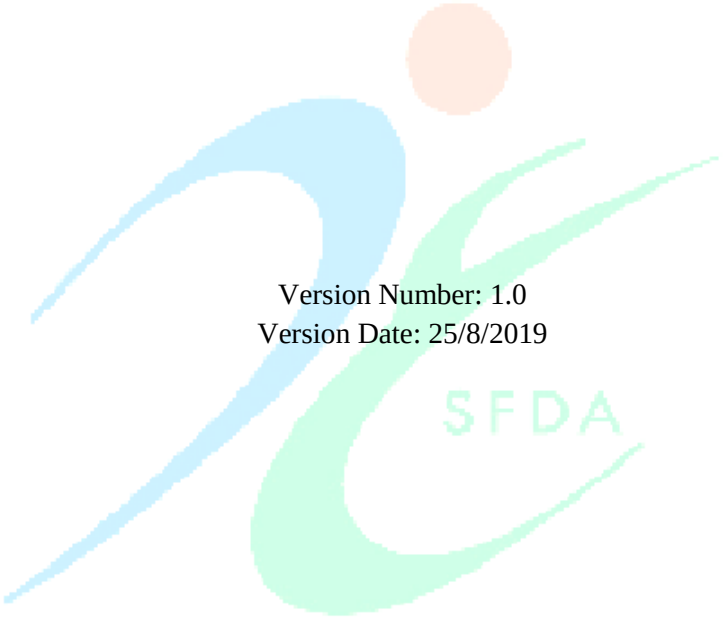
MDS-G39

Guidance on Requirements for Reporting of Incident and Adverse Event of Medical Devices



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Introduction

Purpose

The purpose of this guidance is to specifiy and clarify the requirements for incidents and adverse events reporting to the SFDA that occur:

- within the KSA and associated with medical devices placed on the KSA market.
- outside the KSA, and has potential consequences for a medical device that placed on the KSA market.

Scope

This guidance applies to medical devices manufacturers, authorized representatives and healthcare providers.

Background

SFDA/MDS has issued this guidance document in reference to the following articles of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by decree No. (4-16-1439) dated 27/12/2017:

- Article Nineteen, that requires from manufacturer or its authorized representative to report to the SFDA's National Centre for Medical Device Reporting (NCMDR), any relevant adverse event of which it becomes aware, that involves the medical device placed on the market of the KSA.
- Article Thirty Four, that requires from SFDA to institute and maintain a web-based National Centre for Medical Device Reporting (NCMDR) to encourage the reporting of adverse events by medical device institutions and users, manufacturers, authorized representatives and organizations involved in supplying medical devices to the KSA.

The objective of the incident and 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.

Requirements

General		Manufacturers or thier AR shall report to the SFDA any relevant incident or adverse event, of which it becomes aware, that occures: - within the KSA and involves a medical device placed on the market of the KSA, or - outside the KSA and has potential consequences for a medical device placed on the ksa market.
Manufacturers and ARs Reporting		Manufacturers or thier AR shall report to the SFDA, upon becoming aware that an incident or adverse event has occurred, as following: - not later than (2) calendar days if the the incident or dverse event represents a serious public health threat. - immediately, not later than (10) calendar days for the incident or dverse event that result in unanticipated death or unanticipated serious injury. - not later than (30) calendar days for all other incident and adverse events. and submit documents specified in "Required Documents" section through one of the following: - National Centre for Medical Device Reporting (NCMDR) - Saudi Vigilance System - Email <ncmdr.md@sfda.gov.sa> - Email <ae.md@sfda.gov.sa>
Healthcare Providers Reporting		Healthcare providers should report to the SFDA any incident or adverse event is associated with medical devices occures within their facilities. The report may be submitted through one of the following: - National Centre for Medical Device Reporting (NCMDR) - Saudi Vigilance System - Email <ncmdr.md@sfda.gov.sa> - Email <ae.md@sfda.gov.sa>

Required Documents

	Required Documents	Note
	A. Required Documents for Incident and Adverse Events that are Occur Inside the KSA and Involve the Medical Device Placed on the Market of the KSA	
1	Initial Report	– The choice of report type depends on whether all the applicable data is available within the appropriate report time. For example, a final report may be the first report if the information is complete. – Initial Report is defined as the first sumitted information about the adverse event – Follow-up Report is defined as a report that provides supplementary information about the adverse event that was not previously available – Final Report is defined as the last submitted report about the the adverse event.
2	Follow-up Report	
3	Final Report	
	B. Required Documents for Incidents and Adverse Events Occur Outside the KSA and has Potential Consequences for a Medical Device Placed on the KSA Market	
	All available details on the medical device concerned and the measures taken	
	Field Safety Corrective Action	– If applicable

Annexes

Annex (1): Examples of Incidents and Adverse Events

A. General Examples:

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 strip 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.
14. Unprotected ECG cable plugged into the main electricity supply – patient died.
15. Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.

16. 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.
17. 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.
18. Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

B. Examples for Potential Use Errors

Complaint reports received of incidents and adverse events occurring despite adequate instructions and design according to manufacturer's analysis. Examples include the following:

1. User presses the wrong button.
2. User misinterprets the icon and selects the wrong function.
3. User enters incorrect sequence and fails to initiate infusion.
4. User fails to detect a dangerous increase in heart rate because they have set the alarm limit too high and user is over-reliant on the device's alarm system.
5. User cracks catheter connector when tightening.
6. A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labelling, marking, and product warnings provided with the pump. Some pumps are found to have cracked owing to inadvertent cleaning with alcohol.
7. Unintentional use of pipette out of calibration range.
8. Analyzer placed in direct sunlight causing higher reaction temperature than specified.
9. MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

C. Examples for Potential Abnormal Uses

Potential abnormal uses include complaint reports received of incidents and adverse events occurring despite proper instructions; proper design; or proper training, and are, according to manufacturer's analysis, determined to be beyond any reasonable means of the manufacturer's risk control. Examples include the following:

1. Use of a medical device during installation, prior to completing all initial performance checks as specified by the manufacturer.
2. Failure to conduct device checks prior to each use as defined by the manufacturer.
3. Continued use of a medical device beyond the manufacturer-defined, planned maintenance interval as a result of user's failure to arrange for maintenance.
4. Pacemaker showed no output after use of electrocautery device on the patient, despite appropriate warnings.

5. Product analysis showed that the device was working in accordance with specifications; further investigation revealed that the user was inadequately trained due to failure to obtain proper training.
6. During the placement of a pacemaker lead, an inexperienced physician or other non-qualified individual perforates the heart.
7. The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours 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 bled to death.
8. Safety interlock on a medical laser removed by the user.
9. Filter removed, and intentionally not replaced, resulting in particulate contamination and subsequent device failure.
10. Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
11. Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
12. Pacemaker-dependent patient placed in a MRI system with the knowledge of the physician.
13. Ventilator alarm is disabled, preventing detection of risk condition.

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: ○ Diagnosis, prevention, monitoring, treatment or alleviation of disease, ○ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, ○ Investigation, replacement, modification, or support of the anatomy or of a physiological process, ○ Supporting or sustaining life, ○ Control of conception, ○ Disinfection of medical devices, ○ Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro Medical Devices	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials,

	specimen receptacles, software and related instruments or apparatus or other articles
National Center for Medical Device Reporting (NCMDR)	an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Labeling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.
Incidents	malfunctions or deterioration in the safety, quality or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and undesirable side-effects.
Malfunction or Deterioration	a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.
Adverse Event	means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labeling or the instructions for use which may lead to compromise the health or safety of patients, users or third parties.
Abnormal Use	act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Note: Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.
Intended Purpose	the use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.
Serious Public Health Threat	any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action.
Unanticipated Death or Unanticipated Serious Injury	a death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must

	be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.
Use Error	act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use error includes slips, lapses, mistakes and reasonably foreseeable misuse.