Vigilance and Trend Analysis

Dan O'Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com

OMBU
ENTERPRISES, LLC

FDANEWS

Topics

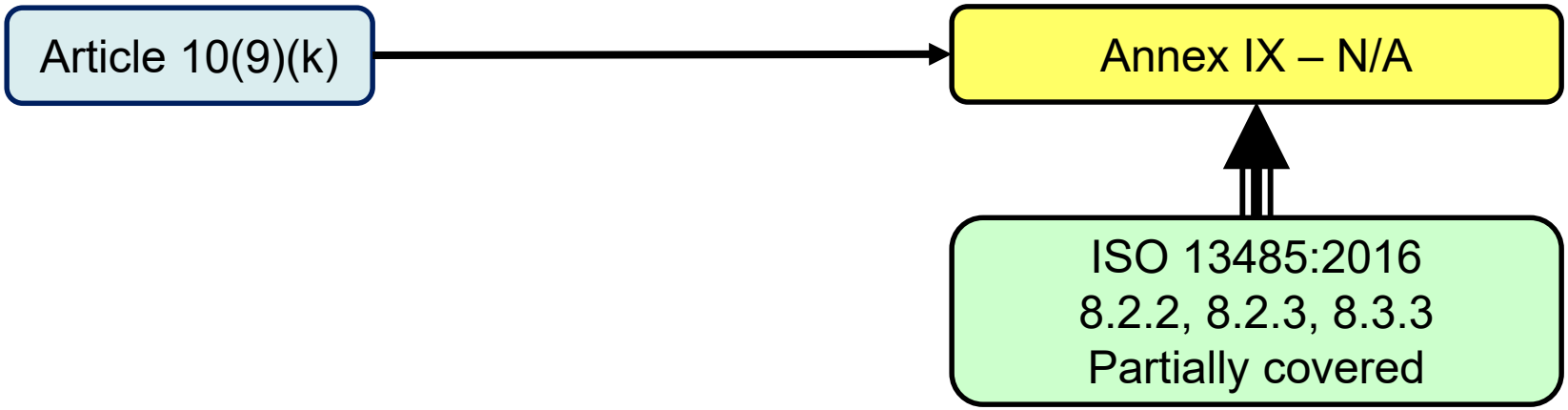
- Vigilance Overview
- Incident Classification
- IMDRF Coding System
- Serious Incident Reporting
- Field Safety Corrective Action
- Trend Reporting (Non-serious Incidents)
- Exercise F1 – Classifying Incidents
- Questions

Vigilance Overview

Vigilance

- Article 10(9)(k)
  - The quality management system shall address processes for reporting of serious incidents and field safety corrective actions in the context of vigilance.

Vigilance


Article 10(9)(k)
Annex IX – N/A
ISO 13485:2016
8.2.2, 8.2.3, 8.3.3
Partially covered

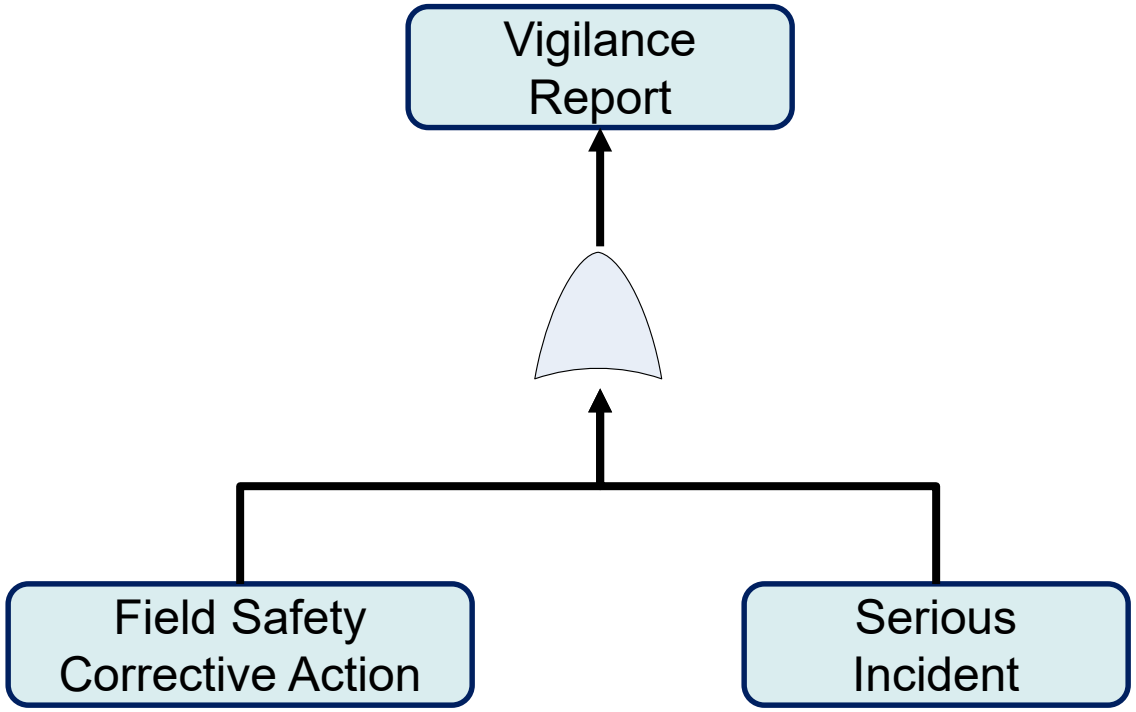
Vigilance

- Annex IX
  - N/A

- ISO 13485:2016
  - 8.2.2 Complaint handling
  - 8.2.3 Reporting to regulatory authorities
  - 8.3.3 Actions in response to nonconforming product detected after delivery

- CEN/TR 17223:2018
  - Partially covered. The standard requires processes for reporting events in accordance with regulatory requirements. However, it does not include the details or timelines for the EU vigilance system.

Vigilance


Vigilance Report
Field Safety Corrective Action
Serious Incident

MEDDEV 2.12-1 Rev 8

- This MEDDEV applies to the MDD, AIMD, and IVDD. Expect an update for the MDR and IVDR.

- The MEDDEV provides details for:
  - Incident Reports
  - Periodic Summary Reports
  - Trend Reports
  - Field Safety Corrective Action
  - Field Safety Notice

Incident Classification

Complaint Definition

- *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices. [ISO 13485:2016, 3.4]

MDR Definitions

- *Incident* means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect [Art. 2(64)]

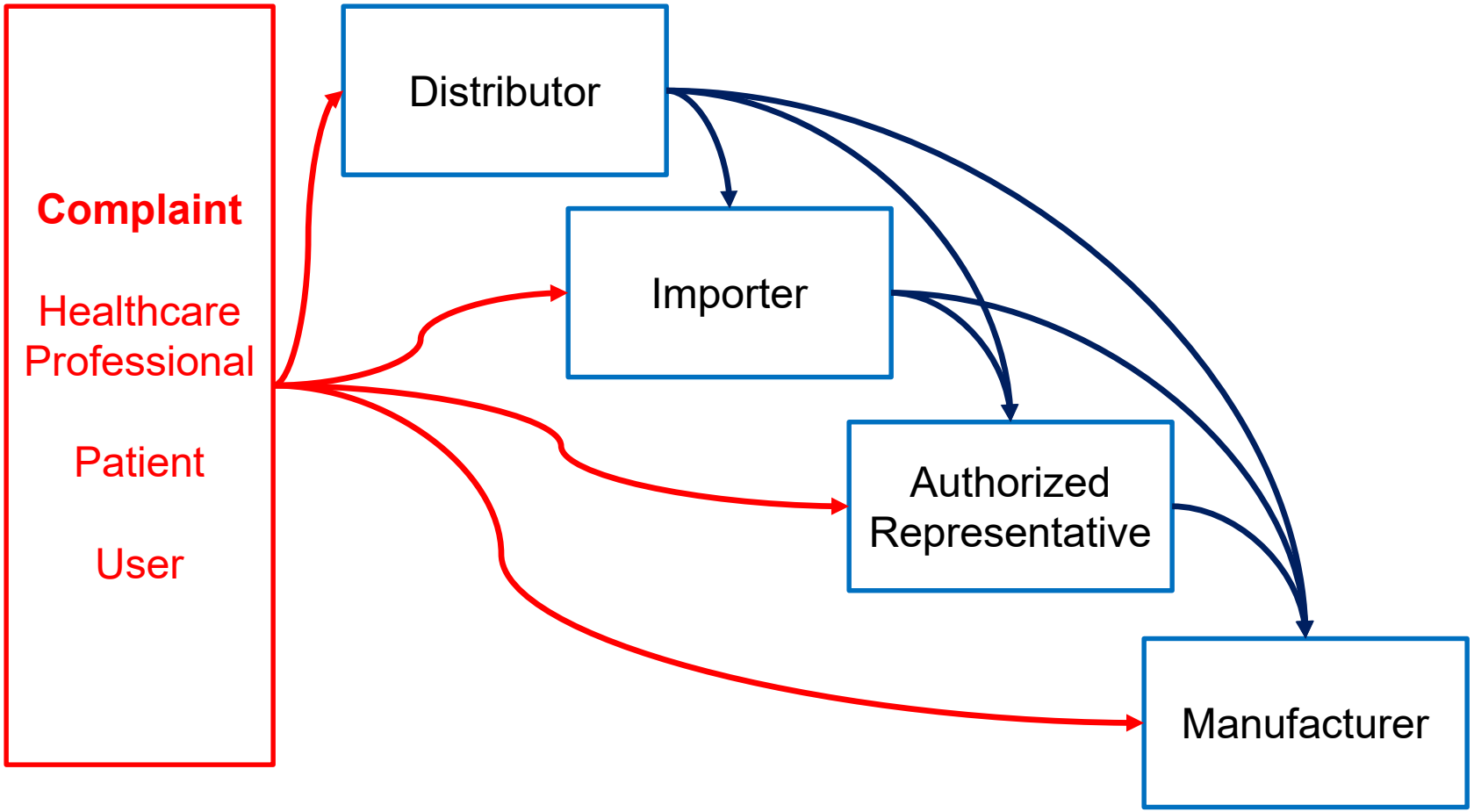
- *Serious Incident* means any incident that directly or indirectly led, might have led or might lead to any of the following:

  (a) the death of a patient, user or other person

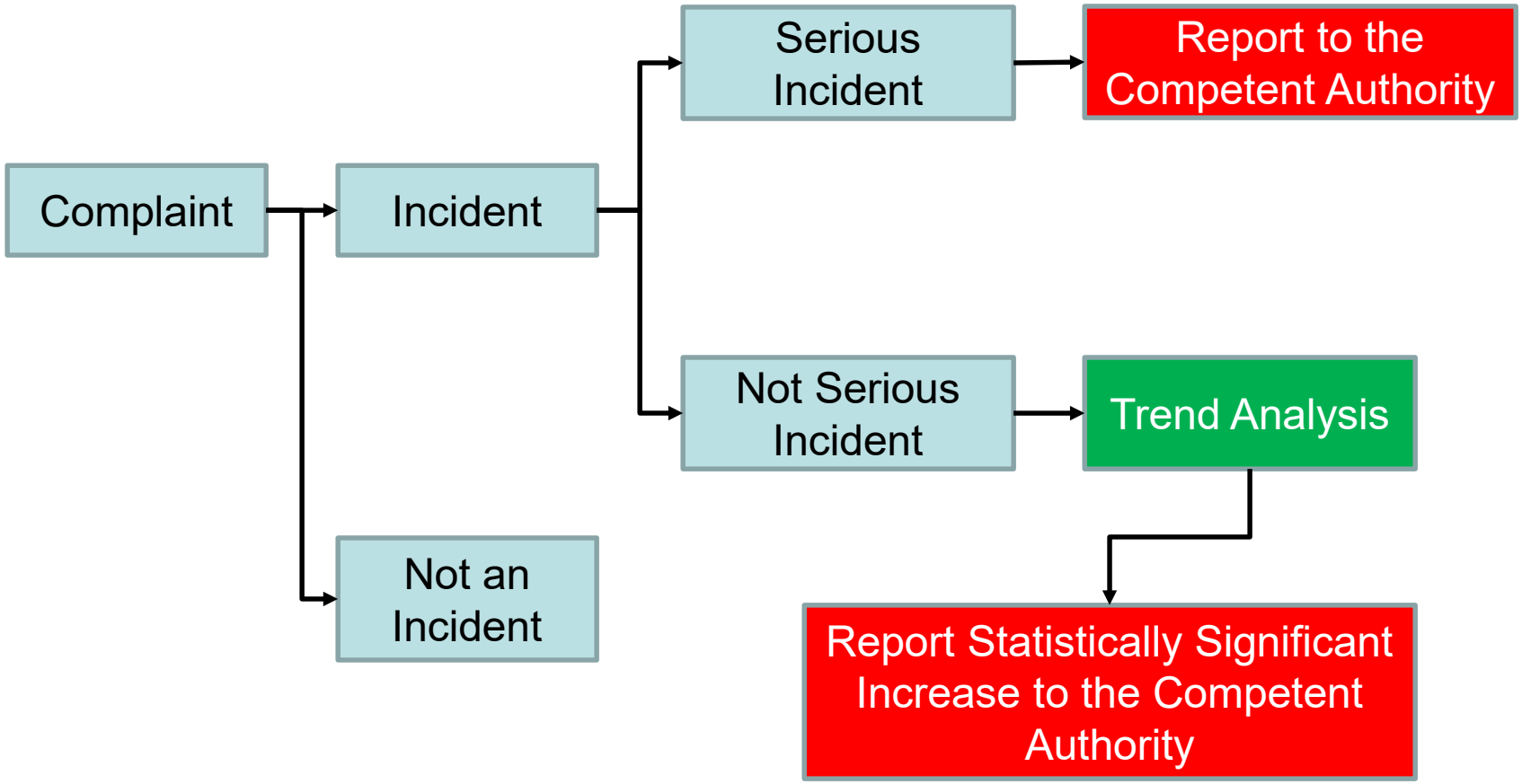
  (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health

  (c) a serious public health threat [Art. 2(65)]

Complaint Flow



Incident Reporting



IMDRF Coding System

The IMDRF Consultations

- The IMDRF work is organized into consultations, which deal with a specified topic.
  - The consultations may close as progress is made followed up another consultation to advance the effort

- The consultations of interest here are:
  - IMDRF Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes [Closed Dec. 2, 2016]
  - IMDRF Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes - Annex B [Closed May 31 2017]
  - Terminologies for Categorized Adverse Event Reporting: Terms, terminology structure and codes [Open – Scheduled to close Oct. 12, 2018]

Documents

- The documents are in two groups, based on the consultation status.
- Edition 2 documents are final
- Edition 3 documents are proposed
  - The Edition 3 documents are open for public comment
  - The comment period closes on October 12, 2018

Documents

- The primary document is *IMDRF Terminologies for Categorized Adverse Event Reporting (AER): Terms, Terminology Structure, and Codes*
  - IMDRF/AE WG/N43FINAL:2017 (Edition 2), September 21, 2017
  - AE WG(PD1)/N43Edition 3)R1, July 12, 2018

- The document provides globally harmonized terminology and associated codes
  - Improve signal detection by adverse event management systems
  - Improve accuracy for capturing and reporting adverse events
  - Increase the accuracy and reliability of information exchanged between regulators

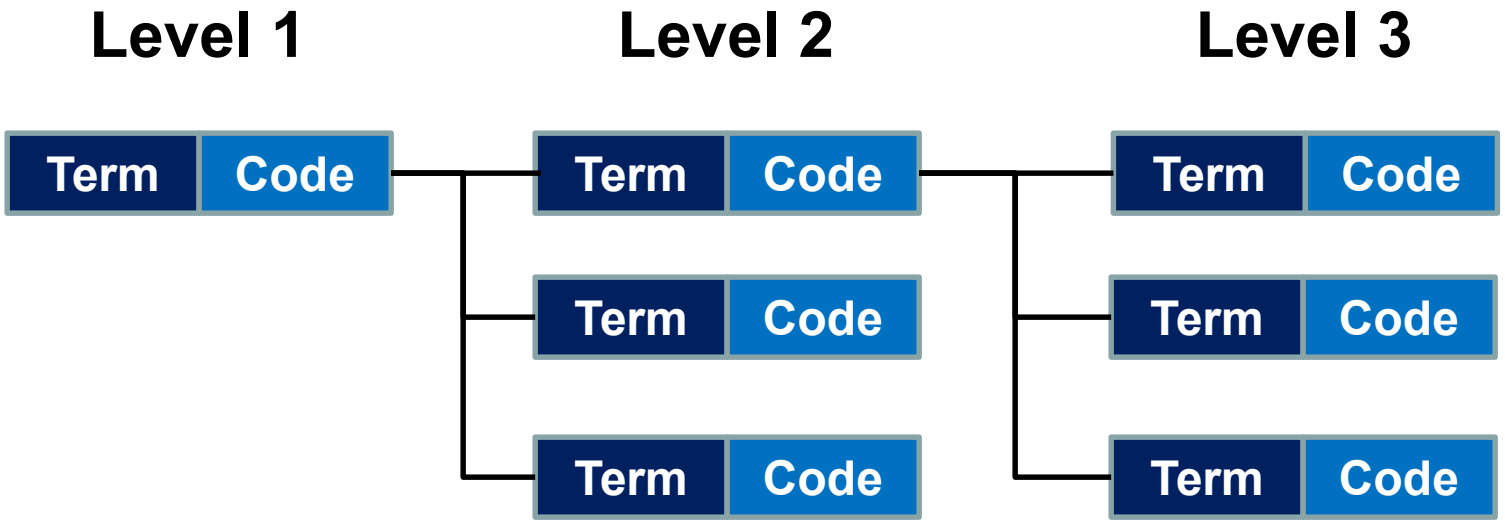
Terminology

- The system provides four sets of *terminology*:
  - Medical device problem
  - Cause investigation
  - Health effect
  - Component

- Each terminology set has *terms* and associated *definitions*
  - Each term has a unique alphanumeric *code*

- The terms (and codes) are organized in a hierarchical structure
  - Generally, there are three levels in the structure

Schematic Diagram



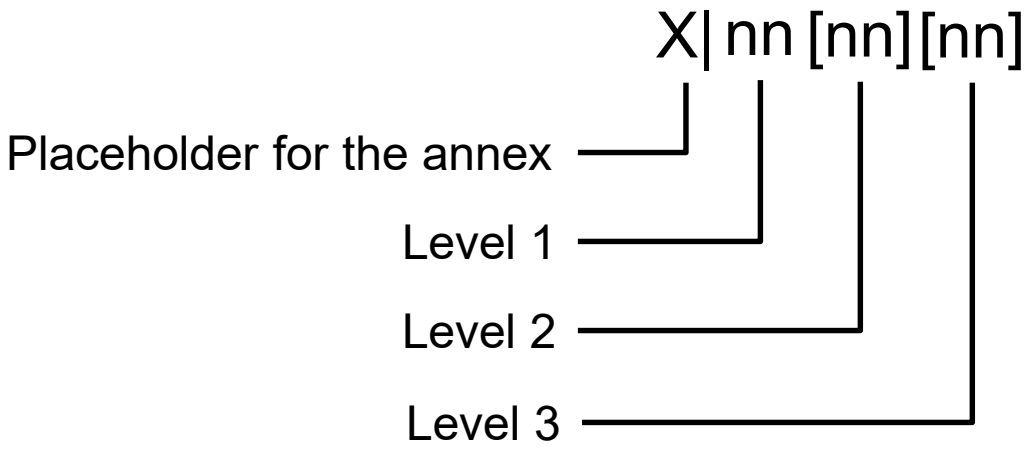
IMDFR Code Types

Terminology, Terms, and Codes

- The system has four sets of terminology represented by terms, definitions, and codes

- The main document uses seven annexes (Annex A to annex G) for the terms, definitions, and codes
  - The annexes are formatted as Excel workbooks

- The alphanumeric codes use the following structure



Terminology, Terms, and Codes

Terminology	Annex	Code
Medical Device Problem	A	A|00[00][00]
Cause Investigation		
Type of Investigation	B	B|00
Investigation Findings	C	C|00[00][00]
Investigation Conclusion	D	D|00[00]
Health Effects		
Clinical Signs, Symptoms, and Conditions	E	E|00[00][00]
Health Impact	F	F|00[00][00]
Component	G	G| … To be defined

Serious Incident Reporting

Reporting

- Article 87(1)
- Report any serious incident involving a device available on the EU market except:
  - Expected side-effects
  - Documented in the product information
  - Quantified in the technical documentation
  - Subject to trend reporting

- Report using Eudamed

Reporting Timeline

- Report serious incidents immediately, but not later than 15 days after becoming aware of the incident

The reporting time in MEDDEV 2.12-1 Rev 8 for the MDD is 30 days.

- In the event of a serious public health threat report immediately, but not later than 2 days after becoming aware of the incident

- In the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately, but not later than 10 days after becoming aware of the incident

- Submit incomplete initial reports on time and then a complete follow-up report

Periodic Summary Reports

- Article 87(9)
- Periodic summary reports are allowed when:
  - {There are similar serious incidents AND
  - The device or device type is the same}
  - The cause is identified or a FSCA implemented OR
  - Incidents are common and well documented

- The Competent Authorities involved and manufacturer agree on the format, content, and frequency

Eudamed

- Eudamed automatically sends incident reports to the Competent Authority of the member state where the incident occurred.

- Eudamed automatically sends periodic summary reports to the Competent Authority of:
  - Member states coordinating in the report
  - Member state in which the manufacturer has a place of business

- In both cases, Eudamed sends the information to the NB that issued the certificate for the device.

Serious Incident Analysis

- Article 89 – Manufacturer's Actions
- After reporting a serious incident, the manufacturer must conduct an investigation.

- The manufacturer's investigation includes a risk assessment of the incident

- The manufacturer provides a final report to thee Competent Authority
  - The report includes findings, conclusions, and corrective action

Serious Incident Analysis

- Article 89 – Competent Authority Actions
- The Competent Authority evaluates the serious incident in consultation with the NB and the manufacturer

- The Competent Authority may require the manufacturer to provide documents

- The Competent Authority monitors the manufacturer's investigation and may intervene

- The Competent Authority notifies other Competent authorities of the manufacturer’s corrective action.

Field Safety Corrective Action

Definitions

- *Field Safety Corrective Action* means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market. [Art. 2(68)]

- *Field Safety Notice* means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action. [Art. 2(68)]

Reporting

- Article 87(1)
- Report any field safety corrective action involving a device available on the EU market
  - Include corrective action in a third-country when the device is also available in the EU

- Report using Eudamed

Field Safety Notice

- For each FSCA the manufacturer prepares an FSN.
- The FSN is in the languages of the member state where the FSCA applies
- The manufacturer submits the FSN to the Competent Authority
- The FSN explains the reason for the FSCA and clearly indicates the actions to take
- The FSN clearly identifies the devices covered including any UDIs and the manufacturer's SRN
- The manufacturer enters the FSN in Eudamed so it is available to the public

FSCA Analysis

- Article 89 – Manufacturer's Actions
- After reporting an FSCA, the manufacturer must conduct an investigation.

- The manufacturer's investigation includes a risk assessment of the incident

- The manufacturer provides a final report to thee Competent Authority
  - The report includes findings, conclusions, and corrective action

FSCA Analysis

- Article 89 – Competent Authority Actions
- The Competent Authority evaluates the FSCA in consultation with the NB and the manufacturer

- The Competent Authority may require the manufacturer to provide documents

- The Competent Authority notifies other Competent authorities of the manufacturer's corrective action.

Trend Reporting
(Non-serious Incidents)

Reporting

- Article 88 Trend Reporting
- Manufacturers report any statistically significant increase in the frequency or severity of:
  - Incidents that are not serious incidents
  - Expected undesirable side-effects

- The manufacturer reports through Eudamed

Methods and Protocols

- Annex III(1.1)(b)(5th indent)
- The PMS plan includes:
  - The methods and protocols to manage the events subject to trend reporting
  - The methods and protocols to establish any statistically significant increase in the frequency or severity of incidents
  - The observation period

- Article 88(1)
- Establish the significant increase compared to the foreseeable frequency or severity
- Specify the period in the technical documentation and the product literature

Exercise

Exercise F1

- Classifying Incidents
- Use complaints and other post-market information to apply the elements of the incident classification system.

QUESTIONS