



IMDRF International Medical
Device Regulators Forum

FINAL DOCUMENT

Title: Maintenance of IMDRF AE Terminologies
Authoring Group: IMDRF Adverse Event Terminology Working Group
Date: 18 March 2020

A handwritten signature in blue ink, appearing to read 'mkl' with a flourish underneath.

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

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1.0 Introduction

The Adverse Event Working Group (“AE WG”) organized under International Medical Device Regulators Forum (“IMDRF”) has developed a harmonized terminology for reporting adverse events (“IMDRF AE Terminology”) that are known or suspected to be linked to the use of medical devices and in vitro diagnostics.

Globally harmonized terminologies for adverse event reporting are a key requirement for more effective reporting, analysis and information exchange of adverse events and will reduce the burden for manufacturers and other reporters (e.g., sponsors).

Once developed and agreed upon, there will be a clear need for an agreed approach for maintenance of these terminologies, ensuring adjustments that may be required over time, especially for:

- a) technical updates and innovations (e.g., new devices, materials)
- b) other developing needs of intended users, such as AE reporters and regulatory authorities

The AE WG has considered the options for ongoing maintenance of the IMDRF AE Terminology. This document is intended to describe the basic procedures that should be followed in order to ensure the IMDRF AE Terminology remain up-to-date, adequate, and accurate following their initial publication.

2.0 Scope

This document sets forth the basic procedures for revising the IMDRF AE terminology described in Annexes A through G of the IMDRF document entitled, “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (IMDRF/AE WG/N43)”.

3.0 Reference

- IMDRF/AE WG/N43 - IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure, and codes

4.0 Definition

“**Member Jurisdiction**” shall mean the jurisdiction to which a member of the AE Terminology Maintenance WG belongs.

“**National Competent Authority**” shall mean any duly authorized regulatory authority affiliated with a national or regional entity, which is tasked with regulating medical devices and in vitro diagnostics in its jurisdiction.

“Stakeholder Organization” shall mean an organization that has any direct or indirect interest in medical devices or in vitro diagnostics (e.g. industry associations, professional associations, professional medical associations, patient associations, etc.).

5.0 IMDRF AE Terminology Maintenance WG

Maintenance of IMDRF AE terminology is conducted by a dedicated IMDRF WG called the IMDRF AE Terminology Maintenance Working Group (“AETM WG”). The AETM WG consists of members from IMDRF Member Jurisdictions and, as appropriate, observers from other jurisdictions.

The AETM WG is chaired by one (1) Member Jurisdiction, on a rotational basis. The chairing jurisdiction also provides a secretariat for handling the request of modification(s) to, deletion(s) from, or addition(s) to the AE Terminologies (“Change Request(s)”) from stakeholders.

The AETM WG has a designated webpage (“AETM Webpage”) on the IMDRF website (<http://www.imdrf.org/workitems/wi-aet-maintenance.asp>) where the most current version of the terminology is published and where the “Change Request Form” (Appendix A) can be downloaded to submit change requests. The AETM WG’s response to reviewed change requests will also be published on this website using the Change Log (Appendix B).

6.0 Maintenance Process

Maintenance of the IMDRF AE Terminology is subject to the approval of the Management Committee (“MC”) of IMDRF, and the maintenance process follows the steps outlined below:

1. Submission of Change Requests using the Change Request Form (Appendix A).
2. Review of Change Requests and development of recommendation to the MC by the AETM WG using the Change Log (Appendix B).
3. MC approval/IMDRF decision of the AE WG recommendation
4. Publication/Explanation of IMDRF decision on webpage by posting the Change Log (Appendix B).

This is an iterative maintenance process that will be conducted at least once per year.

6.1 Submission of Change Requests

6.1.1 How to Submit

Change Requests may be submitted any time via the AETM webpage by either 1) National Competent Authorities or 2) Stakeholder Organizations.

Before submitting Change Requests, submitters should first consult past IMDRF decision documented in the Change Request Form posted on the AETM Webpage to ensure that their proposed change(s) were not already addressed (i.e., rejected) in the past. The same request will be rejected unless a substantial and reasonable rationale for resubmission is also submitted.

The secretariat shall compile a record of all Change Requests and maintain such record until final decisions are reached.

6.1.2 Change Request Form

Change Requests shall be submitted by completing the Change Request form available on the AETM webpage (Appendix A) and sending the completed form to the appropriate address as instructed in the AETM webpage. Change Requests that do not provide sufficient details will not be considered.

The Change Request form shall include each of the following items:

- **Requester information**
 - **Date Submitted** and **Submitter** (organisation name)
- Change Proposal Information
 - Identification of code / term for which proposal is made
 - ✧ **Terminology** (Annex A, B, C, D, E, F, or G) and **Version of Annex**
 - ✧ **Code and Term, Location in the hierarchy, Definition**
 - Proposal of change
 - ✧ **Category of change** (Add, Delete, or Modify)
 - ✧ **Description of change** (e.g. “modification of definition...”)
 - ✧ **Rationale for change** (e.g. “the change is necessary to accommodate a new type of device...”)
 - ✧ **Impact on other existing terms**
 - ✧ **Examples of an incident which would be coded using the proposed term**

6.2 Review and development of recommendation by the AETM WG

The AETM WG will conduct detailed reviews of the submitted Change Requests primarily via regularly scheduled teleconferences or Face to Face meetings.

The AETM WG shall deliberate on the change requests submitted and provide proposed outcomes including the rationale/comments for change requests that were not accepted. These will be presented to the MC to be considered for approval. The outcome of Change Requests shall be prepared using the template form (Appendix A). A change log (Appendix B) will be published on the AETM webpage as a full record of IMDRF decisions in the final step of this process.

6.3 MC approval/IMDRF decision

The MC will review the AETM's final recommendation at their face-to-face meeting or teleconference. Once the MC approves the final recommendations, it will be advanced as an IMDRF decision.

6.4 Documentation of IMDRF decision on webpage

After obtaining final approval for the recommendation from the MC, the AETM WG will revise the IMDRF AE terminology to reflect the IMDRF decision. The revised IMDRF AE terminology will be posted on the IMDRF website.

The revised Terminology Annexes will be designated with an updated version number. The AETM WG will keep a Change Log for each IMDRF terminology for Annexes A through G (Appendix B). These change logs will be published on the AETM Webpage.

Appendix A: Change Request Form

Appendix B: Change Log