Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative

Authoring Group: Working Group 4, Post-Market

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Contents

1. Objectives

1.1 The objective of the adverse event reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.

1.2 This document was developed by Work Group 4 of AHWP to provide guidance and information to Regulatory Authorities (RAs) and the Medical Device Industry (Industry) on the adverse event (AE) reporting.

1.3 This document is a consolidation of AHWP guidance on Adverse Event Reporting. It was prepared by combining the Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (AHWP/WG2/F001:2013) with the following documents:

(a) Medical Device Adverse Event (AE) Report Form (AHWP/WG2/F001:2012) ; and

(b) Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative (AHWP/WG4/F001:2014).

2. Definitions

2.1 **Authorised Representative (AR)** means any natural or legal person[1] established within a country or jurisdiction who has received a written mandate from the manufacturer to act on the manufacturer's behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

2.2 **Manufacturer (or legal manufacturer or known as *"product owner"* in some countries)** means any natural or legal person with responsibility for design or manufacture of a medical device with the intention of making the medical device available for use, under the name of that person; whether or not such a medical device is designed or manufactured by that person or on behalf of that person by another person(s).

[1] The term "**person**" includes legal entities such as a corporation, a partnership or an association.

2.3 **Serious[2] injury (also known as "*serious deterioration in state of health*")** means

(a) A life threatening illness or injury,

(b) A permanent[3] impairment of body function or permanent damage to a body structure, or

(c) A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

2.4 **Serious public health threat** means any event type which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action.

2.5 **Unanticipated** means a condition leading to an event was not considered in a risk analysis performed during the design and development phase of the device.

Note: The reportable AE may be unanticipated because of

(a) A lack of historical information (rare),

(b) A change in the situation in which it is occurring,

(c) A change in the patient, health-care professional or user outcome, or

(d) Off-label use of the device.

2.6 **Use error** means the user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user.

3. Decision Process

Any event which meets the three basic reporting criteria listed in Sections 3.1 through 3.3 below is considered as an AE and should be reported to the relevant RA(s)[4].

Reportable AEs involving In Vitro Diagnosis (IVD) medical devices are further

[2] The interpretation of the term "***serious***" is not easy, and should be made in consultation with a medical practitioner when appropriate.

[3] The term "***permanent***" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

[4] RAs are recommended to specify clearly whether only local AEs or both local AEs and those occur outside their jurisdiction are reportable.

explained in Section 3.4.

A manufacturer or its AR ~~Reporting~~ may be exempted from reporting an AE if any one of the exclusion rules listed in Section 4 is applicable.

- However those AEs involving particular issues of public health concern as determined by the relevant RA should be reported regardless of exemption criteria (see Section 3.1(d)).

- Similarly those AEs which are subject to an exemption become reported to the RA if a change in trend (usually an increase in frequency) or pattern is identified.

Specific rules apply to events involving use error can be found in Section 5.

3.1 An event has occurred

The manufacturer or its AR becomes aware of information regarding an event which has occurred with its device. This also includes situations where testing performed on the device, examination of the information supplied with the device or scientific information indicates some factor that could lead or has lead to an event.

Typical events are:

(a) A malfunction or deterioration in the characteristics or performance

A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

The intended purpose means the use for which the device is intended according to the data supplied by the manufacturer in the labeling, instructions for use or promotional materials.

(b) An inadequate design or manufacture

This would include cases where the design or manufacturing of a device is found to be deficient.

(c) An inaccuracy in the labeling, instructions for use or promotional materials

Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.

(d) A significant public health concern

This can include an event that is significant and of an unexpected nature such as that it becomes alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacod Disease (CJD). These concerns may be identified by the RA or the manufacturer.

(e) Other information becoming available

This can include results of testing performed by the manufacturer on its products, or by the user prior to being used on patients, or by other parties. This can also include information from the literature or other scientific documentation.

3.2 The manufacturer's device is associated with the event

In assessing the link between the device and the event, the manufacturer should take into account:

(a) The opinion, based on available information, from a healthcare professional;
(b) Information concerning previous, similar events; and
(c) Other information held by the manufacturer.

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event.

3.3 The event led to one of the following outcomes

(a) Death of a patient, user or other person;
(b) Serious injury of patient, user or other person; or
(c) No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs.

Some jurisdictions refer to ~~these~~ events in Section 3.3(c) above as near incidents or near misses.

Not ~~A~~all events ~~do not~~ lead to a death or serious injury. The non-occurrence of such a result might have been due to circumstances or ~~to~~ the timely intervention of health care personnel.

The event is considered "adverse" if in the case of reoccurrence, it could lead to death or serious injury.

This applies also if the examination of the device or a deficiency in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an event involving death or serious injury.

3.4 Reportable AEs involving In Vitro Diagnosis (IVD) Medical Devices

As the majority of IVD medical devices do not come into contact with patients and so it is not easy to establish direct harm to patients, unless the device itself causes deterioration in the state of health of a patient. Harm is more likely to be indirect. AEs involving IVD medical devices most likely result as a consequence of a medical decision or action taken or not taken on the basis of information or results(s) provided by the IVD medical devices.

Typical cases of these AEs include:

(a) Misdiagnosis,
(b) Delayed diagnosis,
(c) Delayed treatment,
(d) Inappropriate treatment, and
(e) Transfusion of inappropriate materials.

Examples of Reportable AEs can be found in Appendix 1.

4. Exemption Rules

Whenever any one of the following exemption rules is met, the AE does NOT need to be reported to the RAs.

4.1 Deficiency of a new device found by the user prior to its use

Regardless of the existence of provisions in the instruction for use provided by the manufacture, deficiencies of devices that would normally be detected by the user and where no serious injury has occurred, do not need to be reported.

Examples of non-reportable AEs

- User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured.
- Sterile single use device packaging is labeled with the caution "do not use if package is opened or damaged", but damaging to the packaging was discovered and the device was not used.
- Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.

4.2 Adverse event caused by patient conditions

When the manufacturer has information that the root cause of the AE is due to the patient's condition, the event does not need to be reported. These conditions could be preexisting or occurring during device use.

To justify no report, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contributed to death or serious injury. A person qualified to make a medical judgment would accept the same conclusion.

Examples of non-reportable AEs

- Orthopedic surgeon implants a hip joint and warns against sport-related use. Patient chooses to go water skiing and subsequently requires premature revision due to not following directions.
- Early revision of an orthopedic implant due to loosening caused by the patient developing osteoporosis.
- A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.

4.3 Service life of the medical device

When the only cause for the AE was that the device exceeded its service life as specified by the manufacturer and the failure mode is not unusual, the AE does not need to be reported.

The service life must be specified by the device manufacturer and included in the master record [technical file] or, where appropriate, the instructions for use (IFU). Service life is defined as: the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified. Reporting assessment shall be based on the information in the master record or in IFU.

Reporting of AEs related to the reuse of devices labeled for single use (or labeled “for single use only”) is handled under Section 5: Use Error.

Examples of non-reportable AEs

- Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explantation of pacemaker is required.
- A drill bit was used beyond end of ~~specific~~ its specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty ~~to retrieve~~of retrieving the broken parts.

4.4 Protection against a fault functioned correctly

AEs which did not lead to serious injury or death, because a design feature protected against a fault becoming a hazard (in accordance with relevant standards or documented design inputs), do not need to be reported.

Examples of non-reportable AEs

- An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
- Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
- During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

4.5 Remote likelihood of occurrence of death or serious injury

AEs which could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported.

If an AE resulting in death or serious injury occurs, the AE is reportable and a reassessment of the risk is necessary. If reassessment determines risk remains remote, previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Note that a change in trend of these non-serious outcomes must be reported as specified in Section 3.

Examples of non-reportable AEs

- Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is remote. No patients experienced adverse health effects.
- Manufacturer of blood donor sets obtains repeated complaints of minor leaks of blood from these sets. No patient injury from blood loss or infections of staff has been reported. Chance of infection or blood loss has been reevaluated by manufacturer and deemed remote.

4.6 Expected and foreseeable side effects

Side effects which are clearly identified in the manufacturer's labelling and clinically well known as being foreseeable and having a certain functional or numerical predictability when the device was used as intended need not be reported.

Some of these events are well known in the medical, scientific, or technology field; others may have been clearly identified during clinical investigation or clinical practice and ~~labeled~~ included in device labelling by the manufacturer.

The side effects must also be clinically acceptable in terms of patient benefit and documented in the device master record with an appropriate risk assessment, prior to the occurrence of AEs.

Examples of non-reportable AEs

- A patient got a second-degree burn during the use of an external defibrillator in an emergency. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned of in the instructions for use. The frequency of burns is occurring within the range specified in the device master record.
- A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device master record.
- Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.

- Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labeled side effects.

4.7 Adverse events described in an advisory notice

AEs that occur after the manufacturer has issued an advisory notice need not to be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer or its AR should provide a summary report, the content and frequency of which should be agreed with the relevant RA.

Examples of non reportable AEs

- Manufacturer issued an advisory notice and recall of coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the recall action and individual AEs did not have to be reported.

4.8 Reporting exemptions granted by Regulatory Authorities

Common and well-documented events may be exempted by the RA from reporting or changed to periodic reporting upon request~~ed~~ by the manufacturer.

5. Use Error

5.1 The reportability of AEs involving use error is not globally harmonized. Reportability is subject to requirements of the relevant RA.

5.2 The term ‘use error’ covers unintentional and intentional misuse.

5.3 Some jurisdictions may require reporting of AEs involving use error even though the events did not occur in their own jurisdiction.

5.4 RAs generally prefer to receive use error reports, especially those involving death or serious injury.

5.5 The reprocessing and re-use of device labeled by the manufacturer of single use ("single use only") is a common practice. However, since this is clearly outside the intended use of the device as stated by the manufacturer, reports of AEs potentially associated with reuse should be treated as reports of use error.

5.6 Similarly, AEs due to the use of any device for clinical situations not intended by the manufacturer (also called "off label" use) should be treated similar to use error.

6. Timing for Reporting

6.1 Upon becoming aware that an event has occurred and is associated with one of its devices, the medical device manufacturer or ~~the~~ its AR must determine whether it is an adverse event.

6.2 Adverse events that represent a serious public health threat shall be reported within 48 hours, following the date of awareness of the event by the manufacturer or its AR to the relevant RAs.

6.3 Adverse events that result in unanticipated death or unanticipated serious injury must be reported by the manufacturer or its AR to the relevant RAs immediately, not later than 10 elapsed calendar days following the date of awareness of the event.

6.4 All other reportable events must be reported as soon as possible by the manufacturer or its AR, but not later than 30-elapsed calendar days following the date of awareness of the event.

6.5 If after becoming aware of a potentially reportable adverse event, there is still uncertainty about whether the event is reportable, the manufacturer or its AR must submit a report within the timeframe required for that type of event.

6.6 All reporting timeframes refer to when the relevant RAs[5] must be first notified. This notification may be in the form of

(a) ***Initial report***, which is defined as the first information submitted by the manufacturer or its AR about a reportable event. Any information which is not available upon submission of the initial report or which differs from information submitted on the initial report will need to be submitted in the type of documentation to the RAs as soon as the information is available OR within the timeframe specified by the RAs. The types of documentation include safety notification, follow-up report[6] and final report.

(b) ***Final report,*** which is defined as the last report that the manufacturer or its AR expects to submit about the reportable event. A final report may also be the first report if the information is complete; or

(c) ***Trend report***, which is defined as information supplied as a result of trending upon request of the relevant RAs.

The choice of report types depends on whether all the applicable data specified in the Medical Device Adverse Event (AE) Report Form (Appendix 2) or local regulatory requirements is available within the appropriate report time. If addition information is required, the manufacturer or its AR should provide a follow-up report or final report as soon as the information is available OR as requested by the relevant RAs, e.g. within the timeframe indicated for such report on the Medical Device Adverse Event (AE) Report Form by the RAs.

7. References

7.1 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer (GHTF/SG1/N055:2009)

7.2 Medical Device Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006)

[5] In some countries, the regulatory authority may require the manufacturers or ARs to report adverse events of registered devices occur in a foreign country.

[6] Follow-up report is defined as a report that provides supplementary information about a reportable event that was not previously available.

7.3 Medical Devices: Post-Market Surveillance National Competent Authority Report Exchange Criteria and Report Form (IMDRF/NCAR WG/N14 FINAL:2015)

7.4 Guide to Incident Reporting for *In-vitro* Diagnostic Medical Devices (SUR-G0004-4). Health Products Regulatory Authority (HPRA). 02 August 2012

7.5 Medical Device Guidance, GN-05: Guidance on the Reporting of Adverse Event for Medical Devices (Revision 2). Health Science Authority (HSA). September 2013

7.6 IEC 62366-1 (Ed. 1.0) Medical devices – Part 1: Application of usability engineering to medical devices

Appendix 1 - Examples of Reportable Adverse Events

- Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification.

- On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and the patient's nose was broken. The system was installed, maintained, and used according to manufacturer's instructions.

- It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theater at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer's instructions.

- Sterile single use device packaging is labeled with the caution *'do not use if package is opened or damaged*'. The label is placed by incorrect design on inner packaging. Outer package is removed but device is not used during procedure. Device is stored with inner packaging only which does not offer a sufficient sterile barrier.

- A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

- Premature revision of an orthopedic implant due to loosening. No cause yet determined.

- An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.

- Manufacturer of a pacemaker released on the market identified a software bug. Initial risk assessment determined risk of serious injury as remote. Subsequent failure results in new risk assessment by manufacturer and the determination that the likelihood of occurrence of a serious injury is not remote.

- Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation.

- Manufacturer does not change ablation device label and fails to warn of this side effect which may be produced when the device is working within specification.

- Healthcare professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.

- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died.

- An intravenous set separates, the comatose patient's blood leaks onto the floor, the patient bleeds to death.

- Unprotected ECG cable plugged into the main electricity supply – patient died.

- Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.

- After delivery of an orthopedic implant, errors were discovered in heat treatment records leading to non-conforming material properties, which resulted in risk to public health.

- Testing of retained samples identified inadequate manufacturing process, which may lead to detachment of tip electrode of a pacemaker lead, which resulted in risk to public health.

- Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

- With a particular (unusual) parametric setting with the software on a radiography device created by the operator, no patient name or an incorrect patient name was found printed on the report.

- An IVD manufacturer had identified a problem with their HIV test which can result in the generation of false negative results. The problem is not detected by the device control and therefore the incorrect false negative result could be given to medical staff and the patient. The device is widely used across the world and in some jurisdictions it is used for testing prior to blood / organ donation.

Appendix 2 - Medical Device Adverse Event (AE) Report Form

AR Report Ref
Report No. (Official Use Only)

Medical Device Adverse Event (AE) Report From

For use by **Authorised Representatives (AR)** to report events that have take place in:

I. ADMINISTRATIVE INFORMATION

1. Report Type (select one):

☐ Initial ☐ Follow-up ☐ Final ☐ Trend

2. Classification of Event:

☐ Serious Public Health Concern ☐ Death

☐ Serious Injury ☐ Minor injury

☐ Other Reportable Event

3. Date of this report (dd-mmm-yyyy)	dd-mmm-yyyy
4. Date of adverse event (dd-mmm-yyyy)	dd-mmm-yyyy
5. AR awareness date (dd-mmm-yyyy)	dd-mmm-yyyy
6. Expected date of next report (dd-mmm-yyyy)	dd-mmm-yyyy

Particulars of the AR Submitting this Report:

7. Name	
8. Company	
9. Address	
10. Mobile Phone No	
11. Fax	
12. E-mail	

13. Other Regulatory Authorities to which this report was *also* sent

II. CLINICAL EVENT INFORMATION

1. Event Description:

2. No. of affected people involved		3. No. of devices involved	

III. HEALTHCARE FACILITY INFORMATION (OPTIONAL)

1. Name of the Facility			
2. Name of Contact Person			
3. Facility Report No.			
4. Address			
5. Phone		6. Fax	
7. E-mail			

IV. DEVICE INFORMATION

Device Information

1. Device Name	
2. Product License No.	
3. Product Registration No.	
4. Nomenclature System	AMDNS / UMDNS Code
	GMDN Code
5. Catalogue No.	
6. Serial No.	
7. Lot / Batch No.	

Legal Manufacturer Information

8. Name			
9. Contact Person			
10. Address			
11. Phone		12. Fax	
13. E-mail			

14. Operator of device at the time of the event

☐ Healthcare Professional ☐ Patient ☐ Other ☐None

15. Usage of Device

☐ Initial Use ☐ Reuse of Single-Use Device

☐ Reuse of Reusable Devices ☐ Re-serviced / Refurbished

☐ Other, please specify:

16. Device Disposition / Current Location:

V. RESULT OF MANUFACTURER'S INVESTIGATION

1. Manufacturer's Device Analysis Results:

2. Remedial Action / Corrective Action / Preventive Action:

VI. INFORMATION OF PATIENT (OPTIONAL)

1. Age at time of event (months, years)			
2. Gender (M/F)	(Please select)	3. Weight (kg)	

4. List of devices involved with the patient (see Section IV):

5. Corrective action taken relevant to the care of the patient:

6. Patient outcome:

VII. OTHER REPORTING INFORMATION (OPTIONAL)

Any events with this device with the same root cause?

☐ Yes, please specify the rate: _____ ☐ No

VIII. COMMENTS

IX. SUBMISSION OF REPORT

By Mail:

By Fax: ( ) By e-mail:

X. DISCLAIMER

Submission of this report does not constitute an admission of manufacturer, AR, user, or patient liability for the event and its consequences. It does not, in itself, represent a conclusion by the AR that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device(s) caused or contributed to the adverse event.

GUIDANCE FOR FILLING IN THE ADVERSE EVENT REPORT FORM

GENERAL

All fields must be completed with appropriate information or "NA" if not applicable to the event or "unknown" when the data is not available.

"AR Report No." on the top right hand corner of the first page is the unique number assigned by the AR to identify the report in the AR's internal system

Reasonable effort must be made to address all elements. However, failure or inability to do so is not justification for failing to submit a report within the establishment timeframes.

All AHWP documents referred to in this guidance are available at the AHWP homepage: http://www.ahwp.info/

I. ADMINISTRATIVE INFORMATION

1. Report Type

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

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

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

Trend: defined as information supplied as a result of significant increase in the rate of (i) reportable events, (ii) non-reportable adverse events, or (iii) adverse events scheduled for periodic reporting. Please refer to the related AHWP guidance document(s).

2. Classification of Event

Adverse events that resulted in (i) serious public health concern shall be reported *within 48 hours*, (ii) death, (iii) serious injury shall be reported as soon as possible, but not later than *10 elapsed calendar days* following the awareness of the event.

All other reportable events shall be reported as soon as possible, but not later than *30 elapsed calendar days* following the awareness of the event.

Please note that the following use errors are reportable events

a. Use errors that results in death or serious injury or serious public health concern;
b. When the AR or manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern;
c. When the AR or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.

Other use errors that do not result in death or serious injury or serious public health concern need not be reported.

For details on reportable and non-reportable events, please refer to the related guidance notes.

3 – 6. Dates of this report, date of adverse event, AR awareness date, and expected date of next report

All dates must be formatted as follows: 2 digit day, 3 letter month, 4 digit year, e.g. 01-JAN-2001

Expected date of next report: the date when further information will be provided. This should be "NA" for final report.

7 – 12. Particulars of the AR Submitting this Report

Please fill in the contact details of the AE's reporter.

13. Other Regulatory Authorities to which this report was also sent

Please identify to what other regulatory authorities, such as the FDA (US), MHRA (UK), this report was also sent.

II. CLINICAL EVENT INFORMATION

1. Event Description

Clarification or relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in the report. E.g. "the patient was confused prior to becoming trapped in the bedsides", "the patient was a very low birth weight premature delivery and had a central line placed three days before onset of cardiac tamponade", "the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event", etc.

2. No. of affected people

Please include any affected individual, e.g. user, patient, or third party.

3. No of devices

Please state the number of devices involved in this event.

III HEALTHCARE FACILITY INFORMATION

Please provide information about the place of the event. It could include home care, transport or emergency care site. Information in this section is **optional.**

IV. DEVICE INFORMAITON

1-13. Device information:

Please provide information on the device involved. Please repeat this section for each device in separate sheets.

14. Operator of device at the time of the event

Please indicate the type of operator of the device at the time of the event. “None” means that the problem is noted prior to use.

15. Usage of Device

Please indicate the usage of the device involved

16. Device Disposition / Current Location:

Please provide information on whether and in what state the device is at the time of the report, e.g. “the device has been destroyed”; “the device remains implanted in patient”, “the device was returned to the manufacturer”, the device remains under investigation”, etc.

V. RESULTS OF MANUFACTURER’S INVESTIGATION

1. Manufacturer’s Device Analysis Results:

Specify, for this event, details of investigation methods, results and conclusions.

Alternatively, manufacturer’s device analysis report may be submitted.

2. Remedial Action / Corrective Action/ Preventive Action

Specify if action was taken by manufacturer or AR for the reported specific event or for all similar types of products. Include what action was taken by the manufacturer or AR to prevent recurrence. Clarify the timeframes for completion of various action plans.

VI. INFORMATION OF PATIENT (OPTIONAL)

Please provide individual patient information (including information of any affected individual, e.g. user, patient, or third party) for each element as appropriate. Please repeat this section for each patient involved in separate sheets.

Please note that in some cases, the patient’s age, gender and weight might be irrelevant. In some cases, they are essential, e.g. the age and weight of the patient in regards to some implants.

Some events are caused by the combined action of two or more devices, medical or non-medical. Please provide a brief list of devices involved.

Information in this section is **optional**.

VII. OTHER REPORTING INFORMATION (OPTIONAL)

If the manufacturer or the AR is aware of similar events with this device with the same root cause, please provide the number of such events. The number should be specified in terms of event per unit sold, or the number of event per unit sold / in use in a region, etc.

Information in this section is optional, and is applicable for **final reports** only.

VIII. COMMENTS

Please provide any additional details that are relevant and not requested elsewhere in this report.