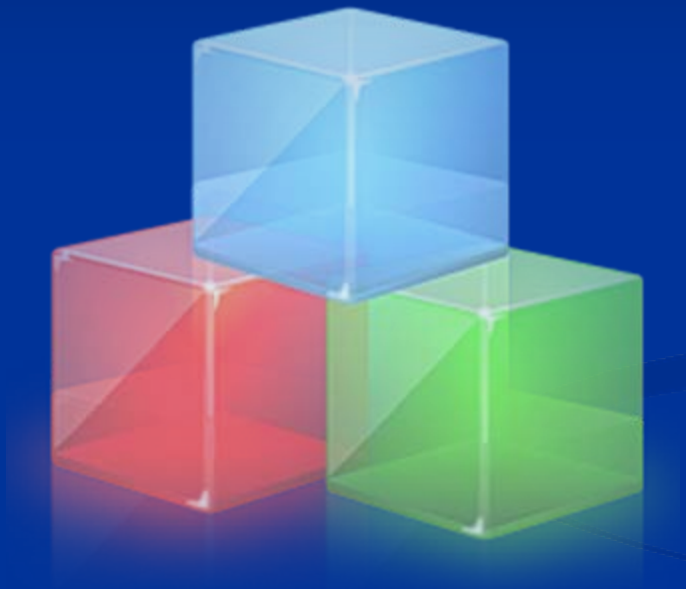
Electronic Medical Device Reporting (eMDR)



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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).

Process

- Submitted Via Electronic Submissions Gateway (ESG)
  - B2B (High Volume/Batch Reporting)
  - WebTrader (Low Volume/Single Reports)
- ESG sends to CDRH
  - CDRH validates message and loads into MAUDE database

Getting Onboard

1. Get a test account with the ESG.
2. Send a letter on non-repudiation (authenticating your digital identity).
3. Get a digital certificate.
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 (High Volume/Batch Reporting)
  - WebTrader (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

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

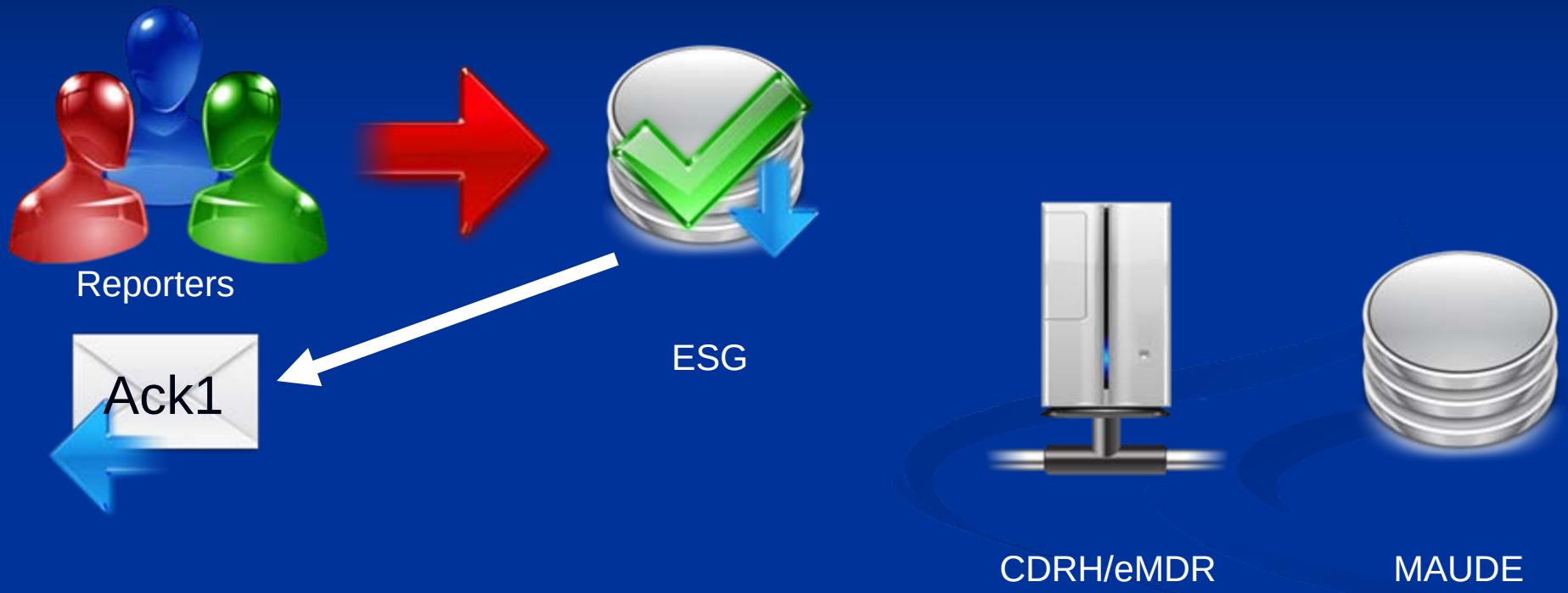
DateTime Receipt Generated: 07-31-2007, 18:17:27

CDRH has received your submission

Acknowledgment 3

Submission Summary	
Core ID:	1185920151277.11322@llntap02
Batch ID:	2939301-20070731181208
Date Entered:	Tue Jul 31 18:18:17 EDT 2007
Summary:	passed: 1, Failed: 0
Report List:	
Report Number:	[redacted]-2007-06009, passed.

Acknowledgements



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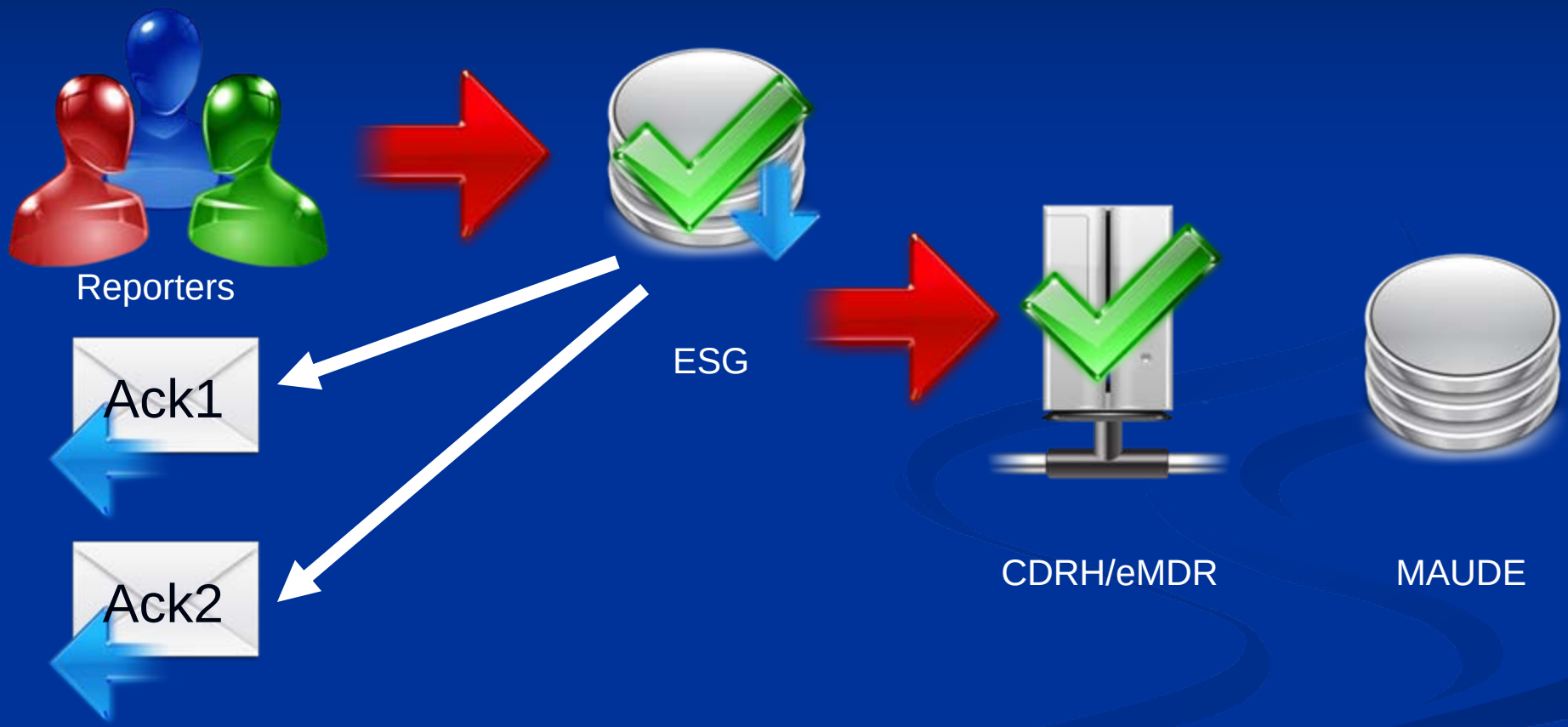

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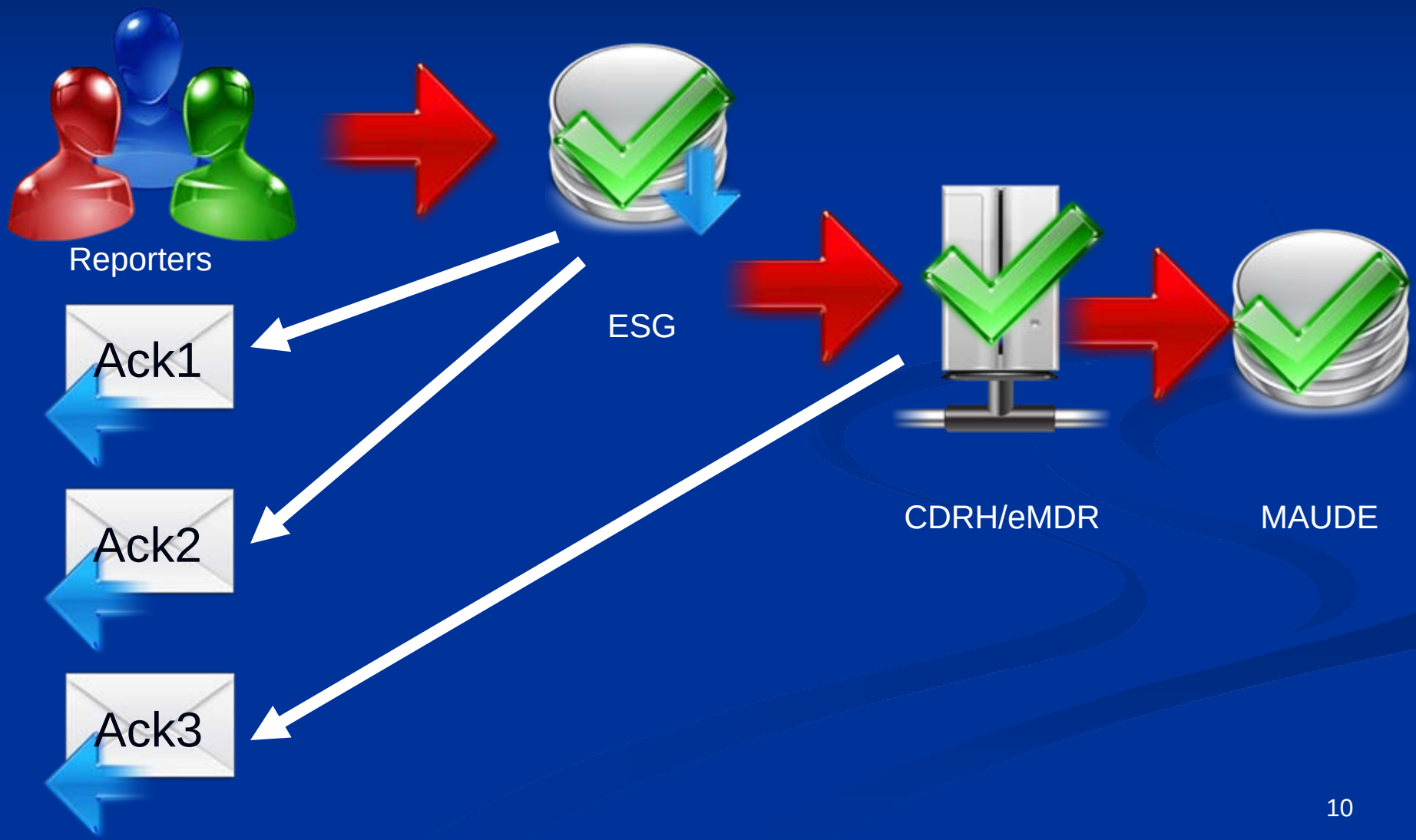

Failed Ack Scenarios

- 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.

High Volume Submitting

- Utilizes Health Level 7 (HL7) Individual Case Safety Report (ICSR) version 3 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 specifications on website
  - http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107914.htm
  - « FDA eMDR Technical Information » in Google or Bing

High Volume Implementation

- Health Level Seven (HL7) Individual Case Safety Reporting (ICSR) Files
  - Implementation Spec
  - Schemas
- 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
  - **Strongly Encouraged**
- 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

Low Volume Submitting

- 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 only 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)
  - Response to Additional Information letters
  - Source reports
- Sign up to receive updates by e-mail at http://service.govdelivery.com/service/subscribe.html?code=USFDA_60
- Check the website for System Status for both eMDR and the ESG

FDA Event Problem Codes

- New Patient, Device, and Component Event Code hierarchy more flexible in describing events: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm
- eSubmitter allows entry of only codes in the new hierarchy, B2B users need to add that logic.
- Manufacturer evaluation codes undergoing same hierarchical revision.

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