IMDRF International Medical Device Regulators Forum

APEC RHSC

Adverse Event Terminology and Coding

Exploration of IMDRF Adverse Event Terminology
IMDRF Web Browser

Oct 2020

IMDRF Working Group Chair:

H. Ishikawa

Pharmaceuticals and Medical Devices Agency

How to find the documents

- **IMDRF "Document" section** http://www.imdrf.org/documents/documents.asp
  - IMDRF/AE WG/N43 Final :2020 (Edition 4.0)for AE terminplogy
  - N43 attached Excel files. (Annnex A~G) (Edition 4.1)
  - Release Note

- **IMDRF "Information Document"section** http://www.imdrf.org/documents/documents.asp
  - IMDRF/AE WG/N44 FINAL:2020 (Edition 3) for maintenace

- **IMDRF "Work Item" Section** http://www.imdrf.org/workitems/wi-aet.asp

  Adverse Event Terminology section
  - IMDRF/AE WG/N43 Final :2020 (Edition 4.0)for AE terminology
  - N43 attached Excel files. (Annex A~G) (Edition 4.1)
  - IMDRF/AE WG/N44 FINAL:2020 (Edition 3) for maintenace
  - Release Note

How to find AE Terminology from IMDRF Web Site

When you want to find suitable terminology for AE Report, there are two way to find for each Group of terminology;

Adverse Event , Investigations, Health Impacts and Components.

（A) to find from Excel File, or

（B) from Browser

This is up to you to use either way.

Benefit is that you can create your own list of terminology from Excel file or you may create your own DB from Browser.

IMDRF WEB site

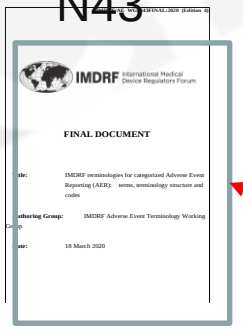
http://www.imdrf.org/index.asp

(A) Finding from IMDRF Document File

Search IMDRF and
find “Document” (IMDRF Document),
you will find GHTF document too.
(GHTF SG2 N54, 87)

http://www.imdrf.org/documents/documents.asp

N43



IMDRF International Medical Device Regulators Forum

Documents

This page contains final documents only for both IMDRF and GHTF.

- IMDRF documents
- GHTF final documents

IMDRF documents

In this section: Technical documents | Procedural documents | Information documents | Outcome statements

IMDRF technical documents

IMDRF code	Document title	Date posted	Pages
IMDRF/AE WG/N43 FINAL:2020 Updated Annexes (Edition 4.1)	Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem - XLSX (51kb) Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Type of Investigation - XLSX (13kb) Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings - XLSX (24kb) Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Conclusion - XLSX (14kb) Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions - XLSX (160kb) Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact - XLSX (16kb) Annex G: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Component - XLSX (33kb) Release Notes: IMDRF terminologies for categorized Adverse Event Reporting (AER) Edition 4.1 - TXT (1kb)	27 July 2020	23
IMDRF/AE WG/N43FINAL:2020 (Edition 4)	Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes - PDF (1.21Mb) Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes - DOCX (280kb)	20 April 2020	23

Excel files

Find Excel Files from Document section

IMDRF/AE 2020 Updated WG/N43 FINAL:Annexes (Edition 4.1)	Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem - XLSX (51kb) Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Type of Investigation - XLSX (13kb) Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings - XLSX (24kb) Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Conclusion - XLSX (14kb) Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions - XLSX (160kb) Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact - XLSX (16kb) dverse Event Reporting (AER) - Medical Device Component - zed Adverse Event Reporting (AER) Edition 4.1 - TXT (1kb)	27 July 2020

Type	Terms Category
A	Medical Device Problem
B	Type of Investigation
C	Investigation Finding
D	Investigation Conclusion
E	Clinical Signs and Symptoms or Conditions
F	Health Impact
G	Components

Annex A~G Display (Excel File)

Annex Name:
Annex Title: Medical Device
Annex Version: 1.1
Annex Description:
Annex Instructions:

Annex Approval Date: 25 June 2020

Administrative Information about the Annex

Terms Hierarchical structure

Annex E only

change Information

Just for information for Browser

Level 1 Term	Level 2 Term	Level 3 Term	Term Code	Definition	Non-IMDRF Code	Primary Secondary	Status	Status Description	Code Hierarchy
XX			AXX	AAAAAAA					AXX
	XY		AXXYY	BBBBBBB			modify	20' editorial	AXX,XXYY
		YZ	AXXYYZA	CCCCCCC					AXX XXYY XXYYZA
		ZX	AXXYYZB	DDDDDDD					AX XXYY XXYYZB

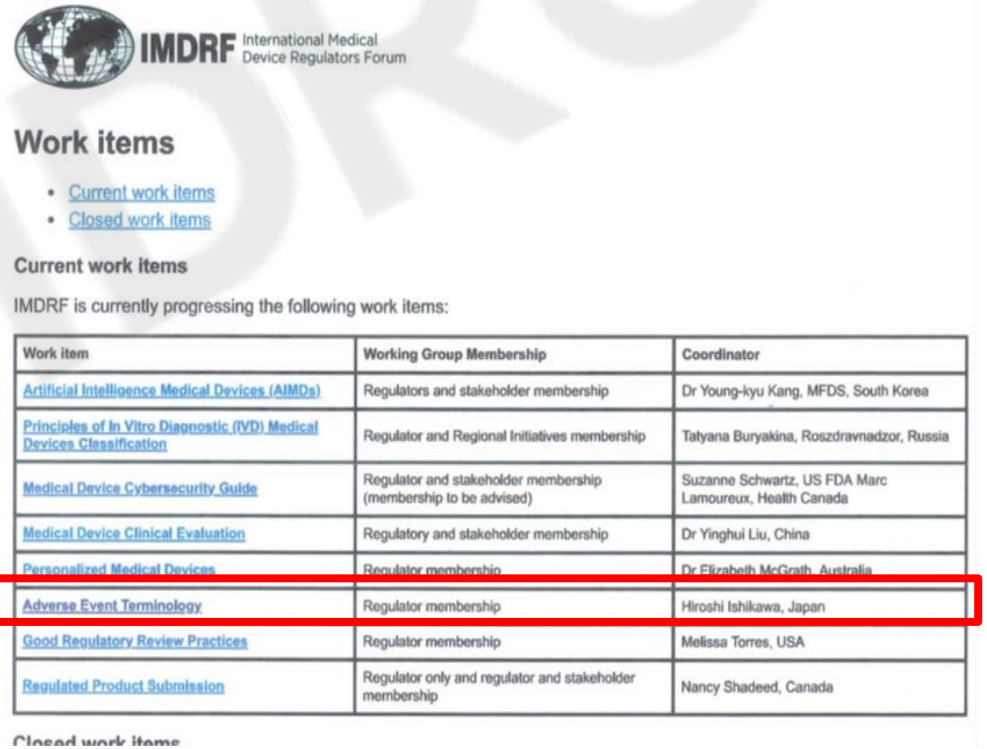
IMDRF WEB site

http://www.imdrf.org/index.asp

(B) Finding from IMDRF Work Item Section

Search IMDRF and find “Work Item”
http://www.imdrf.org/workitems/work.asp

And find “ Adverse Event Terminology”



IMDRF International Medical Device Regulators Forum

Work items

- Current work items
- Closed work items

Current work items

IMDRF is currently progressing the following work items:

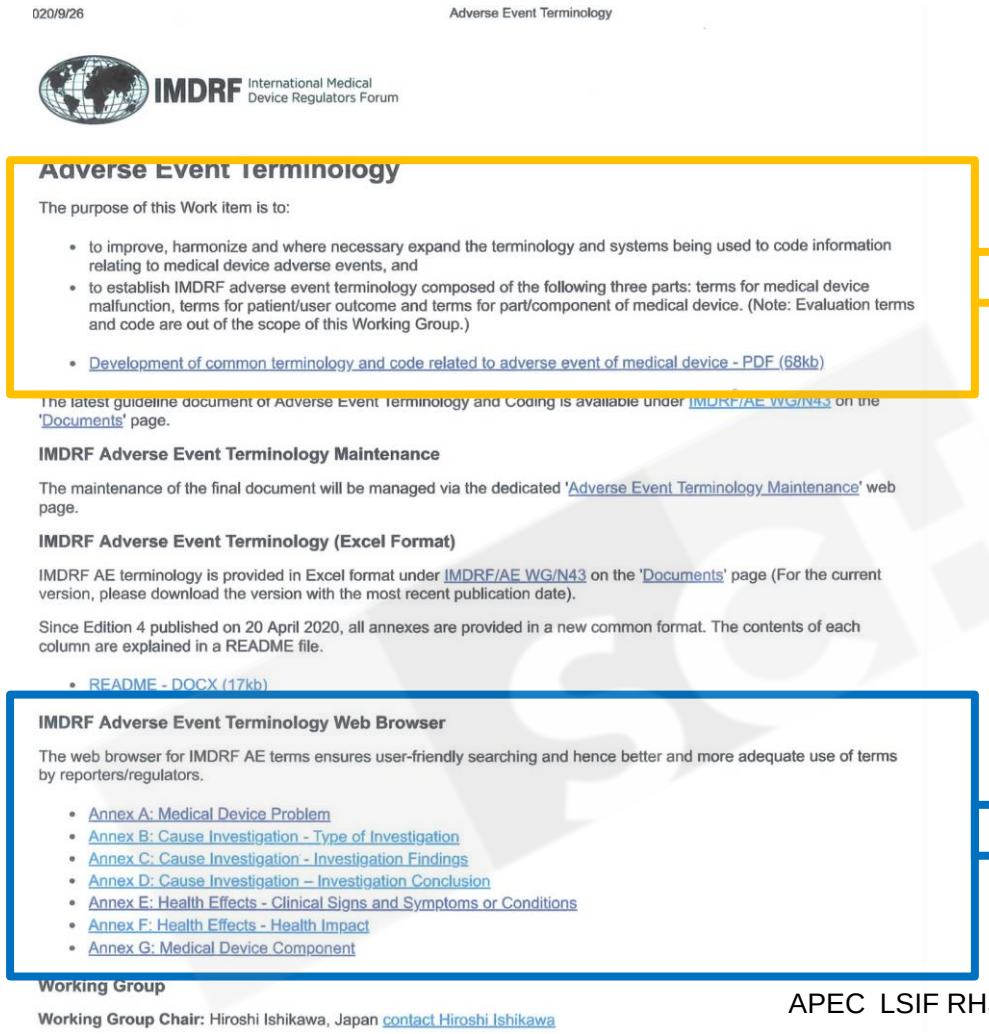
Work item	Working Group Membership	Coordinator
Artificial Intelligence Medical Devices (AIMDs)	Regulators and stakeholder membership	Dr Young-kyu Kang, MFDS, South Korea
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	Regulator and Regional Initiatives membership	Tatyana Buryakina, Roszdravnadzor, Russia
Medical Device Cybersecurity Guide	Regulator and stakeholder membership (membership to be advised)	Suzanne Schwartz, US FDA Marc Lamoureux, Health Canada
Medical Device Clinical Evaluation	Regulatory and stakeholder membership	Dr Yinghui Liu, China
Personalized Medical Devices	Regulator membership	Dr Elizabeth McGrath, Australia
Adverse Event Terminology	Regulator membership	Hiroshi Ishikawa, Japan
Good Regulatory Review Practices	Regulator membership	Melissa Torres, USA
Regulated Product Submission	Regulator only and regulator and stakeholder membership	Nancy Shadeed, Canada

Closed work items

Adverse Event Terminology	Regulator membership	Hiroshi Ishikawa, Japan

http://www.imdrf.org/workitems/wi-aet.asp

Work Item Section



020/9/26 Adverse Event Terminology

IMDRF International Medical Device Regulators Forum

Adverse Event Terminology

The purpose of this Work item is to:

- to improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events, and
- to establish IMDRF adverse event terminology composed of the following three parts: terms for medical device malfunction, terms for patient/user outcome and terms for part/component of medical device. (Note: Evaluation terms and code are out of the scope of this Working Group.)

- Development of common terminology and code related to adverse event of medical device - PDF (68kb)

The latest guideline document of Adverse Event Terminology and Coding is available under IMDRF/AE WG/N43 on the 'Documents' page.

IMDRF Adverse Event Terminology Maintenance

The maintenance of the final document will be managed via the dedicated 'Adverse Event Terminology Maintenance' web page.

IMDRF Adverse Event Terminology (Excel Format)

IMDRF AE terminology is provided in Excel format under IMDRF/AE WG/N43 on the 'Documents' page (For the current version, please download the version with the most recent publication date).

Since Edition 4 published on 20 April 2020, all annexes are provided in a new common format. The contents of each column are explained in a README file.

- README - DOCX (17kb)

IMDRF Adverse Event Terminology Web Browser

The web browser for IMDRF AE terms ensures user-friendly searching and hence better and more adequate use of terms by reporters/regulators.

- Annex A: Medical Device Problem
- Annex B: Cause Investigation - Type of Investigation
- Annex C: Cause Investigation - Investigation Findings
- Annex D: Cause Investigation – Investigation Conclusion
- Annex E: Health Effects - Clinical Signs and Symptoms or Conditions
- Annex F: Health Effects - Health Impact
- Annex G: Medical Device Component

Working Group

Working Group Chair: Hiroshi Ishikawa, Japan contact Hiroshi Ishikawa

Explanation

IMDRF AE WG and finding Document

Adverse Event Terminology

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Explanation for WEB Browser

Work Item Section

http://www.imdrf.org/workitems/wi-aet.asp

Adverse Event Terminology

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•README - DOCX (17kb)

Excel Form Explanation Refrain

IMDRF Adverse Event Terminology Web Browser

The web browser for IMDRF AE terms ensures user-friendly searching and hence better and more adequate use of terms by reporters/regulators.

Browser

http://www.imdrf.org/workitems/wi-aet.asp

(B) IMDRF Adverse Event Terminology Web Browser

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- Annex G: Medical Device Component

Browser

- **A01 - Patient Device Interaction Problem**

•Problem related to the interaction between the patient and the device.

- **A0101 - Patient-Device Incompatibility**
- Problem associated with the interaction between the patient's physiology or anatomy and the device that affects the patient and/or the device.
- **A0102 - Osseointegration Problem**
- Problem associated with interconnection between the bone tissue and the implanted device.
- **A0103 - Loosening of Implant Not Related to Bone-Ingrowth**
- Problem associated with the loss of direct anchorage of an implanted device over time or due to an injury.
- **A0104 - Migration or Expulsion of Device**
- Problem with an implanted or invasive device moving within the body, or being completely expelled from the body.

- **A02 - Manufacturing, Packaging or Shipping Problem**

•Problem associated with any deviations from the documented specifications of the device that relate to nonconformity during manufacture to the design of an item or to specified manufacturing, packaging or shipping processes (out of box problem).

- **A0201 - Product Quality Problem**
- Problem associated with an inherent device characteristic that is not satisfactory as specified or delivered.
- **A0202 - Defective Component**
- Problem associated with a device component having flaws of dimensional deviations greater than acceptable for the intended use.
- **A0203 - Defective Device**
- Problem associated with having flaws or dimensional deviations greater than acceptable for the intended use of the device.
- **A0204 - Device Damaged Prior to Use**
- Problem associated with packaging or shipping damage prior to the use of the device.
- **A0205 - Packaging Problem**
- Problem associated with the materials used to construct the cover or outer wrapping of the device.
- **A0206 - Device Misassembled During Manufacturing /Shipping**
- A device found incorrectly assembled when delivered to the user facility.
- **A0207 - Shipping Damage or Problem**
- Problem associated with shipping damage or problem prior to the use of the device.

- **A03 - Chemical Problem**

•Problem associated with any from the documented specifications of the device that relate to any chemical characterization, i.e., element, compound, or mixture.

Browser

- **- E01 - Nervous System**
- Nervous System

  Status: Not selectable
  Status Description: Please use more detailed term within the hierarchy

Do not use E01 and instruction

- **E0101 - Balance Problems**
- A feeling of falling down which can occur whether the person is standing, sitting or lying down.

  Non-IMDRF Code: MedDRA:10049848:Balance disorder

MedDRA mapping Information

- **- E0102 - Brain Injury**
- Damage to the brain.

  Non-IMDRF Code: MedDRA:10060690:Traumatic brain injury
  Primary Category: Nervous System
  Secondary Category: Injury

Primary secondary
In this case same term could use Injury section

  - **E010201 - Encephalocele**
  - Hernia of brain substance and meninges through a congenital or traumatic opening of the skull.

    Non-IMDRF Code: MedDRA:10014617:Encephalocele
    Primary Category: Nervous System
    Secondary Category: Injury

Request for addition or modification

Details are indicated at **Work Item** section. http://www.imdrf.org/workitems/wi-aet.asp

IMDRF Adverse Event Terminology Maintenance
The maintenance of the final document will be managed
via the dedicated 'Adverse Event Terminology Maintenance' web page

http://www.imdrf.org/workitems/wi-aet-maintenance.asp

•The terms in the Annexes of the final version of the guideline document are maintained by the AE Working Group (AE WG) as a pilot in accordance with the "Maintenance of IMDRF AE Terminologies" (**IMDRF/AE WG/N44)FINAL:2020**).
•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.

Request for addition or modification

•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 below:
Appendices A & B: Change Request Form and Change Log - XLSX (16kb)

Appendix A: Change Request Form

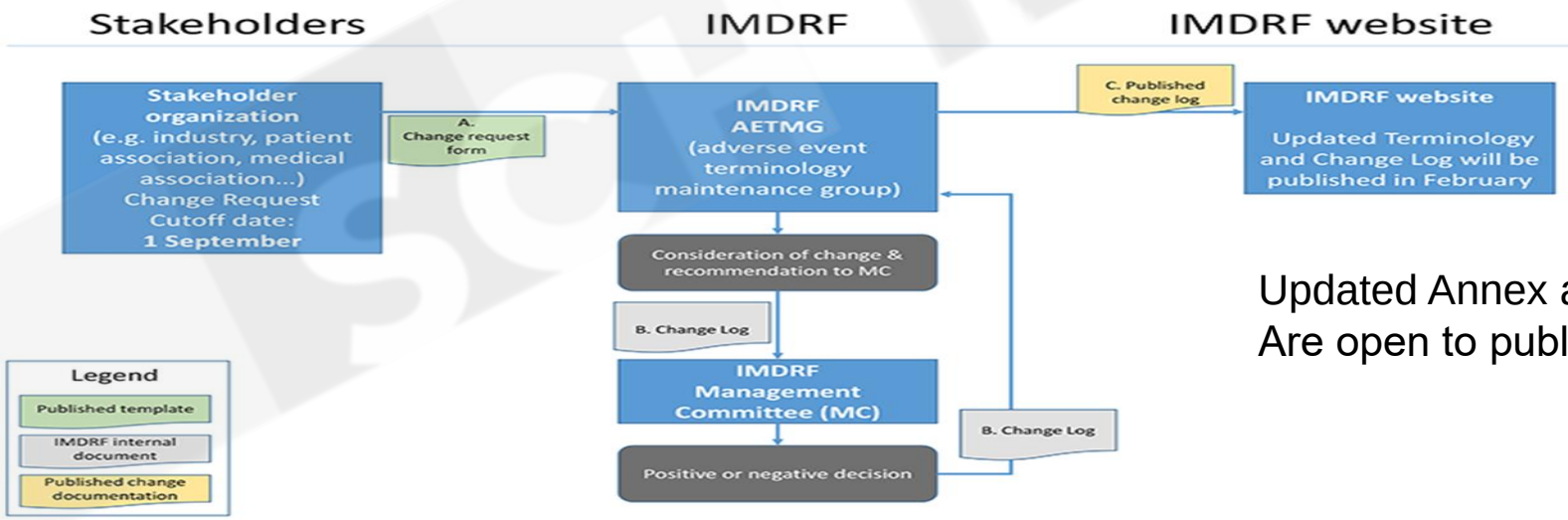
Requester information		Change Proposal Information										
		Identification of code / term for which proposal is made						Proposal of change				
Date submitted (DD/MM/YYYY)	Submitter (organization name)	Terminology (Annex A, B, C, D, E, F, G)	Version of Annex	Code	Term	Location in the hierarchy	Definition	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 coded using the proposed term

•Please send the completed form to: imdrf-aewg-chair@pmda.go.jp

Request for addition or modification

Appendix B: Change Log

Requester information		Change Proposal Information											IMDRF Decision			
		Identification of code / term for which proposal is made						Proposal of change								
Date submitted (DD/MM/YYYY)	Submitter (organization name)	Terminology (Annex A, B, C, D, E, F, G)	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 coded using the proposed term	Outcome of change request (ACCEPTED or REJECTED)	Justification	New code if applicable	Date Published (DD/MM/YYYY)



Updated Annex and Browser
Are open to public with this “Change Log”

Take Home Message

1. Open IMDRF WEB site

2. Work Plan

   http://www.imdrf.org/workitems/work.asp

3. Adverse Even Terminology

   http://www.imdrf.org/workitems/wi-aet.asp

3. Excel file

   IMDRF/AE WG/N43 Go to Document section

3. Browser

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Thank You