



# ARE YOU READY? U.S. MEDICAL DEVICE REPORTING CODE TRANSITION

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This white paper outlines current coding requirements for reporting adverse medical device events to the U.S. Federal Food and Drug Administration and the International Medical Device Regulators Forum. It also discusses how some of these codes will become aligned effective July 5, 2018.

## FDA Medical Device Reporting Background

### FDA MEDICAL DEVICE REPORTING (MDR) OF ADVERSE EVENTS

Each year, several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions are reported to the U.S. Food and Drug Administration (FDA).<sup>1</sup> As one of its post-market surveillance tools, FDA uses Medical Device Reporting (MDR) to monitor device performance, detect potential device-related safety issues and contribute to benefit-risk assessment of these products. While reporting is mandatory for manufacturers, device user facilities and importers, FDA also encourages users such as healthcare professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events and product problems. MDR reports, along with other sources of data, help to provide critical information to improve device design and patient safety.

The MDR regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers and device user facilities to report device-related adverse events and other problems to FDA. For each group, the specific requirements for mandatory medical device reporting are:<sup>1</sup>

- > Manufacturers must report to FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. In addition, manufacturers must report malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Manufacturers must establish and maintain procedures for receiving, reviewing and evaluating complaints to determine if they meet criteria for a reportable adverse event.
- > Importers must report to both FDA and the manufacturer when they learn that any of their devices may have caused or contributed to a death or serious injury. Importers must report to

**Note:** Complaints are any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution.



the manufacturer any malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur. Similar to manufacturers, importers must establish and maintain procedures for receiving, reviewing and evaluating complaints to determine if they meet criteria for a reportable adverse event.

- > Device user facilities, defined as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility that is not a physician's office, must report suspected medical device-related deaths to both FDA and the manufacturer. Any medical device-related serious injuries must be reported to the manufacturer or to FDA, if the manufacturer is unknown.

## eMDR AND ADVERSE EVENT CODING

As of August 2015, manufacturers and importers must submit all MDRs to FDA in an electronic format that can be processed, reviewed and archived. User facilities may submit electronic MDR (eMDR) reports, but are also allowed to submit paper reports. The eMDR system uses a system of codes, terms and definitions to describe and categorize medical device adverse events. There are six code types: <sup>3</sup>

- > **Device Problem Code:** Device failures or issues related to the device during the reported event through observational language
- > **Manufacturer Evaluation Method Code:** The method of investigation of the device involved in the reported event

- > **Manufacturer Evaluation Result Code:** Specific findings from the investigation of the device involved in the reported event, typically an explanation for the device problem observed
- > **Manufacturer Evaluation Conclusion Code:** Conclusions from the investigation of the device involved in the reported event, typically a root cause for the device problem observed
- > **Patient Problem Code:** Actual adverse effects on a patient that may be related to the device problem observed during the reported event
- > **Device Component Code:** Specific device components or assemblies associated with the device problem observed during the reported event

## USING THE MDR CODING STRUCTURE

Each code type is organized into a hierarchical structure with up to six levels of subsequent codes. Similar to a tree in structure, the parent code (level 0) is the most generic, while subsequent child code levels increase in specificity. Each set of child codes can be considered a member of a set of problems or observations that is described by the parent code. MDR codes are given a two to four-digit numeric identifier, assigned sequentially based on internal guidelines. This means that numbers assigned to each code are not related to the code's location within its hierarchical structure and that codes with similar numbers are not necessarily related.

Reporters should code to the most specific level available in each category to describe the event, investigation or findings.

## SUBMISSION INSTRUCTIONS AND METHODS

Manufacturers must submit an eMDR using the Electronic Submissions Gateway (ESG) eSubmitter system which utilizes a Form 3500A wizard to guide submitters through the process. Importers and user facilities must complete section F of the form. Section F10 includes event problem codes, and the reporter must specify a device problem code and a patient problem code to complete the section.



Manufacturers must complete section H of the form. Section H6 includes adverse event codes, and the reporter must designate at least one of each of the device problem codes, patient problem codes, manufacturer evaluation method codes, manufacturer evaluation result codes and manufacturer evaluation conclusion codes.

According to new eMDR requirements, manufacturers and importers are required to submit MDRs to FDA in an electronic format.<sup>4</sup> User facilities have the option to submit Form 3500A electronically or in writing. Regardless of the form of submission, reporters must select the most detailed level of codes to describe the event. Typically, the root-level parent code will not be accepted as it is too generic. To select the appropriate codes, FDA recommends that reporters become familiar with each hierarchy before beginning a report.<sup>5</sup>

All current FDA MDR adverse event codes can be found on the FDA's website.<sup>6</sup>

## International Medical Device Regulators Forum (IMDRF) Coding Background

### IMDRF AER CODING BACKGROUND

The International Medical Device Regulators Forum (IMDRF) published a final document on September 21, 2017, *IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes*. The document,<sup>7</sup> developed by the IMDRF Adverse Event Terminology Working Group, resulted out of the charge to develop a harmonized terminology and coding system for reporting adverse events related to medical devices and in-vitro diagnostics (IVDs). Doing so is expected to improve signal detection and enable a faster response by both industry and regulatory authorities.

The use of globally harmonized terminology and associated codes has four main benefits in that it:<sup>8</sup>

- > Provides consistency for manufacturers reporting to multiple jurisdictions

- > Supports analysis for regulatory authorities that can be shared globally and increase accuracy
- > Enables faster local and international response and protects patients
- > May enhance accuracy, reliability and utility of the reports for healthcare providers

The adverse event terminology outlined in the document can be used as a tool for reporting adverse events in both the pre-market and post-market period. The tool overall reduces ambiguity in the reporting process and decreases the need for narrative text.<sup>8</sup>

### LEVELS AND TERMINOLOGIES

The IMDRF document follows a hierarchical structure, similar to International Standard Organization (ISO) standards *ISO 19218-1, Medical devices – Hierarchical coding structure for adverse events – Part 1: Event-type codes* and *ISO 19218-2, Medical devices – Hierarchical coding structure for adverse events – Part 2: Evaluation codes*. This hierarchical structure works as a logical decision tree that coded terms fall under (Figure 1). Under the Global Harmonization Task Force (GHTF), ISO was authorized to develop a hierarchal coding structure for device problems and evaluations, which was later adopted by GHTF and many participating countries. The ISO standards were reevaluated by the IMDRF working group, which changed them to be more concise and to include terms that were not previously included. In the near future, due to IMDRF's ability to readily make as-needed changes to the coding structure, the original ISO standard codes will be obsolete and become replaced by the IMDRF codes.

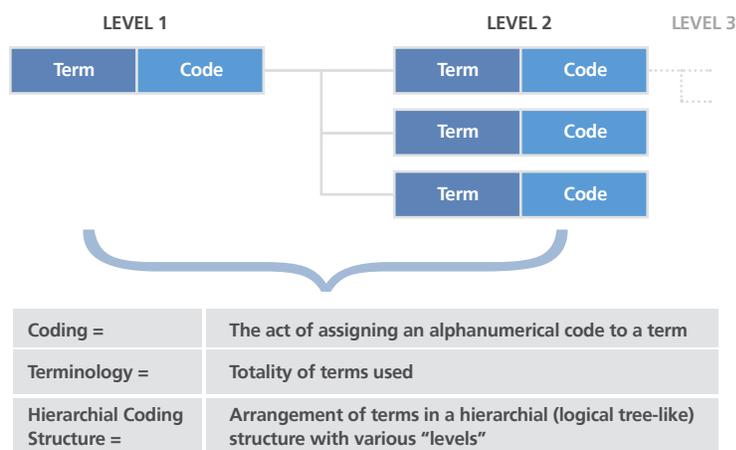


Figure 1: Schematic summary of relevant key words and hierarchical structure of IMDRF coding system<sup>8</sup>





The structure created is comprised of three levels: Level 1 is entry level and contains more general terms, and Levels 2 and 3 branch out with more complex and detailed options of the starting term. Effectively, as the levels increase, there is a higher resolution and descriptive power in the coding process. Due to the constantly evolving nature of the medical device industry, implementation of the hierarchical structure will involve maintenance to ensure effectiveness, and the following must be considered:<sup>8</sup>

- > Level 1 terms must be kept to a small number to ease entry into the hierarchical coding structure.
- > The arrangement of higher levels must follow intrinsically and/or map logical options.
- > Codes must not be duplicated in order to avoid confusion

The document outlines that the complete AER process will be comprised of four sets of terminologies (listed below). Each set has associated alphanumeric codes, and adverse event reporters are encouraged to code to the most detailed level, using multiple codes if necessary, while adhering to relevant jurisdictions.<sup>8</sup>

The terminology sets and subsets each have corresponding annexes, for a total of six (Annexes A-F). Each annex provides further detail regarding the process of coding an adverse event that falls under its scope. The annexes are also important because they play a

crucial role in the code structure nomenclature. The four terminologies, their annexes and scope are:<sup>8</sup>

- > **Medical Device Problem terms/codes (Annex A)** – Capture observations of the problems encountered during the event without yet describing possible reasons or causes.
- > **Cause investigation terms/codes (Annex B-D)** – Capture the type of investigation conducted, the findings, and the conclusion of root cause from the investigation. These codes are further divided into three subsets:
  - **Type of Investigation terms/codes (Annex B)** – Provide what was investigated and what kind of investigation was conducted.
  - **Investigation Findings terms/codes (Annex C)** – Provide the findings in the specific investigation that are keys to identify the root cause.
  - **Investigation Conclusion terms/codes (Annex D)** – Provide the conclusion derived from the investigation.
- > **Patient problem terms/codes (Annex E)** – Still under development
- > **Component terms/codes (Annex F)** – Still under development



## IMDRF NAMING CONVENTION

The code structure developed by the IMDRF document is

**X[nn][nn][nn]<sup>8</sup>**

where X is a placeholder that corresponds to the annex under which the code is being produced, and nn is a variable in Arabic numbers that corresponds to the terms within the different levels in AER. Level 1 occupies digits 1-2, Level 2 occupies digits 3-4 and Level 3 occupies digits 5-6. It is important to note that all previous digits are maintained as the level is increased.

For example, let's say a medical device that is used during a surgery causes a serious injury to a patient due to harmful leachates within the device. Problem terms and codes are located in Annex A, thus the reporting code would be:

**A[nn][nn][nn]**

Problems arising from patient-device interaction are located under the Level 1 code A01, thus the reporting code becomes:

**A01[nn][nn]**

Problems concerning patient-device incompatibility are located under the Level 2 code A0101, thus the reporting code becomes:

**A0101[nn]**

Finally, specific problems regarding undesirable effects due to biocompatibility are located under the Level 3 code A010101, thus the final (and complete) reporting code is:

**A010101**

This nomenclature system reflects the relationship within the code of the parent-child term and the body it belongs to. Two digits per level also makes changes in the future (additions/deletions) more efficient and sustainable.<sup>8</sup>

## TERMINOLOGY MAINTENANCE

Periodic review and maintenance of the terminologies and codes will occur as required. The addition, modification or removal of adverse event terms should be restricted to those absolutely necessary since new changes will require re-programming of existing coding systems at the level of industry, healthcare facilities and regulators alike.<sup>8</sup> Frequent changes are not anticipated, but it is understood that the medical device problem terms, and their associated component terms, will need to be updated and adapted as needed to match technical progress in the medical device industry.

IMDRF will execute the maintenance of adverse event terminology in accordance with the maintenance of IMDRF AER terminologies final document,<sup>8</sup> published by the IMDRF Adverse Event Terminology Working Group on September 21, 2017.

## EFFECTS ON FDA'S ELECTRONIC MEDICAL DEVICE REPORTING (eMDR) SYSTEM

In 2017, FDA's Center for Devices and Radiological Health announced plans to migrate from its current eMDR adverse event coding system to harmonize with the coding system outlined by IMDRF. Initially, FDA announced the transition to IMDRF codes would occur on April 6, 2018. However, on March 29, 2018, FDA announced it would be delaying the transition to **July 5, 2018**, providing additional time for reporters to develop and validate the necessary changes to their adverse event complaint handling systems using the test eMDR system updated March 6, 2018.

Currently, FDA plans to align only four of its eMDR codes with the IMDRF terminology:

- 1. Device Problem Code:**  
Will align with IMDRF Annex A
- 2. Manufacturer Evaluation Method Code:**  
Will align with Annex B
- 3. Manufacturer Evaluation Result Code:**  
Will align with Annex C
- 4. Manufacturer Evaluation Conclusion Code:**  
Will align with Annex D



FDA will eventually harmonize all remaining codes with the IMDRF adverse event terminology and remove all retired codes. The agency intends to update the guidance on the new sets of codes, terms, and definitions throughout the harmonization process. Once the preliminary transition goes into effect on July 5, 2018, relevant expired codes will be rejected by eMDR's eSubmitter software.<sup>11</sup>

## ENSURING A SMOOTH TRANSITION

The first step manufacturers must take to ensure a smooth transition is to map their current preferred FDA MDR adverse event coding system to IMDRF's coding system.

To properly map current FDA MDR adverse reporting codes to each of the IMDRF Annex A-D reporting codes, FDA has created a set of hierarchy and disposition files (Figure 2) to help assist manufacturers and reporters during this transition. The hierarchy files contain current codes, terms, definitions and relationships in the harmonized code sets and a mapping between existing FDA and IMDRF codes. The disposition files, on the other hand, contain the set of FDA codes that will be retired as of July 5, 2018 and a rationale for why each specific code was retired. When looking at the disposition files, it is important to note that the recommended code indicated for the retired code corresponds to the current FDA MDR reporting codes, not IMDRF harmonized codes. Figure 3 shows a process flow to ensure all codes are properly mapped to IMDRF codes.

Of the current categories, FDA's manufacturer evaluation method code category will have the most retired codes. Many of these codes were inactivated due to duplication between lists of tests found in the Evaluation Method Code and evaluation result code sets. The evaluation result code, and corresponding IMDRF Annex C code, necessitate that the test required and the type of device used for testing to find the result must be indicated, reducing the need for the evaluation method code.

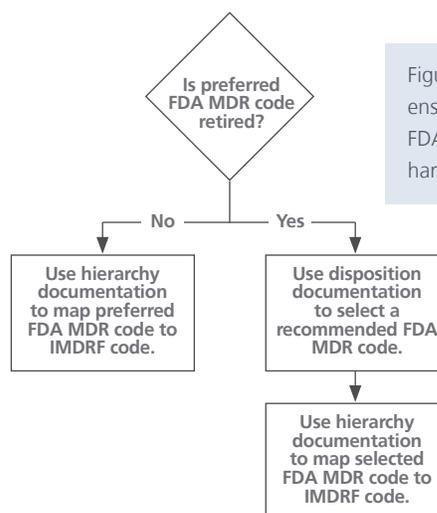


Figure 3: Process flow to ensure proper mapping from FDA MDR coding to IMDRF harmonized coding

The hierarchy and disposition files can be found under the Coding Resources tab of FDA's MDR Adverse Event Code website.<sup>4</sup> Since IMDRF has yet to release a set of codes to harmonize FDA's patient problem code and device component code, manufacturers and reporters can continue to use FDA's current MDR coding system for these categories.

Once the mapping has been performed and all FDA MDR adverse reporting codes have a one-to-one match with IMDRF harmonized codes, manufacturers and reporters must ensure their quality management system and adverse event reporting system are updated according to the new coding structure. Additionally, it is important to ensure that all retired codes are removed from the system as FDA will not accept them following the transition date. Depending on the state of the quality management system and the adverse event reporting system, this may be the most time-consuming process throughout this transition.

Due to the short timeline, it is encouraged that manufacturers and reporters perform this transition as soon as possible. One of the things to consider is what the user will see. For example, the manufacturer or reporter can decide to have: 1) only the description of the code, 2) only the code, or 3) both the description and the code displayed. This decision will be based on what the manufacturer or reporter feels is best for the user.

Figure 2: Hierarchy and disposition files created by FDA to assist with the mapping process<sup>4</sup>

Code Type	Hierarchy	Disposition
Device Problem Code	DPC Hierarchy	DPC Disposition
Manufacturer Evaluation Method Code	EMC Hierarchy	EMC Disposition
Manufacturer Evaluation Result Code	ERC Hierarchy	ERC Disposition
Manufacturer Evaluation Conclusion Code	ECC Hierarchy	ECC Disposition

By ensuring these steps are completed prior to the July 5, 2018 deadline, manufacturers and reporters should have an easy and quick transition to using IMDRF codes.



## ABOUT THE AUTHORS



**Kim Trautman** has over 30 years of experience in medical device quality systems and international regulatory affairs. She is focused on expanding international regulatory affairs and compliance services for NSF's medical device clients, including expanding medical device training services worldwide and spearheading the development of an independent, third-party regulatory certification program. Ms. Trautman was previously Associate Director for International Affairs in the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) where she led the CDRH's international efforts and initiatives. She was responsible for writing the current U.S. FDA Medical Device Quality System regulation and preamble published in 1996. She also developed and implemented the extensive quality system regulation roll out and training programs, and led continuing harmonization efforts with ISO 13485.



**Mary Weick Brady, MSN, RN** is a Principal Consultant with NSF International, providing expertise in global medical device regulatory policy, labeling, adverse event reporting, and complaint handling. Ms. Brady retired from the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH) as a senior policy advisor on post market regulations, guidance, and international standards. She represented the US on ISO standards for home use and symbols and represented the FDA on the Global Harmonization Task Force's (GHTF) post market study group, developing documents for regulatory agencies to use in complaint handling and adverse event reporting, including a standardized coding structure for reporting.

She also developed CDRH's Home Care Initiative to assure the safety of prescription medical devices being used in the home environment. Ms. Brady worked at the FDA for 25 years; prior to this, she worked in numerous clinical settings including visiting nurses, the DC government's ambulatory health program, the Washington Home and Hospice, Peace Corps/Ecuador's public health program, and the Mayo Clinic.

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