

醫療儀器的規管

Regulation of
Medical Devices

**Guidance Notes for
Adverse Incident Reporting by Local Responsible Persons**

Guidance Notes: GN-03 (2005 Edition)



中華人民共和國

香港特別行政區政府衛生署

Department of Health

Government of the Hong Kong Special Administrative Region

The People's Republic of China

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1. Introduction

- 1.1 The purpose of this booklet is to assist Local Responsible Persons (LRP) in understanding and complying with the adverse incident reporting requirements under the Medical Device Administrative Control System (MDACS).
- 1.2 The objective of the Adverse Incident Reporting System is to improve the protection of health and safety of patients, users and others by disseminating information that may reduce the likelihood of, or prevent repetition of adverse incidents associated with medical devices, or alleviate consequences of such repetition.
- 1.3 Under the MDACS, the LRPs are required, among other things, to report and manage adverse incidents happening in Hong Kong concerning their listed medical devices (section 4.4.8 of the Guidance Notes GN-01). This booklet provides guidance on the types of adverse incidents that should be reported by the LRPs to the Medical Device Control Office (MDCO) and the timescales for reporting respective types of adverse incidents.

2. Scope

- 2.1 The LRPs are required to report adverse incidents occurring in Hong Kong with regard to their listed medical devices under the MDACS (please refer to section 4.4.8 of the Guidance Notes GN-01). Incidents occurring outside Hong Kong do not need to be reported.
- 2.2 Notwithstanding section 2.1, if adverse incidents that occur outside Hong Kong lead to corrective or preventive actions relevant to listed medical devices (i.e. safety alerts/recalls either initiated voluntarily by the manufacturer or requested by a regulatory authority), the LRP must notify the MDCO of the related details and actions to be taken in Hong Kong as soon as possible but not later than 10 elapsed calendar days after the manufacturer has initiated the actions. The notification should provide but not be limited to the following information:
 - 2.2.1 a description of the medical device, the make and model designation,
 - 2.2.2 the serial numbers or other identification (for instance batch or lot numbers) of the medical devices concerned,
 - 2.2.3 the actions to be taken and the reasons,
 - 2.2.4 the distribution volume of the concerned medical device in Hong Kong and the distribution list (if such information is available),
 - 2.2.5 the contact details of personnel responsible for corrective action in Hong Kong, which should include those for the MDCO and those for the general public,
 - 2.2.6 any advice regarding possible hazards, and
 - 2.2.7 any consequent actions to be taken

3. Definitions and Abbreviations

For the purposes of this booklet, the definitions and abbreviations given in Section 2 of the Guidance Notes GN-01 and the following apply.

- 3.1 **Abnormal use** means intended act or intended omission of an act by the user or operator of medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Some examples of abnormal use are provided below:

- Deliberate failure to conduct device checks prior to each use as provided in the device labelling
 - Filter removed and intentionally not replaced despite clear warnings in the device labelling, resulting in particulate contamination and subsequent device failure
 - The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours in duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bleeds to death
 - Alarm is intentionally disabled, preventing detection of risk condition
- 3.2 **Serious injury** (also known as serious deterioration in state of health) means either:
- 3.2.1 Life threatening illness or injury;
 - 3.2.2 Permanent impairment of a body function or permanent damage to a body structure;
 - 3.2.3 A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
- 3.3 **Serious public health concern** means any incident type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action to prevent significant risk of substantial harm to the public.
- 3.4 **Service life of a device** means the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified by the manufacturer.
- 3.5 **Use error** means act or omission of an act that has a different result to that intended by the manufacturer or expected by the operator. Some examples of use error are provided below:
- Operator misinterprets the icon and selects the wrong function
 - Operator fails to detect a dangerous increase in heart rate because the alarm limit is mistakenly set too high and operator is over-reliant on alarm system
 - Operator cracks catheter connector when tightening

4. Adverse Incidents to be Reported under the MDACS

- 4.1 Any incident that meets all of the following three basic reporting criteria is considered a reportable adverse incident and should be reported to the MDCO within the timeframe of respective incident (please refer to section 6). Examples are given in Appendix 1:
- 4.1.1 The LRP becomes aware of information regarding an incident that has occurred with his listed device(s).
 - 4.1.2 The LRP's device is associated with the incident. In assessing the link between the device and the incident, the LRP should take into account:
 - The opinion, based on available information, from a healthcare professional;
 - Information concerning previous, similar incidents;

- Other information held by the LRP or the manufacturer.
- 4.1.3 The incident led to one of the following outcomes:
- Death of a patient, user or other person;
 - Serious injury of a patient, user or other person;
 - No death or serious injury occurred but the incident might lead to death or serious injury of a patient, user or other person if the incident recurs.
- 4.2 Use errors meeting any of the following criteria are also reportable:
- 4.2.1 Use error that results in death or serious injury / serious public health concern.
- 4.2.2 When the LRP 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.
- 4.2.3 When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.
- 4.3 If the LRP is not certain whether an adverse incident is reportable, he must submit a report to the MDCO within the timeframe required for that type of incident (please refer to section 6 regarding the timeframes for reporting).

5. Incidents Exempt from Reporting under the MDACS

- 5.1 Whenever any of the following exemption rules is met, the adverse incident does not need to be reported. Explanations of the exemption rules can be found in Appendix 2:
- 5.1.1 Deficiency of a new device found by the user prior to its use
 - 5.1.2 Adverse incident caused by patient conditions
 - 5.1.3 Use of a medical device beyond its service life
 - 5.1.4 Protection against a fault functioned correctly and where no death or serious injury occurs
 - 5.1.5 Remote likelihood of occurrence of death or serious injury
 - 5.1.6 Expected and foreseeable side effects
 - 5.1.7 Adverse incidents described in an advisory notice previously sent to users, and where no serious injury or death occurs
 - 5.1.8 Adverse incidents caused by use errors other than those specified in section 4.2
 - 5.1.9 Adverse incidents caused by abnormal use of medical devices
- 5.2 Notwithstanding the exemption criteria in Section 5.1, all adverse incidents involving issues of serious public health concern should be reported to the MDCO.
- 5.3 Similarly, those incidents that are subject to an exemption (Section 5.1) become reportable if a change in trend (usually an increase in frequency) or pattern is identified. Please refer to GHTF document of ref.: SG2/N36R7:2003 for guidance on trend reporting of adverse incidents.

6. Timeframes for Submitting Adverse Incident Reports

- 6.1 Adverse incidents that result in death or serious injury or of a serious public health concern must be reported by the LRP to the MDCO as soon as possible, but not later than 10 elapsed calendar days after the LRP becomes aware of the incident.

- 6.2 All other reportable adverse incidents must be reported by the LRP to the MDCO as soon as possible, but not later than 30 elapsed calendar days after the LRP becomes aware of the incident.
- 6.3 The LRP must submit a report to the MDCO with as much information as possible within the required timeframe. Incomplete information is not an excuse for not meeting this requirement.

7. Means of Reporting Adverse Incidents

The Medical Device Adverse Incident Report Form AIR-LRP (Appendix 3) should be used by the LRP to report adverse incidents that have taken place in Hong Kong. This form is also available on the MDCO website at <http://www.mdco.gov.hk>. Alternatively, the on-line reporting on the MDCO website may be used.

8. Important Points to Note

- 8.1 Submission of an adverse incident report does not constitute an admission of manufacturer, LRP, user, or patient liability for the incident and its consequences. It does not, in itself, represent a conclusion by the LRP 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 incident.
- 8.2 The reporting requirements are conditions for the listing of medical devices under the MDACS (section 4.4.8 of the Guidance Notes GN-01). Failure to comply with the requirements of the MDACS may lead to permanent or temporary delisting of the concerned medical devices (section 5.11(a) of the Guidance Notes GN-01).
- 8.3 The LRP may wish to have access to the medical device involved in the adverse incident to help in the investigation. Such access would be at the sole discretion of the user or owner of the medical device.
- 8.4 The LRP may wish to contact the MDCO immediately after becoming aware of adverse incidents that may present serious public health concerns. In this case the LRP should use the telephone and facsimile numbers in section 9 to contact the MDCO within office hours. Outside office hours, the LRP should contact the Duty Officer of the Department of Health by calling 7116 3300 and asking for no. 9178.

9. Enquiries

Enquiries concerning this booklet and the Adverse Incident Reporting System should be directed to:

Medical Device Control Office,
Department of Health,
~~18/F, Wu Chung House~~ Rm 3101, 31/F, Hopewell Centre,
~~213 Queen's Road East~~ 183 Queen's Road East,
Wanchai, Hong Kong
Facsimile number: 3157 1286
Telephone number: ~~2961 8788~~ 3107 8484
E-mail address: mdco@dh.gov.hk

Latest versions of the Guidance Notes for the MDACS and the application forms for listing are available at the website: <http://www.mdco.gov.hk>

10. References

- [1] Global Harmonization Task Force. Adverse Incident Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative. Final Document SG2/N21R8. <http://www.ghtf.org> accessed on 28 February 2005.
- [2] Global Harmonization Task Force. Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative. Final Document SG2/N31R8. <http://www.ghtf.org> accessed on 28 February 2005.
- [3] Global Harmonization Task Force. Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Incident Reports. Final Document SG2/N33R11. <http://www.ghtf.org> accessed on 28 February 2005.
- [4] Global Harmonization Task Force. Manufacturer's Trend Reporting of Adverse Incidents. Final Document SG2/N36R7. <http://www.ghtf.org> accessed on 28 February 2005.

Examples of Reportable Adverse Incidents

The following examples of reportable adverse incidents are extracted from the GHTF document of ref. SG2/N21R8:1999:

1. 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.
2. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer's instructions.
3. 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.
4. Sterile single use device packaging is labelled 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.
5. 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.
6. Premature revision of an orthopedic implant due to loosening. No cause yet determined.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.
14. Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.
15. 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.
16. 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.
17. Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

Explanations and Examples of Exemption Rules

I. 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 manufacturer, deficiencies of devices that would normally be detected by the user and where no death or serious injury has occurred, do not need to be reported.

Examples of non-reportable adverse incidents:

- (i) 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.
- (ii) Sterile single use device packaging is labeled with the caution '*do not use if package is opened or damaged*'. Open package seals are discovered prior to use, device is not used.
- (iii) 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.

II. Adverse incident caused by patient conditions.

If information is available that the root cause of the adverse incident is due to patient condition, the incident does not need to be reported. These conditions could be preexisting or occurring during device use.

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

Examples of non-reportable adverse incidents:

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

III. Use of a medical device beyond its service life

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

Note: 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). Reporting assessment must be based on the information in the master record or IFU.

Examples of non-reportable adverse incidents

- (i) 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 required.
- (ii) A drill bit was used beyond end of specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.

IV. Protection against a fault functioned correctly and where no death or serious injury occurs

Adverse incidents that 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 adverse incidents:

- (i) 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.
- (ii) 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.
- (iii) 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.

V. Remote likelihood of occurrence of death or serious injury

Adverse incidents that 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.

Note: If an adverse incident resulting in death or serious injury occurs, the adverse incident 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 change in trend of these non-serious outcomes must be reported, as specified in section 5.3.

Examples of non-reportable adverse incidents:

- (i) 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.
- (ii) 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 have been reported. Chance of infection or blood loss has been reevaluated by manufacturer and deemed remote.

VI. Expected and foreseeable side effects

Side effects that are clearly identified in the labelling or are 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.

Note: Some of these incidents are well known in the medical, scientific, or technology field; others may have been clearly identified during clinical investigation and provided in the labelling. Documentation, including risk assessment, for the particular side effect should be available in the device master record prior to the occurrence of adverse incidents: it cannot be concluded in the face of incidents that they are foreseeable unless there is prior supporting information.

Examples of non-reportable adverse incidents:

- (i) A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
- (ii) A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device master record.

- (iii) Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.
- (iv) Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.

VII. Adverse incidents described in an advisory notice previously sent to users, and where no serious injury or death occurs

Adverse incidents that occur after the LRP has issued an advisory notice need not be reported individually if these are specified in the notice and have not caused any serious injury or death. The notice should have been previously sent to users and submitted to the MDCO prior to the occurrence of adverse incidents.

Examples of non-reportable adverse incidents:

- (i) Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration did not have to be reported if they did not cause any serious injury or death.

VIII. Adverse incidents caused by user errors other than those specified in section 4.2

Errors in the use of medical devices can be divided into two distinct groups: use error and abnormal use. Not all incidents caused by such errors are reportable incidents. Only those caused by use error and meeting any of the criteria specified in section 4.2 must be reported. However, all of them must be evaluated within the manufacturer's quality system and the results documented and kept by the manufacturer and the LRP.

Examples of non-reportable adverse incidents:

- (i) Operator enters incorrect sequence and fails to initiate infusion. The device labelling is consulted and the correct sequence entered. The infusion starts. Patient is not injured.

IX. Adverse incidents caused by abnormal use of medical devices

Adverse incidents caused by abnormal use need not be reported under the MDACS. If the LRP becomes aware of abnormal use, they may bring this to the attention of appropriate organizations and healthcare facility personnel.

Examples of non-reportable adverse incidents:

- (i) Contrary to the instructions for use, the device was not sterilized prior to implantation.