O1

IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

IMDRF Open Stakeholders Forum Webinar
March 2021

Presented by
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Pharmaceuticals and Medical Devices Agency (PMDA)

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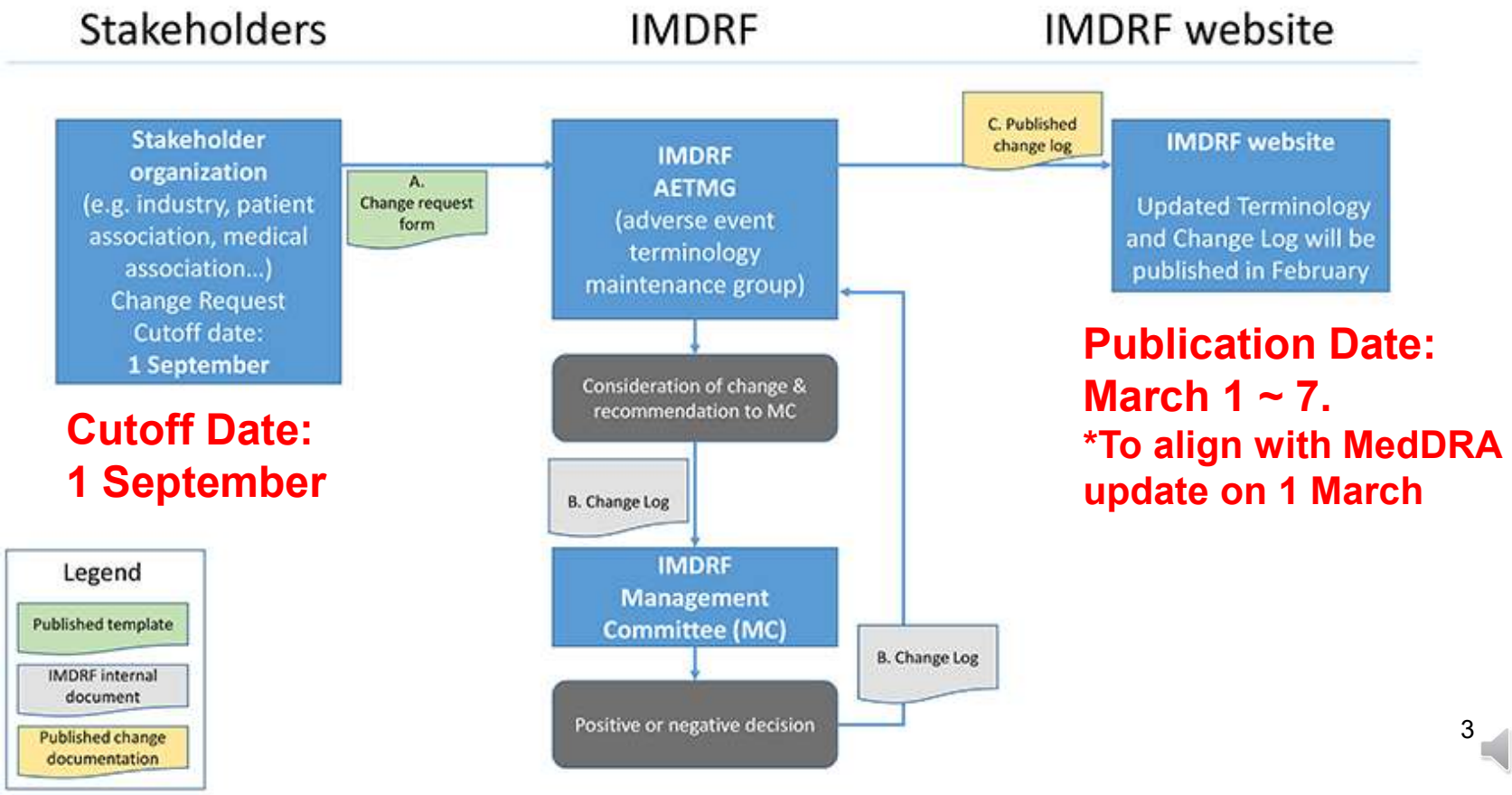
O1 Owner, 2021-02-13

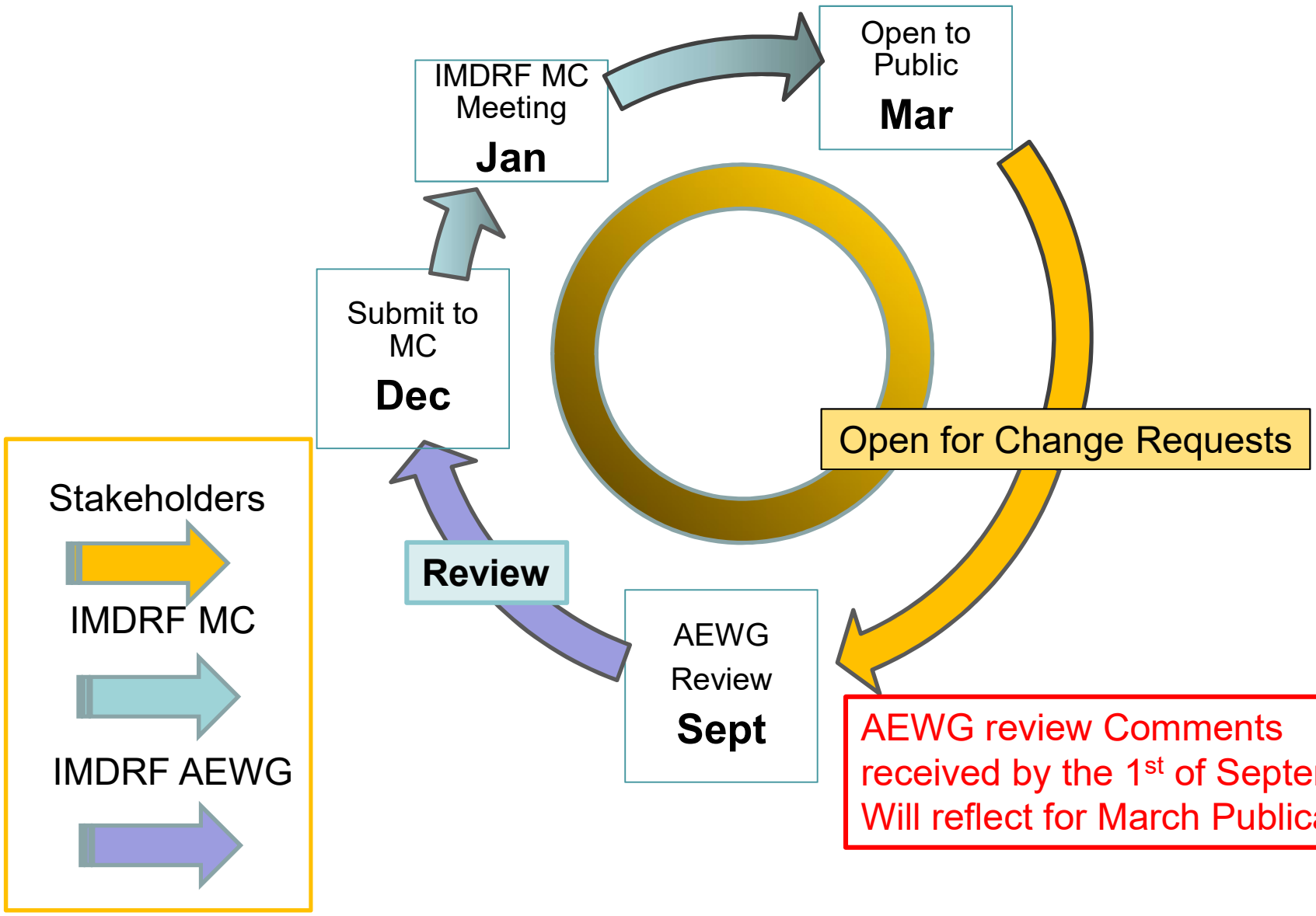
1. OVERVIEW OF ANNUAL MAINTENANCE PROCESS

Maintenance Process

- The maintenance process and Change Request form are available on the IMDRF AE Terminology Maintenance webpage.



2 HOW TO SUBMIT CHANGE REQUESTS


IMDRF MC Meeting
Jan
Open to Public
Mar
Open for Change Requests
AEWG Review
Sept
Review
Submit to MC
Dec
Stakeholders
IMDRF MC
IMDRF AEWG
AEWG review Comments received by the 1st of September Will reflect for March Publication

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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 made on the most recent published version (available here). If you are commenting on an archived version, please check the newest version to make sure your comment has not already been addressed.
5		Code	IMD
6		Term	IMD
7		Location in the hierarchy	Level 1,
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.
		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.
		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.

Clear description of changes

Rationale

Examples

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Outcomes of Change Requests are 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 March.
- **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								
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 coded using the proposed term	Outcome of change request (POSITIVE or NEGATIVE)	Justification	New code if applicable	Date Published (DD/MM/YYYY)

Outcome of change request	Results of Review （ACCEPTED or REJECTED）
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.

Before Submitting a Change Request,
Please review the most recent Change Log!

- The Change Log for IMDRF Terminology Edition 5.0 has been published on the IMDRF website.
- Please review past resolutions to ensure that your comment has not already been addressed.

3. RELEASE OF IMDRF TERMINOLOGY EDITION 5.0

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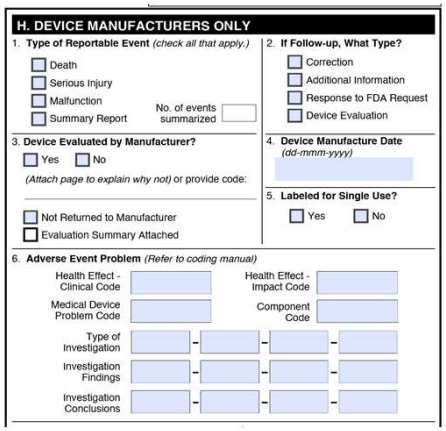
Current Activities

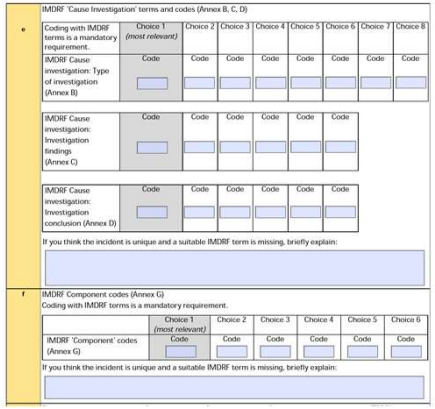
Finding other necessary terms for signal detection purpose from currently using AER forms



H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
   - ☐ Death
   - ☐ Serious Injury
   - ☐ Malfunction
   - ☐ Summary Report — No. of events summarized
2. **If Follow-up, What Type?**
   - ☐ Correction
   - ☐ Additional Information
   - ☐ Response to FDA Request
   - ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Yes ☐ No
   (Attach page to explain why not) or provide code:
   - ☐ Not Returned to Manufacturer
   - ☐ Evaluation Summary Attached
4. **Device Manufacture Date** *(dd-mmm-yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect - Clinical Code		Health Effect - Impact Code	
Medical Device Problem Code		Component Code	
Type of Investigation			
Investigation Findings			
Investigation Conclusions			



e — IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

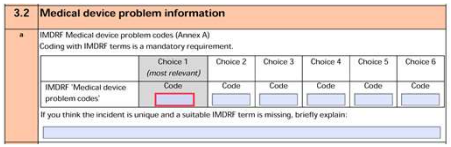
Coding with IMDRF terms is a mandatory requirement.	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code		
IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code		

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f — IMDRF Component codes (Annex G)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

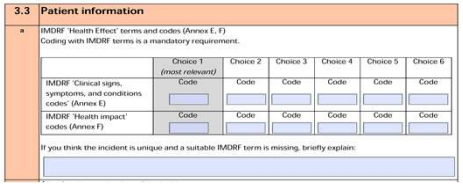


3.2 Medical device problem information

a — IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:



3.3 Patient information

a — IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

Image of Signal detection

Thank you for your kind attention!

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)