PROCEDURE FOR ADVERSE EVENT INVESTIGATION AND REPORTING

Code: 

Version: 0.1

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1. Purpose, scope and users

The purpose of this procedure is to define the process of incident investigation, and the minimum requirements for the reporting, investigating, and communicating of adverse events and notification of complaints that meet specified reporting criteria of adverse events used in the QMS (Quality Management System).

This procedure applies to all processes within the QMS scope.

Users of this document are all employees of [organization name] inside the scope of the QMS.

2. Reference documents

- ISO 13485:2016 standard, clause 8.2.3
- ISO 9001:2015 standard, clause 8.5.5
- [national regulations for vigilance system]

3. Adverse Event Investigation

An adverse event is any unwanted medical device-related incident that may occur during utilization of the device or subsequent to its use if it was misused or if the device was not properly used by the intended user.

An adverse event is any event that meets the criteria mentioned below, and must be communicated to the organization.

Criteria for reporting on adverse events are:

- A serious injury or death of a patient
- A serious injury or death of a healthcare professional
- A device malfunction that directly results in a patient injury

[Job title] is responsible for conducting the investigation in a timely manner, and documenting the information in the following link [insert link].

If the incident has the sort of consequences where authorities must conduct the investigation, all necessary documents are provided to the authorities.

3.1. Reporting (adverse event notification)

The organization should ensure that it maintains confidentiality of incidents.
The incident or adverse event must be reported to [job title], who will fill out an Incident

- [job title] needs to provide a detailed description of the incident, including:
  - any actions taken to prevent the incident,
  - any preventive measures implemented,
  - any corrective actions taken,
  - any investigations conducted,
  - any training or education provided,
  - any other available information.

The report must be issued no later than 12 hours following the incident, or 24 hours for low-level

In determining the nature of the investigation, the resources needed, and the priority to be given to

The report must then be sent out [describe the means to be used] by the incident owner to the

Adverse events must be communicated by [job title] to a National Competent Authority (NCA)

3.2. Incident investigation objectives

- prevention of reoccurrence by prescribing the corrective actions
- determination of basic QMS failures

3.3. Determining the cause of the incident
3.4. Analysis of the causes of the incident

The incident investigation conducted by [job title] must cover:

3.4.1. Possible causes

Possible causes are all causes that could result in an incident. Identifying possible causes represents a basis for understanding the occurrence of the incident and how it can be prevented in the future. The possible causes are taken into account in further analysis. If the source or the root is supported by the facts, it becomes a possible cause.

3.4.2. Root/source of possible cause (underlying cause)

The real cause (root or source) is the source of the real event or occasion that directly triggered the incident. Identifying the real cause requires an analysis of all possible causes and documenting them in the Incident Investigation Report. After the investigation, [job title] completes the Incident Investigation Report and delivers it to the

3.5. Incident investigation follow-up

[Job title] conducts the investigation of the real cause by applying the following steps:

- repetition and assessment of what is happening in a controlled environment
- repetition of the incident
- identification of contributing factors
- repetition of the incident with corrections

After the investigation, [job title] completes the Incident Investigation Report and delivers it to the

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The [job title] in charge of enforcing corrective actions defines the deadline for the action

4. Managing records kept on the basis of this document

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5. Appendices

- Appendix 1 – Investigation Report

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