



IMDRF

International Medical
Device Regulators Forum

Adverse Event Terminology and Coding Working Group

IMDRF Open Stakeholders Forum Webinar
September 2020

Presented by T. Kusakabe, Office of International Programs
on behalf of H. Ishikawa, Working Group Chair

Pharmaceuticals and Medical Devices Agency (PMDA)



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1. INTRODUCTION



Overview

IMDRF AEWG established March 2015

Mission: Development of a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).

Purpose: To improve the efficiency of the adverse event management systems for faster response by **both industry and regulatory agencies**, with the use of a single, appropriate adverse event terminology and coding system.

Benefits:

- **Improved accuracy**
- **Reduced ambiguity**
- **Better usability**, for **More sophisticated signal detection** and **Trending analysis**



Scope

- This document provides the **IMDRF terms**, definitions and **IMDRF alpha-numerical codes** to be used for Adverse Event (AE) reporting concerning medical devices and in vitro diagnostics both pre and post market.
- Notably, the precise criteria for reporting adverse events are defined by each regulatory authority and are not subject to this guidance document. Reference is made to the relevant guidance documents of each jurisdiction and the GHTF document on Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (**GHTF SG2 Document N54**, 2006).
- Intended for use by reporters and regulators.



Meetings

Members (Regulators Only)

Australia (TGA)
Brazil (ANVISA)
Canada (Health Canada)
European Union
Japan (MHLW/PMDA)
Russia (Roszdravnadzor)
Singapore (HSA)
South Korea (MFDS)
UK (MHRA)
US (FDA)
WHO (Official Observer)

Face to Face Meetings

| | | |
|-----------------|------------|----------------------|
| 1 st | June 2015 | Washington D.C., USA |
| 2 nd | April 2016 | Tokyo, Japan |
| 3 rd | Dec 2016 | Tokyo, Japan |
| 4 th | June 2017 | Ispra, Italy |
| 5 th | Dec 2017 | Moscow, Russia |
| 6 th | April 2018 | Canberra, Australia |
| 7 th | Nov 2018 | Singapore, Singapore |
| 8 th | March 2019 | Brasilia, Brazil |
| 9 th | Nov 2019 | Geneva, Switzerland |

Teleconferences

30 teleconferences



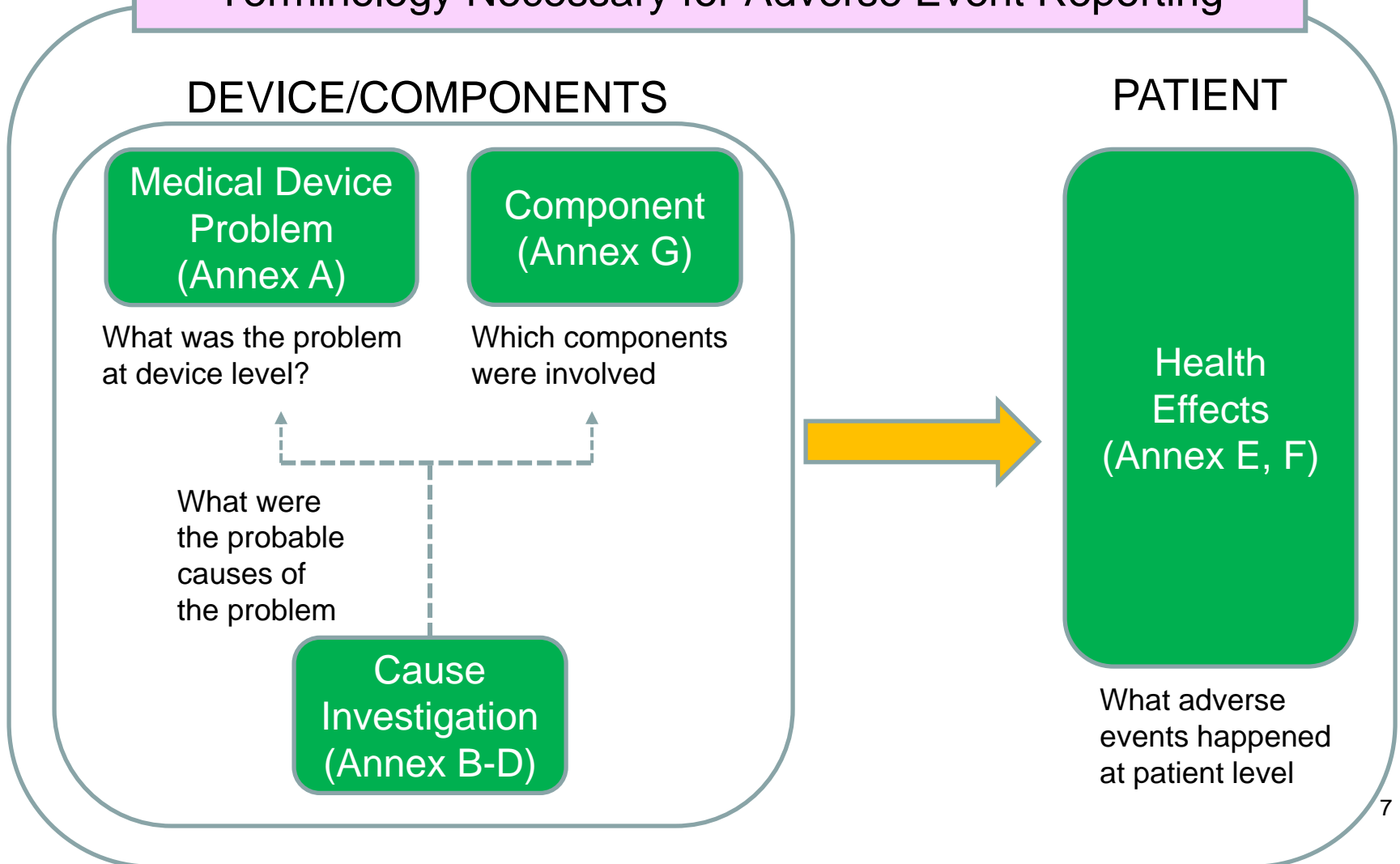
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2. COMPLETION AND STANDARDIZED FORMAT FOR ALL IMDRF TERMINOLOGY



Terminology Necessary for Adverse Event Reporting





Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

[Main Body \(2017\)](#)

Annexes with IMDRF Terminology:
Medical Device Problem

Annex A (2017)

Investigation

Annex B Type of Investigation (2017)

Annex C Investigation Finding (2017)

Annex D Investigation Conclusion (2017)

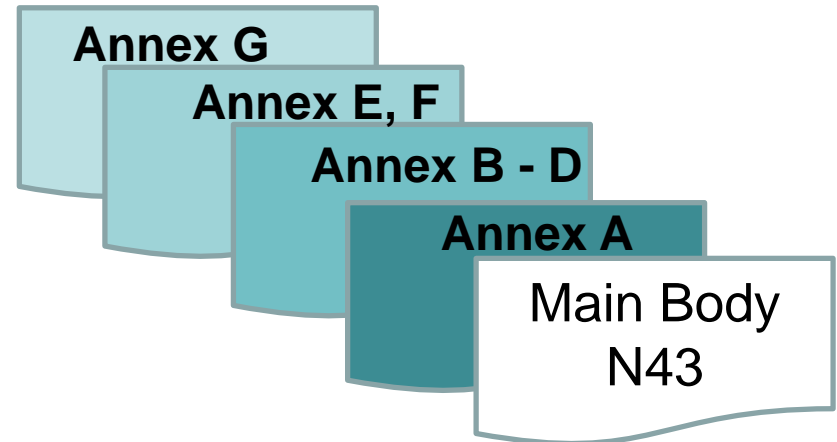
Health Effects

Annex E Clinical signs Symptoms and conditions (2019)

Annex F Health Impact (2019)

Component

Annex G (2020)



All Annexes are now complete and published



Standardized Format for All Annexes

- **All Terminology Annexes (Annex A – G) were published in a new common format.** For details, please refer to the [README file](#).
- **The purpose of the changes is to improve usability, particularly for machine readability.**
- Overview of changes:
 - All annexes are now published using one term per line, while still retaining level 1, 2, and 3 terms in separate columns to illustrate the hierarchical structure of terms.
 - There are no merged cells, and excel formatting (bold text, colored fonts, etc.) which are difficult to export into other formats have been kept to a minimum.
 - A common header is included in all annexes.
 - Annex E contains additional columns for primary and secondary categories of terms, as well as a separate tab for mapping to MedDRA terms, but otherwise follows the same format.
- The Annexes are provided as [downloadable excel files](#) and in a searchable [web browser](#) format.
- We DO NOT intend to provide the annexes in other file formats, but users are free to modify and convert the excel files into desired file formats.
- While the AE WG has checked the annexes, we anticipate that there are still some artifacts from the machine conversion from the old to the new format. The WG will rectify these editorial issues in future releases.



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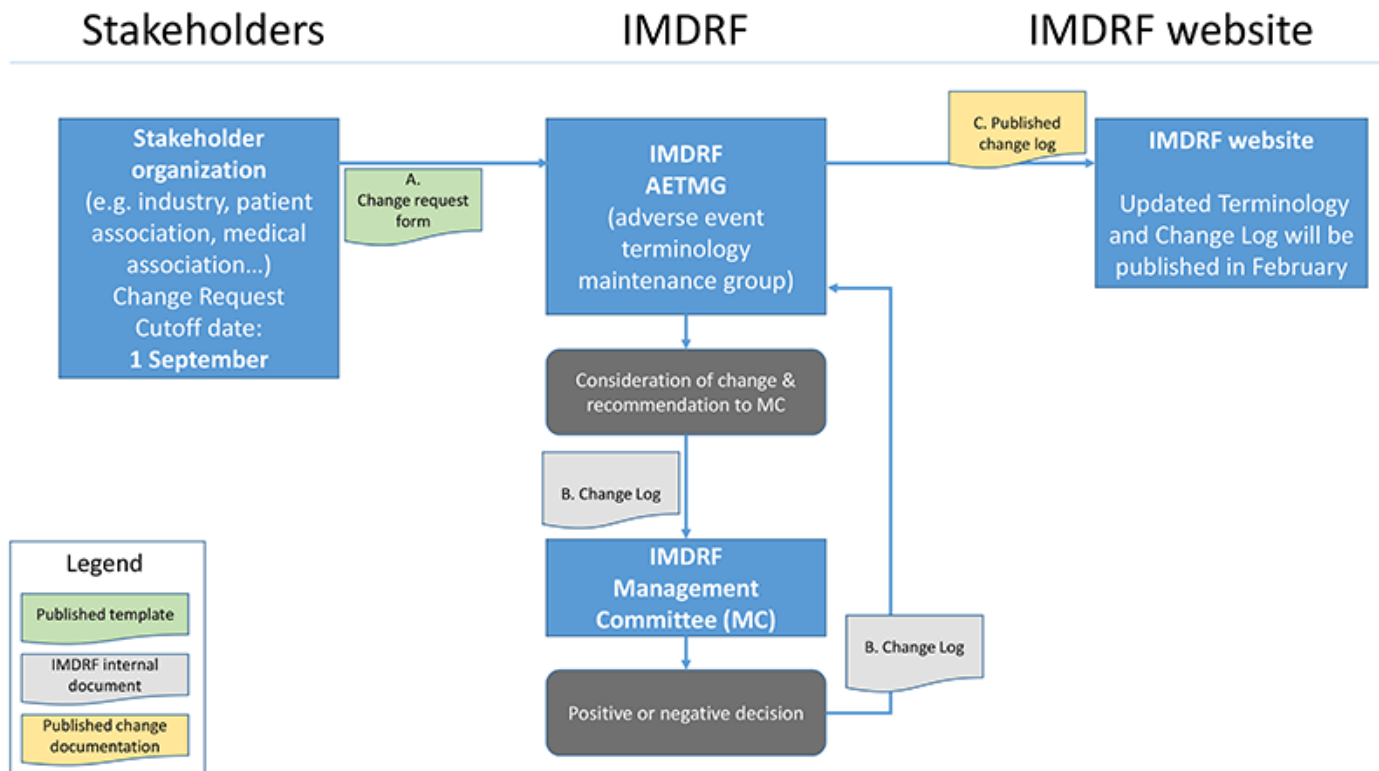
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3. MAINTENANCE OF IMDRF TERMINOLOGY



Maintenance Process

- The maintenance process and Change Request form are available on the [IMDRF AE Terminology Maintenance webpage](#).





Submission of Change Requests

How to submit a change request:

- The terminology is always open for Change Requests. The process is outlined in the figure below. **The cutoff date for inclusion in the next release is 1 September.** The Change Requests will then be reviewed by IMDRF, and the updated terminology and outcome of Change Requests will be published in February.
- Proposal of addition/modification/deletion of the terms must be submitted to AE WG by either **National Competent Authorities** or **Stakeholder Organizations**, using the Change Request form. **No proposal from an individual will be accepted.**
- Please use the most recent [Change Request form](#) (see next slide for details on how to fill out the form).
- Please send the completed form to: imdrf-aewg-chair@pmda.go.jp



How to Fill in the Change Request Form

| | | Item | Description |
|----|--|---|---|
| 1 | Requester information | Date submitted (DD/MM/YYYY) | DD/MM/YYYY |
| 2 | | Submitter | Organization name |
| 3 | Identification of code / term for which proposal is made | Terminology (Annex A, B, C, D, E, F, G) | Please indicate which Annex |
| 4 | | Version of Annex | The version number is indicated in cell A3 of the excel files. In general, comments should be based on the most recent published version (available here). If you are commenting on an older version (an archived version), please check the newest version to make sure that your comment hasn't already been addressed. |
| 5 | | Code | IMDRF Term code # |
| 6 | | Term | IMDRF Term |
| 7 | | Location in the hierarchy | Level 1, 2, or 3 |
| 8 | | Definition | The current definition of the IMDRF Term |
| 9 | Proposal of change | Category of change | Please select either Add, Delete, or Modify. Unless a term is clearly duplicated, the WG will generally not delete terms. In the case a term is "deleted," it will be indicated as "retired" but still maintained in the terminology list for recordkeeping purposes. |
| 10 | | Description of change | Describe the suggested change (e.g., "modify the definition to ..."). To maximize chances that your change is considered, please suggest a concrete change. |
| 11 | | Rationale for change | Describe the reasons for the change. (e.g. "the change is necessary to accommodate a new type of device..."). To maximize chances that your change is considered, please provide an adequate rationale for the change. |
| 12 | | Impact on other existing terms | If the relevant terms or definition may impact other terms or definition, describe the impact along with the relevant code and term. |
| 13 | | Example of an incident which would be coded using the proposed term | Along with the rationale, please provide a concrete example of an incident (s) which would be coded using the term. This field is also critical for considering a change request. |



Outcomes of Change Requests will be published in a Change Log

Documentation of IMDRF decision on webpage

- IMDRF AE WG will review the request and make a recommendation
- After IMDRF MC approval, the results of the change requests will be published as a Change Log.
- The revised Terminology Annexes will be designated with an updated version number and published in February.
- **Note that all information provided in the Change Request Form will be published as part of the Change Log.**

Change Log

| Requester information | | Change Proposal Information | | | | | | | | | | IMDRF Decision | | | | |
|-----------------------------|-------------------------------|--|------------------|------|------|---------------------------|------------|--|---|---|--------------------------------|--|---------------|------------------------|-----------------------------|---|
| | | Identification of code / term for which proposal is made | | | | | | Proposal of change | | | | Outcome of change request (POSITIVE or NEGATIVE) | Justification | New code if applicable | Date Published (DD/MM/YYYY) | |
| Date submitted (DD/MM/YYYY) | Submitter (organisation name) | Terminology (Annex A, B, C, D, E, F, Q) | Version of Annex | Code | Term | Location in the hierarchy | Definition | Category of change (Select: Add, delete, 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 | | | | | Example of an incident which would be avoided using the proposed term |
| | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |

| | |
|---------------------------|---|
| Outcome of change request | Results of Review (POSITIVE or NEGATIVE) |
| Justification | An explanation of the outcome of the change request. |
| New code if applicable | If the request was to add a new term, the new code will be indicated |
| Date Published | This is the date of publication of the terminology based on the change request. |



Resources

IMDRF Terminology

- [IMDRF AE WG Webpage](#) (Includes links to the terminology web browser)
- [IMDRF AE Terminology \(Current Version\)](#)
- [IMDRF AE Terminology \(Archived Versions\)](#)

IMDRF Terminology Maintenance

- [IMDRF Terminology Maintenance Webpage](#)
- [Change Request Form](#)

Related Documents

- [IMDRF AE Terminology Guideline Main Body \(N43 Document\)](#)
- [IMDRF Terminology Maintenance \(N44 Document\)](#)



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Thank you for your kind attention!