APEC 2023 SCH Medical Device CoE Training

Adverse Event Terminology and Coding

Generation of data related to the use of Medical Device Adverse Event (MDAE)

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Who am I

Small self introduction

1972 Graduate Tohoku University
1972 Enter Toshiba Co. Medical Div.
1993 Join GHTF SG2 member
2001 Join GHTF SC member
2006 Publish N54 (team leader)
2008 Join APEC LSIF RHC
2009 Join APEC LSIF AHC Advisory (till 2011)
2011 Join PMDA
2012 IMDRF UDI WG member (UDI WG disbanded 2019)
2105 IMDRF AEWG Chair
2017 IMDRF Standards WG (Standards WG disbanded 2019)
2019 IMDRF GRRP member
2022 Join Univ. of Yamanashi

Adverse Event Terminology and Coding
Generation of data related to the use of Medical Device Adverse Event (MDAE)

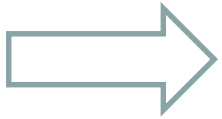
Contents

1. Background for creating IMDRF AE terminology and coding
2. What terms that IMDRF AEWG set the harmonized terminology for AE Reporting with harmonized definition
3. Explanation for 7 categories of Terms How to use
4. How to use those terms (virtual case) and how regulator observe it

Assuming that understanding of GHTF N54 document and its related document

This presentation includes personal

1. Background for creating IMDRF AE terminology and coding



IMDRF International Medical Device Regulators Forum

- Foundational **GHTF N54** document established the foundations for international harmonization of post-market reporting requirements and information.
- **GHTF N87** document established XML format for electrical reporting.
- Those are provide globally common use terms**. Appendix A for N54**
- Contents are
  - **What is an event?**
  - **What should be reported?**
  - **What is exempt?**
  - **To whom and when to report?**
  - **What information should be reported?**

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

Benefits;
- **Improved accuracy of capturing and reporting adverse events,**
- **Reduced ambiguity**
- **Better usability**
- **More sophisticated signal detection** (i.e. the identification of potential novel risks), and
- **Trending analysis**

For both regulatory agencies and device manufacturers.

What happened since GHTF developed N54 document

- Actuary, GHTF SG2 activities is not create single document, there were so many documents had been published and 2006 ,**N54 was published as the summary of the document.**
- Leading by US FDA, other SG2 member country started to **implement their own Post Market regulation.**
- 2012 ,ISO, international Standard organization TC210 also try to establish "Event Type Code" and "Evaluation Code". **Limited scope.**

Medical Field **Rapid technical Innovation**

- During these 15 years, many innovative devices are developed.
- New technology provide new terms for the event.
- Necessity to corroborate with ICH in terms of Health Effect issue.(MedDRA)
- Some specific field such as Stand Alone Software becomes Medical Device

What happened since GHTF developed N54 document

Regulators thoughts

Based on the situation that most of the jurisdiction applying **Electrical Form** for the ARE and necessity to exchange information for Signal detection purpose in a global manner.

- Required more specific information by text
- Also need to share the same understanding of the terminology
  - Standardized terms
  - Standardized definition of the relevant terms
  - Universal Coding system
- Frequent maintenance system (at least once a year)

2015, IMDRF AEWG has been set up to develop standardized terms which use for the ARE and its definition with IMDRF code.

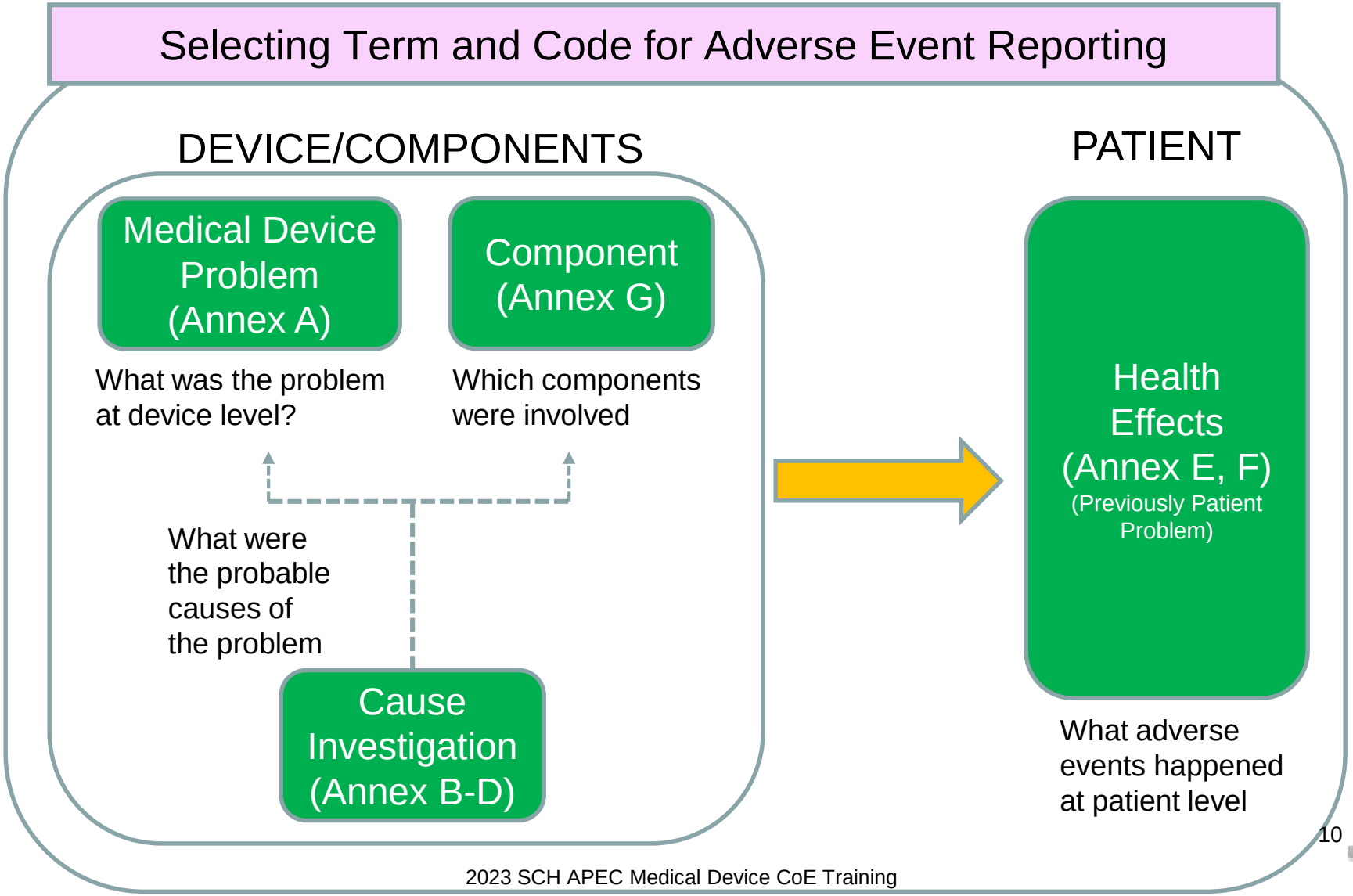
- Product Problem and related components or parts
- Investigational terms and
- Health related terms

2. What terms that IMDRF AEWG set the harmonized terminology for AE Reporting with harmonized definition

GHTF N54 Appendix A 5.0 **Data Set Elements and Guidance**

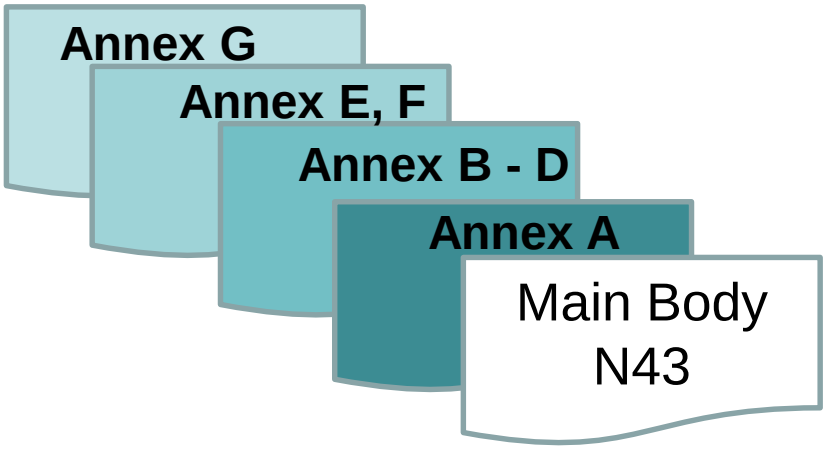
I. **Administrative Information**
II. **Clinical Event Information**
III. Healthcare Facility Information
IV. **Device Information** (Repeat this section for each device involved)
V. **Results of Manufacturer's Investigation**
VI. Patient information (Repeat this section for each patient involved)
Includes any affected individual e.g. user, patient, or third party.
VII Other Reporting Information (to be included in final reports only)
VIII Comments
IX Manufacturer Disclaimer

GHTF Study Group 2 - Post-market Surveillance/Vigilance (imdrf.org)


Selecting Term and Code for Adverse Event Reporting
DEVICE/COMPONENTS
PATIENT
Medical Device Problem (Annex A)
Component (Annex G)
What was the problem at device level?
Which components were involved
What were the probable causes of the problem
Cause Investigation (Annex B-D)
Health Effects (Annex E, F)
(Previously Patient Problem)
What adverse events happened at patient level

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

Started from 2015



Main Body N43 (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 published (2020July)

Relation with GHTF N54 Appendix A and IMDRF Annex

GHTF Appendix A Data set contents	IMDRF Annex
I Administrative Information	
E. Classification of event	F
Unanticipated Death, unanticipated Serious Injury, or Serious Public Health Threat	
All other reportable events	
II Clinical Event Information	
A. Event description narrative	E
IV Device Information	
F. Device Disposition/Current Location	A G
e.g., device has been destroyed, remains implanted in patient, was returned to the manufacturer, remains under investigation,	B
V. Results of Manufacturer's Investigation	
Manufacturers Device Analysis Results	B C D
Specify, for this event, details of investigation methods, results, and conclusions	

3. Explanation for 7 categories of Terms

Recommend to review definition of terms by yourself.

Annex A: Medical Device Problem Terms and Codes

Describing **problems** (malfunction, deterioration of function, failure) of medical devices that have occurred in **pre- or post-market contexts**
(e.g. clinical studies, clinical evaluation or post-market surveillance)

A01	Patient Device Interaction Problem	**A15**	Activation, Positioning or Separation Problem
A02	Manufacturing, Packaging or Shipping Problem	**A16**	Protective Measures Problem
A03	Chemical Problem	**A17**	Compatibility Problem
A04	Material Integrity Problem	**A18**	Contamination /Decontamination Problem
A05	Mechanical Problem	**A19**	Environmental Compatibility Problem
A06	Optical Problem	**A20**	Installation-Related Problem
A07	Electrical /Electronic Property Problem	**A21**	Labelling, Instructions for Use or Training Problem
A08	Calibration Problem	**A22**	Human-Device Interface Problem
A09	Output Problem	**A23**	Use of Device Problem
A10	Temperature Problem	**A24**	Adverse Event Without Identified Device or Use Problem
A11	Computer Software Problem	**A25**	No Apparent Adverse Event
A12	Connection Problem	**A26**	Insufficient Information
A13	Communication or Transmission Problem	**A27**	Appropriate Term/Code Not Available
A14	Infusion or Flow Problem	**469 terms could be selectable**	

Annex G Components

Describing the **parts and components** which were **involved in**, or affected by, the medical device adverse event/incident.

G01	Biological and Chemical
G02	Electrical and Magnetic
G03	Measurement
G04	Mechanical
G05	Optical
G06	Safety
G07	Others

Seven categorized terms (G01-G07) could not be used for Reporting. Use L2/L3 for reporting

When select Product Problem and then Component will associate with that term.

i.e.
When select under A05 Mechanical problem Select appropriate term from G04 Mechanical Category L2/L3.

There are several measurement by using mechanical or electrical, so Safety related Components could select from G06 L2/L3

Annex E Clinical Signs, Symptoms and Conditions Terms and Codes

Describe the **observed condition of the affected persons** after the medical device adverse event occurs.
As a reference **Mapping Information with MedDRA** are including.

1. Nervous System	13. Kidney and Urinary Tract
2. Mental, Emotional and Behavioural Disorders	14. Reproductive System and Breast
3. Blood and Lymphatic System	15. Pregnancy, Childbirth and the Puerperium
4. Immune System	16. Musculoskeletal System
5. Vascular System	17. Skin and Subcutaneous Tissue
6. Heart	18. Neoplasms Benign, Malignant and Unspecified
7. Respiratory System	19. Infections
8. Eye	20. Injury
9. Ear and Labyrinth	21. Procedural Complications
10. Gastrointestinal System	22. Investigations and Diagnostic Tests
11. Hepatic and Biliary System	23. General Disorders
12. Endocrine, Metabolism and Nutrition	24. Others

Note: Those 24 category indicated in L1 could not be used for the report.

Annex E: Special case for coding

- One term has one code.
  - Some terms belongs to two categories. In such case, the only code assigned to the term in the category taking priority is also applied to the same term in the other category.
  - Other applicable category for the term is shown in the term list and the prioritized category is written in red and bold.

e.g.

Category 17. Skin and Subcutaneous Tissue

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Skin Erosion	E17XX	20. Injury	3				

Category 20. Injury

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Erosion	E20YY			Skin Erosion	E17XX Not E20YYZZ	**17. Skin and Subcutaneous Tissue**	**2**

Annex F: Health Impact Terms and Codes

Describing the **consequences of the medical device adverse event/incident on the person affected.** (e.g., death, hospitalization, unexpected medical intervention, wrong intervention due to incorrect diagnosis)

F01	Change in Therapeutic Response	F15	Recognized Device or Procedural Complication
F02	Death	F16	Reduction in Life Expectancy
F03	Brain Death	F17	Sedation
F04	Delay to Diagnosis	F18	Rehabilitation
F05	Delay to Treatment/ Therapy	F19	Surgical Intervention
F06	Disruption of Subsequent Medical Procedure	F20	Serious Public Health Threat
F07	Exacerbation of Existing Condition	F21	Unexpected Deterioration
F08	Hospitalization or Prolonged Hospitalization	F22	Unexpected Diagnostic Intervention
F09	Fetal Harm	F23	Unexpected Medical Intervention
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	F24	Insufficient Information
F11	Minor Injury/ Illness / Impairment	F25	Unanticipated Adverse Device Effect
F12	Serious Injury/ Illness/ Impairment	F26	No Health Consequences or Impact
F13	Misdiagnosis/ Misclassification	F27	No Patient Involvement
F14	Prolonged Episode of Care	F28	Appropriate Term/Code Not Available

Annex B-D: Cause Investigation Terms and Codes

Those terms are used any type of report and not only for the Final ARE report

Annex B: Type of Investigation (1 level) **For finding Root Cause**

- What was investigated
- What kind of investigation was conducted

(e.g**., Testing of Actual/Suspected Device, Testing of Device from Same Lot/Batch, Trend Analysis**)

Annex C: Investigation Findings (3 levels) **Keys to identify Root Cause**

- finding the specific investigation

Jurisdictions could allow to choose the level of coding.

(e.g., **Biological Problem Identified, Cytotoxicity Problem Identified, Microbial Contamination**)

Annex D: Investigation Conclusion (2 levels)

Conclusions delivered from the investigation

Jurisdictions allow to choose the level of coding to use.

(e.g., **Cause Traced to Device Design, Cause Traced to Manufacturing, Quality Control Deficiency)**

Annex B-D: Cause Investigation Level 1 Terms and Codes

B=25 (24)terms

B01	Testing of Actual/Suspected Device
B02	Testing of Device from Same Lot/Batch Retained by Manufacturer
B03	Testing of Device from Same Lot/Batch Returned from User
B04	Testing of Device from Other Lot/Batch Retained by Manufacturer
B05	Testing of Device from Other Lot/Batch Returned From User
B06	Testing of Model Variant
B07	Testing of Raw/Starting Materials
B08	Testing of Patient Sample or Reference Material Using Manufacturer's Device
B09	Testing of Patient Sample or Reference Material Using Reference Method
B10	Testing of Patient Sample or Reference Material Using Competitor's Device
B11	Historical Data Analysis
B12	Trend Analysis
B13	Communication/Interviews
B14	Analysis of Production Records
B15	Analysis of Data Provided by User/Third Party
B16	Device Not Manufactured by Reporting Manufacturer
B17	Device Not Returned
B18	Device Discarded
B19	Incomplete Device Returned
B20	Device Not Accessible for Testing
B21	Type of Investigation Not Yet Determined
B22	Insufficient Information Available
B23	Specimen Requested But Not Provided
B24	Event History Log Review (Add 2022)
B25	Particulate Testing (Add 2023)

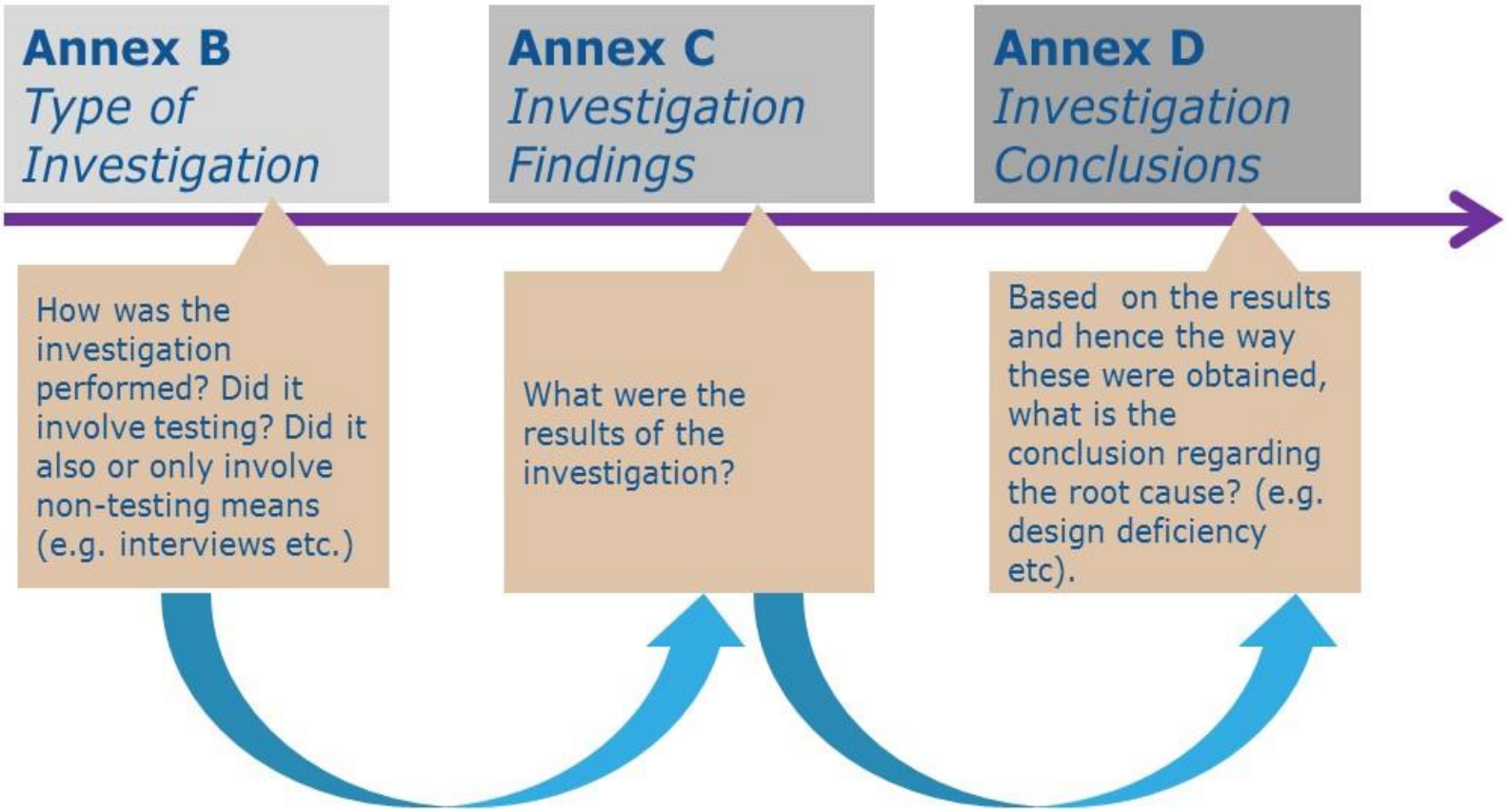
C= 24(23)terms

C01	Biological Problem Identified
C02	Electrical Problem Identified
C03	Electromagnetic Compatibility Problem Identified
C04	Interoperability Problem Identified
C05	Labeling and Instructions for Use/Maintenance
C06	Material and/or Chemical Problem Identified
C07	Mechanical Problem Identified
C08	Optical Problem Identified
C09	Clinical Imaging Problem Identified
C10	Software Problem Identified
C11	Thermal Problem
C12	Protective System Problem Identified
C13	Operational Problem Identified
C14	Patient Sample Problem
C15	Environment Problem Identified
C16	Manufacturing Process Problem Identified
C17	Maintenance Problem Identified
C18	Transport/Storage Problem Identified
C19	No Device Problem Found
C20	No Findings Available
C21	Results Pending Completion of Investigation
C22	Appropriate Term/Code Not Available
C23	Usage Problem Identified
C24	Malfunction Observed Without Conclusive Finding

D= 21(19)terms

D01	Cause Traced to Device Design
D02	Cause Traced to Component Failure
D03	Cause Traced to Manufacturing
D04	Cause Traced to Transport/Storage
D05	Cause Traced to Infrastructure
D06	Cause Traced to Environment
D07	Cause Traced to Maintenance
D08	Cause Traced to Training
D09	Cause Traced to Labeling
D10	Cause Traced to Non-Device Related Factors
D11	Cause Traced to User
D12	Known Inherent Risk of Device
D13	Falsified Device
D14	No Problem Detected
D15	Cause Not Established
D16	Conclusion Not Yet Available
D17	Appropriate Term/Code Not Available
D18	Cause Traced to Software Coding
D19	Cause Traced to Artificial Intelligence Training/Validation Process
D20	Cause Traced to Another Device
D21	Cause Traced to Health Disparity

Concept of Annex B-D: Cause Investigation Terms and Codes



Annex B: Cause Investigation Terms and Codes
Type of Investigation

B01	Testing of Actual/Suspected Device
B02	Testing of Device from Same Lot/Batch Retained by Manufacturer
B03	Testing of Device from Same Lot/Batch Returned from User
B04	Testing of Device from Other Lot/Batch Retained by Manufacturer
B05	Testing of Device from Other Lot/Batch Returned From User
B06	Testing of Model Variant
B07	Testing of Raw/Starting Materials
B08	Testing of Patient Sample or Reference Material Using Manufacturer's Device
B09	Testing of Patient Sample or Reference Material Using Reference Method
B10	Testing of Patient Sample or Reference Material Using Competitor's Device
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B12	Trend Analysis
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B14	Analysis of Production Records
B15	Analysis of Data Provided by User/Third Party
B16	Device Not Manufactured by Reporting Manufacturer
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B18	Device Discarded
B19	Incomplete Device Returned
B20	Device Not Accessible for Testing
B21	Type of Investigation Not Yet Determined
B22	Insufficient Information Available
B23	Specimen Requested But Not Provided
B24	Event History Log Review (Add 2022)
B25	Particulate Testing (Add 2023)

Analysis of particulate or foreign material returned from user for evaluation.

B01 and B25 **Use Actual Device** suspected

B02-B10 **Use NOT Actual Device** suspected
- same Lot/Bach
- other Lot Bach
- tested at sight/ manufacturer site
- testing use sample or reference material

B11-B15 and B24 Use NOT Device suspected but **other data**
- Historical Data/Record
- information from user
- Analysis

B14,15,and 25 are for making analysis

B16 could use C20and D14

B17,B19,B23 use when still **waiting for return**

B18.B20,B22 move back to B02-B15

B21 **Could not start investigation** in any reasons

Annex C: Cause Investigation Terms and Codes Investigation Finding

C01	Biological Problem Identified
C02	Electrical Problem Identified
C03	Electromagnetic Compatibility Problem Identified
C04	Interoperability Problem Identified
C05	Labeling and Instructions for Use/Maintenance
C06	Material and/or Chemical Problem Identified
C07	Mechanical Problem Identified
C08	Optical Problem Identified
C09	Clinical Imaging Problem Identified
C10	Software Problem Identified
C11	Thermal Problem
C12	Protective System Problem Identified
C13	Operational Problem Identified
C14	Patient Sample Problem
C15	Environment Problem Identified
C16	Manufacturing Process Problem Identified
C17	Maintenance Problem Identified
C18	Transport/Storage Problem Identified
C19	No Device Problem Found
C20	No Findings Available
C21	Results Pending Completion of Investigation
C22	Appropriate Term/Code Not Available
C23	Usage Problem Identified
C24	Malfunction Observed Without Conclusive Finding
	Malfunction was verified but no conclusive finding is available.

Some terms **related with D conclusion** terms(private opinion)

C01–C04,C06-C09

C05–D09 Labeling

C10–D18 Software Coding D19 Artificial Intelligence Training/Validation

C15–D06 Environment

C16–D03 Manufacturing

C17 –D07 Maintenance

C18 –D04 Transport/Storage

C19 –D10 Non-Device Related Factors,D14 No Problem Detected

C20 –D15, Not Established D16 Not Yet Available

C21 –D15 Not Established,D16 Not Yet Available

C23–D05- Infrastructure D10 Non-Device Related Factors

C24–D15, Not Established D20 Another Device

Annex D: Cause Investigation Terms and Codes Investigation Conclusion

D01	Cause Traced to Device Design
D02	Cause Traced to Component Failure
D03	Cause Traced to Manufacturing
D04	Cause Traced to Transport/Storage
D05	Cause Traced to Infrastructure
D06	Cause Traced to Environment
D07	Cause Traced to Maintenance
D08	Cause Traced to Training
D09	Cause Traced to Labeling
D10	Cause Traced to Non-Device Related Factors
D11	Cause Traced to User
D12	Known Inherent Risk of Device
D13	Falsified Device
D14	No Problem Detected
D15	Cause Not Established
D16	Conclusion Not Yet Available
D17	Appropriate Term/Code Not Available
D18	Cause Traced to Software Coding
D19	Cause Traced to Artificial Intelligence Training/Validation Process
D20	Cause Traced to Another Device
D21	Cause Traced to Health Disparity

D01-04 ,09 Find Root Cause
- Design / Manufacturing/ package/transportation

D05-06 Related to the **user side**
- Infrastructure/ envelopment

Related outside of factory but real root cause may happen to original manufacturer

D07,08 ,08 **Supporting system**
- Training/Maintenance

D10 Other reasons and **NOT this device is the cause**.

D11 **Caused by User**

D12 **Known Risk** Labeled

D13 **Falsified Product**

D14 **Root Cause could not find** based on the several Investigation methods and their findings

D15-16 **Still Investigating** ant NOT reach to the conclusion.

D18 Software D19 AI related

D20 Other device is the cause

D21 Health Disparity is the cause

Summary

（　）2022

As of 2023　Jan

Annex	Title	Version	L1	L2	L3	Total	Approved
A	Medical Device Problem	2023	27 (27)	17 6 (173)	27 8 (278)	48 1 (478)	31　Jan 2023
B	Cause Investigation - Type of Investigation	2023	25 (24)	NA	NA	25 (24)	31　Jan 2023
C	Cause Investigation - Investigation Findings	2023	24 (23)	97 (92)	36 (36)	157 (151)	31　Jan 2023
D	Cause Investigation – Investigation Conclusion	2023	21 (19)	22	NA	43 (41)	31　Jan 2023
E	Health Effects - Clinical Signs and Symptoms or Conditions	2023	24 (24)	636 (613)	249 (247)	909 (884)	31　Jan 2023
F	Health Effects - Health Impact	2023	28 (28)	37 (36)	2 (2)	67 (66)	31　Jan 2023
G	Medical Device Component	2023	7 (7)	224 (221)	69 (68)	300 (289)	31　Jan 2023
G Total	usable terms					1982 (1933)	

Release Notes for IMDRF Terminology Release Number 2023.

Release Number 2023 incorporates the Change Requests received for the 2022 maintenance cycle.

Overview of changes:
Annex A: Added 4 new terms (A2501,A0514,A050408,A0723), modified 4 terms (A050405, A07,A14,A1412) and retired 1 term (A071205).
Annex B: Added 1 new term (B25) and modified 3 terms (B15,B16,B24).
Annex C: Added 6 new terms (C0109,C0210,C0708,C2301,C2302,C24) and modified 2 terms (C1302,C160504).
Annex D: Added 2 new terms (D20,D21).
Annex E: Added 19 new terms (E0209,E0520,E0624,E0625,E0626,E0627,E0854,E0855,E0856,E0857, E1212,E1312,E1313,E1314,E1419,E1420,E1727,E2124,E2343)
and modified 13 terms (E040202,E0607,E0824,E0827,E0845,E090801,E090802,E120501,E1308,E2012, E2302,E2322,E2401)
Annex F: Added 1 new term (F2307) and modified 5 terms (F11,F19,F1907,F2202,F24).
Annex G: Added 4 new terms (G0200804,G03014,G03015,G03016) and modified 2 terms (G0200401,G04097).

Annex A
Retired one 071205 (L3) move up to independent L2 term A0723 newly added. Same definition.

From the Information of IMDRF WEB site
you will find the changes from previous year.

As of 2023 Jan

AnneX	A	B	C	D	E	F	G	
Add New	4	1	6	2	1 9	1	4	3 7
Modify	4	3	2	0	0	5	2	1 4
Retired	1							－1

Action to be taken
1. Add new terms and definition on your own database
2. Modify your current database according th the IMDRF modification information
3. Remove the term and code from your database

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

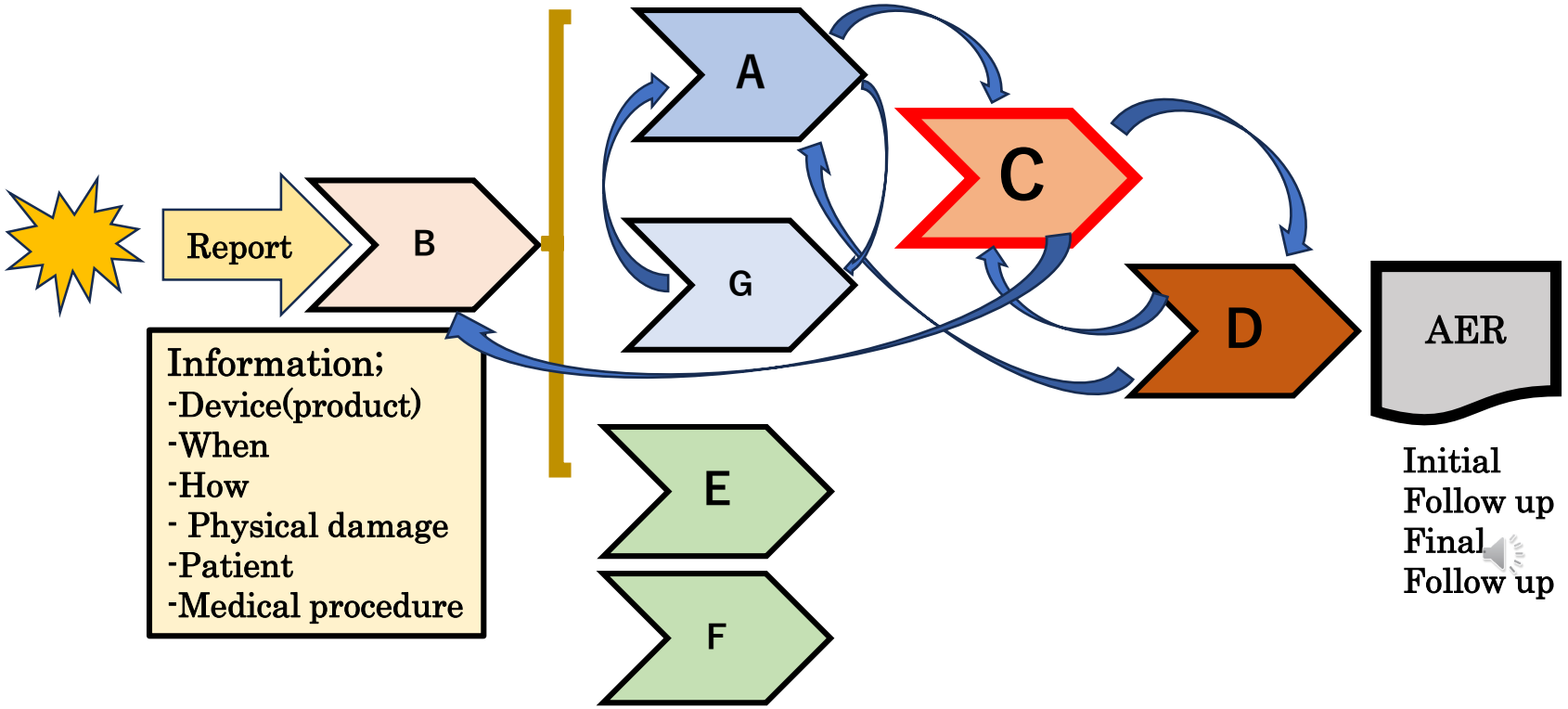
Just for information for Browser

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

4. How to use those terms (virtual case) and how regulator observe it

Thinking Process for making AE report

By utilizing IMDRF AE terms and code



Virtual Case and Kye Point

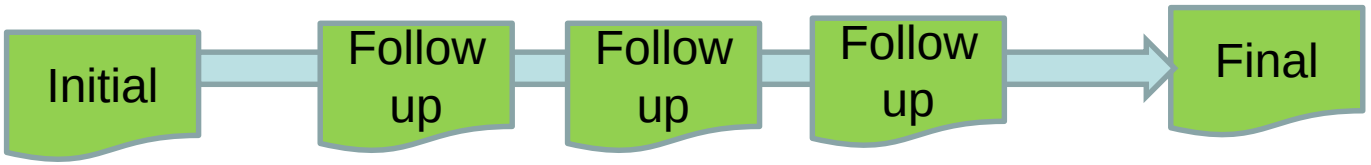
Report Type

GHTF N54 Appendix A

Initial Report : defined as the **first information** submitted by the manufacturer about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate notification

Follow-up Report : defined as a report that provides **supplemental information** about a reportable event that was not previously available

Final Report : defined as **the last report** that the manufacturer expects to submit about the reportable event. A final report may also be the first report



Nature of Information	Very Limited	Supplemental and adding cause analysis	Conclusive Results of cause analysis

Virtual Case and Kye Point

This is my personal observation and not offitial

Manufacturer Received AE information from User(or find by himself)

- Device stopped during the normal operation
- This is Not a new device and using 1 years but nothing happened like this
- Patient health impact and current situation is as follows・・・・・

Manufacturer response

- Ask User by phone and try to find the more details ,such as “ normal operation”
- Any sound or noise come out when it stopped
- How the device stopped suddenly or gradually.

Manufacturer investigate to find the root cause and make report within regulated Period with text description.

- Device provided the safety lock, so something happened for fail that function.
- So the something electrical parts may have damage
- But need to investigate more intensively.

Some virtual example for utilize AE terms for your e-MDAR

In case Initial Report

Not real report

		Situation	Selecting Term	Selecting Code
Problem	A	Device stopped suddenly in normal procedure	Fail-Safe Problem	A1602
Parts and Components	G	Looks electronic parts	Switch/Relay	G02034
Type of Investigation	B	Ask user to find the details by phone	Communication/Interviews	B13
Results of Investigation	C	Under investigation	Results Pending Completion of Investigation	C21
Investigation Conclusion	D	Not reached to the conclusion	Conclusion Not Yet Available	D16
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	In hospitalization	Hospitalization or Prolonged Hospitalization	F08

Virtual Case and Kye Point

This is my personal observation and not offitial

Manufacturer investigate to find the root cause continue

- Ask user to send back the device
- At the interview with the operator and found that they hard some noise, when the device stopped.
- They use almost 3 times a week in average.
- Investigate actual suspected device and try to find the real root cause

Manufacturer investigate to find the root cause

- Looks electrical function may have a problem and then mechanically stopped.
- Fail safe function dose not operate because of activation part looks stacked.
- Actually inverter seems to have some problem
- But still not reached to the conclusion because need to investigate other device which has same mechanism such as different Lot/Butch device, because of the noise.

In case Follow up Report (not reached to the conclusion to find the root cause)

More		Situation	Selecting Term	Selecting Code
Problem	A	Device electronic stopper function dose not operate	Activation Problem	A1501
Parts and Components	G	Seems electrical inverter	Inverter	G02022
Type of Investigation	B	Investigate the problemed device itself at our factory	Testing of Actual/Suspected Device	B01
Results of Investigation	C	Still need more investigation	Device Difficult to Operate	C1303
Investigation Conclusion	D	Not reached to the conclusion	Conclusion Not Yet Available	D16
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	Still in hospitalization	Hospitalization or Prolonged Hospitalization	F08

Virtual Case and Kye Point

This is my personal observation and not offitial

Manufacturer investigate to find the root cause continue

- Investigate the other device with different Lot use with factory stocked
- From section to section quality inspection process, electrical safety function has no problem and could not find significant root cause.

Manufacturer investigate to find the root cause and **made final decision**

- Actually electrical function may not have a problem.
- Investigate mechanical fail safe function, because noise comes first before stopped and find mechanical stopper such as open/close function cause damage to electrical portion.
- Actually mechanical stopper has not tightened enough according to the manufacturing process specification.
- The same lot device behave similar
- Reproducibility experiment shows the manufacturing process is the cause

In case Final Report

		Situation	Selecting Term	Selecting Code
Problem	A	Device Mechanical stopper failure	Activation Failure	A150101
Parts and Components	G	Stopper	Stopper	G04124
Type of Investigation	B	Investigated at our Factory	Testing of Device from Other Lot/Batch Returned From User	B05
Results of Investigation	C	Mechanical parts that is function to open and close has been damaged	Assembly Problem Identified	C1601
Investigation Conclusion	D	Root cause is the mechanical stopper has not been tightened enough under less torque during manufacturing process	Manufacturing Deficiency	D0301
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	In hospitalization but now back to home	Hospitalization or Prolonged Hospitalization	F08

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More		Situation	Selecting Term	Selecting Code
Problem	A	Device stopped suddenly in normal procedure Device electronic stopper function dose not operate Device Mechanical stopper failure	Fail-Safe Problem Activation Problem Activation Failure	A1602 A1501 A150101
Parts and Components	G	Looks electronic parts Seems electrical inverter Stopper	Switch/Relay Inverter Stopper	G02034 G02022 G04124
Type of Investigation	B	Investigate the problemed device itself at our factory Investigated at our Factory	Communication/Interviews Testing of Actual/Suspected Device Testing of Device from Other Lot/Batch Returned From User	B13 B01 B05
Results of Investigation	C	Under investigation Still need more investigation Mechanical parts that is function to open and close has been damaged	Results Pending Completion of Investigation Device Difficult to Operate Assembly Problem Identified	C21 C1303 C1601
Investigation Conclusion	D	Not reached to the conclusion Root cause is the mechanical stopper has not been tightened enough under less torque during manufacturing process	Conclusion Not Yet Available Manufacturing Deficiency	D16 D16 D0301
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	In hospitalization Still in hospitalization	Hospitalization or Prolonged Hospitalization	F08

Virtual Case and Kye Point

From regulator side observation and consideration

This is my personal observation and not offitial

Manufacturer investigation conclusion

- Use real device and same lot device and different lot device
- Find the cause by reproducibility and lead to make occlusion that root cause is manufacturing process deficiency.

Regulator side question from the view of "**Prevention from the same event**".

- Root cause is "Manufacturing deficiency" such as person who assemble the device did not follow the manufacturing specification. QMS issue.
- The torque gauge is well maintained? Or specified the specification?
- Specification of torque force is suitable to this Device?
- Is there any thought about the design specification is suitable or not because event happened just a year. And probably same thing will happen.
- Once manufacturing process has been improved and then nothing happened in future? And Manufacture assure to prevent the same event?
- **Is't it design problem and need to review design specification?**

Summary

Investigation terms are very important.

Manufacturer know everything about their Product through development stage to manufacturing process. On the other hand , User or Regulator has no knowledge how the device was developed and manufactured.
In that sense, Regulator could only make observation like third party review.

Lets take a look back why we have the AER system. Both party wants to use Device for Patient and keep their health in good condition by using the most sophisticated technology.
AE Report and its investigational information might help for both party to make sure that the corrective action should be the best preventive action.

Simply User do not want to be suffered by the same event to the patient, and believe that Regulator dose not want to take same legal action repeatedly.
So that both Manufacturer and Regulator should work together to keep patient safety.

Resources

When preparing AER, find terms from IMDRF WEB site.
[Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes | International Medical Device Regulators Forum (imdrf.org)]

N43

Technical document
Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes
IMDRF Code IMDRF/AE WG/N43
Published date 20 April 2020
Status Final

IMDRF Terminology

- web browser（JSON）and XLXS Files Annex A-G

IMDRF Terminology Maintenance

- Appendix B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Change Log

- Release Notes: IMDRF terminologies for categorized Adverse Event Reporting (AER)

Resources

When requesting new term for AER

N44

Information document

Maintenance of IMDRF AE Terminologies | International Medical Device Regulators Forum

Maintenance of IMDRF AE Terminologies
IMDRF Code IMDRF/AE WG/N44
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Appendices A & B: Change Request Form and Change Log

Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes
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Thank you

Asia-Pacific Economic Cooperation

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