- No Ack2/Ack3
- – FDA ESG down or unable to send to CDRH
- – *Contact ESG (esgreg@gnsi.com)*

- No Ack3
  - – MDR processing failed due to CDRH server being down, or the MDR HL7 message has wrong format.
  - – *Contact CDRH (emdr@fda.hhs.gov)*
  - – Wait 24 hours from sending to ESG before contacting CDRH.

Automated Submitting

- Utilizes Health Level 7 (HL7) version 3 Individual Case Safety Report (ICSR) release 1
- Submit MDRs as xml files (attachments encoded in Base64)
- Submit via FDA Gateway (B2B)
- Submit one report or a batch of reports
- Technical files and schemas on website http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127951.htm
  - « FDA eMDR Technical Information » in Google or Bing

Implementation of Automated Solution

- Health Level Seven (HL7) Individual Case Safety Reporting (ICSR) Files
- Null Flavors vs. Blank Data
  - ASKU – asked but unknown
  - NI – no information; answer could be available, but no information was provided
  - NA – not applicable; this question does not apply to the situation
  - **As a "nullFlavor" attribute and NOT as a value.**
- Use Webtrader (low volume submitting) as a back-up.
- Testing the high volume solution works better when both business and IT groups are involved in the company

nullFlavor

- Data Quality Issues

```
<detectedIssueEvent>
        <code code="C53571"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="Type_of_Report" />
<value xsi:type="CE" nullFlavor="ASKU"        <-------------------  GOOD CODE
        codeSystem="2.16.840.1.113883.3.26.1.1">
</detectedIssueEvent>
```

VS.

```
<detectedIssueEvent>
        <code code="C53571"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="Type_of_Report" />
        <value xsi:type="CE" code="ASKU"  <-------------------  BAD CODE
                codeSystem="2.16.840.1.113883.3.26.1.1">
</detectedIssueEvent>
```

nullFlavor

- Schema Validation Issues

```
<detectedIssueEvent>
        <code code="C53571"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="Type_of_Report" />
<value xsi:type="CE" nullFlavor="NA"          <-------- GOOD CODE
        codeSystem="2.16.840.1.113883.3.26.1.1">
</detectedIssueEvent>
```

VS.

```
<detectedIssueEvent>
        <code code="C53571"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="Type_of_Report" />
        <value xsi:type="CE" code="Na"          <-------- BAD CODE
                codeSystem="2.16.840.1.113883.3.26.1.1">
</detectedIssueEvent>
```

nullFlavor

- Resolution
  - Documentation
  - Extensive testing with industry partners generating their own files to send to CDRH
  - Example files made available to industry partners

Submitting Manually

- Utilizes free FDA eSubmitter Application
- Fill out a 3500A form for one report (following 3500A instructions)
- ***Submit the eSubmitter-packaged file (.zip) to submit via the ESG using WebTrader***
- Zip file will include an HL7 xml and any attachments
- pdf/zip are the preferred file types accepted for attachments
- http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm
- « FDA eSubmitter » in Google or Bing

Submitting In General

- Once you begin electronic reporting, submit all documents electronically
  - Initial reports
  - Supplemental/follow-up reports
  - Attachments (must be either .pdf or .zip)
  - Responses to Additional Information letters
  - Source reports (e.g. user facility reports)

- Sign up to receive updates by e-mail at http://service.govdelivery.com/service/subscribe.html?code=USFDA_60

Contact

- e-mail
  - eMDR@fda.hhs.gov

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

– « FDA eMDR » in Google or Bing