MEDICAL DEVICES SECTOR

Guidance Document for Effective Operation & Maintenance of Medical Devices Based on the Life Cycle at Healthcare Facilities

Department of Surveillance & Biometrics
Our mission is to ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

SFDA

Our mission is to ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products.

Medical Devices
FOREWORD

Guidance document is a set of systematically developed standards or rules which assist in the decision about how to apply the policy or appropriate management of specific conditions to provide assistance to health care professionals on how to comply with governing statutes and regulations, Guidance documents also provide assistance to staff on how MD – SFDA mandates and objectives should be implemented in a manner that is fair consistent and effective.

This guidance document note does not address device performance per use, but rather procedures and practices that will help ensure that a medical device is operated, maintained and managed as recommended by the manufacturer to ensure that its performance will be maintained throughout its lifetime.

As a corollary to the above, it is equally important to note that MDS – SFDA reserves the right to request information or material, or define conditions not specially described in this document, in order to allow the sector to ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products.

MDS – SFDA is committed to ensuring that such requests are justifiable and that decisions are clearly documented.
Table of Contents

1. Introduction............................................................................................................................................. 6
   1.1 Aim..................................................................................................................................................... 7
   1.2 Scope.................................................................................................................................................. 7

2. Inspection process................................................................................................................................... 8
   2.1 Healthcare inspection process........................................................................................................... 9

   3.1 Medical Devices Life Cycle................................................................................................................. 10
   3.2 Purchase Stage...................................................................................................................................... 10
   3.3 Installation Stage................................................................................................................................. 13
      3.3.1 Prior to installation....................................................................................................................... 13
      3.3.2 Upon receipt.................................................................................................................................... 13
      3.3.3 After installation ............................................................................................................................ 14
   3.4 Acceptance stage ............................................................................................................................. 15
   3.5 Operation & usage stage..................................................................................................................... 16
   3.6 Maintenance and repair stage........................................................................................................... 17
   3.7 Device transfer and stage of medical devices within the healthcare facility........................... 19
      3.7.1 Permanent transfer ....................................................................................................................... 19
      3.7.2 Temporary transfer ....................................................................................................................... 20
      3.7.3 Storage of medical devices .......................................................................................................... 20
   3.8 Device calibration............................................................................................................................ 21

© Saudi Food and Drug Authority - Governmental Document
Page 4 of 54
3.9 Disposal stage ........................................................................................................... 21

4. Training ....................................................................................................................... 22

4.1 Technical personal training .................................................................................. 22

4.2 User training .......................................................................................................... 23

5. Reporting of Adverse Events .................................................................................. 23

5.1 NCMDR standard operating procedure ............................................................. 24

5.2 Healthcare providers- entering adverse event report ....................................... 25

5.2.1 Personal information ....................................................................................... 26

5.2.2 Device information .......................................................................................... 28

5.2.3 Event description ............................................................................................ 30

5.2.4 Viewing exciting adverse event report ......................................................... 31

6. Technical Inspection survey ..................................................................................... 33

Appendix A ................................................................................................................... 48
1. Introduction

- Medical devices play a crucial role in care and treatment. Effective operation and maintenance management of medical devices is so important to ensure safety of medical device and used as intended by the manufacturers. Education and training of users, and the continued assessment of medical devices in use is as important as product control.

- Patient safety is the most critical national and international health care challenge because of countless bad-practice events also related to biomedical technology management. To improve patient safety relating to biomedical instrumentations, Effective operation and maintenance management of medical devices can be considered efficient and effective tools.

- **The main objective of Surveillance medical devices at Operation places** is to reduce the risk of injury or unfavorable impact on patient care and also on operative staff. The possibility of preventing breakdowns and failures of medical technologies is guaranteed by the periodic check on their well-functioning. Gradual equipment deterioration without operation & maintenance management may bring the safety level below an acceptable level of manageable risk, also referred to the difficulties of reducing user injuries.

- Referring to the Surveillance tasks on the official order of SFDA system, article forty-fifth that mention the "SFDA shall monitor the obligation of healthcare facilities with international standards of safety performance for medical devices", because of that we prepared guidelines for effective operation and maintenance management of medical devices or system. This guidance note does not address device performance per use, but rather procedures and practices that will help ensure that a medical device is operated, maintained and managed as recommended by the manufacturer to ensure that its performance will be maintained throughout its lifetime.
1.1 Aim

The aim of this guidelines to help ensure that risks associated with the use of medical devices are minimized and that the medical devices are:

- suitable for its intended purpose;
- maintained in a safe and reliable condition;
- operated in accordance with the manufacturer’s instruction by users and professionals who have obtained and maintained the correct level of knowledge and competency necessary, disposed of appropriately at the end of its useful life.

1.2 Scope

During inspection, will audit requirements for complete lifecycle medical devices such as procurements, installation, maintenance, training, tagging, calibrations and disposal for medical devices.
This Guidance will apply to any medical device used as part of the routine care of patients, including health care organizations as a whole, divisions and departments within the health care organizations.

2. Inspection process

- **Scheduling**
  - Designate the healthcare facility that will be inspected based on the priority or date

- **Pre-inspection**
  - Assemble a team
  - Prepare checklist for inspection and other documents needed for inspection
  - Send a letter to healthcare facility for preparation

- **On-site inspection**
  - Initiate the inspection with opening meeting
  - Collect and verifying information by the checklist and interviews
  - Record the information
  - Generate the non-compliance finding
  - Conduct the closing meeting

- **Post-inspection**
  - Generate the final inspection result report
  - Verify the final result report by the department head
  - Record it in the data base
  - Send the final report to the healthcare facility
2.1 Healthcare inspection workflow

Scheduling  ➔  Pre-inspection  ➔  On-site inspection  ➔  Post-inspection

- Assign a team for on-site inspection
- Initiate the inspection with opening meeting
- Collect and verifying information by the checklist and interviews
- Conduct the closing meeting
- Accept the schedule date
- Yes
- Collect all needed documents
- Review the last inspection reports
- Yes
- Generate healthcare facility list for inspection
- No
- Selection for healthcare facility will be inspected based on the priority or date
- No
- Yes

No
3. Maintenance & Management Based On Device Life Cycle:

3.1 Medical Device Lifecycle

In general, the lifecycle consists the following main stages:

- Purchase Planning
- Installation
- Operation
- Maintenance
- Transfer and storage
- Device Calibration
- Disposal

3.2 Purchasing Stage

Purchase Workflow Stage

The Purchasing process is acknowledged as being a key factor in the ability to manage medical devices successfully.
a) This process will apply to any new devices that will be purchased.

b) These devices shall be evaluated against criteria listed in down Table.

   *A Selection Criteria Check List (i.e. Performance characteristics like accuracy, precision, sensitivity, specificity, Physical requirements, electrical, re-wiring, drains, plumbing, Full support from manufacturers in terms of training, installation, service and repair) will assist in purchasing the most appropriate piece of equipment to meet the departments needs, e.g. Cost, Manufacturer and Support, Availability, Model*

c) The evaluation and decision making shall be duty of clinical user, Clinical Engineer and other relevant parties.

d) The evaluation shall be documented and made readily available at later stages should the need arise.

e) Where medical devices requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Life Span of Device</strong></td>
<td>Devices with longer life span are usually constructed more rigidly and are more expensive.</td>
</tr>
<tr>
<td><strong>Electrical specification</strong></td>
<td>The frequency of medical devices shall be 60 Hertz. minimum safety standards of 3 wire AC line cord with hospital grade plug and the outlet shall be grounded.</td>
</tr>
<tr>
<td><strong>Guarantee / Warranty</strong></td>
<td>The terms and conditions are not always the same for every supplier, and the cost may reflect this differences.</td>
</tr>
<tr>
<td><strong>Service Support</strong></td>
<td>Availability of hot line and quick response time are usually very important factors but it can cost more. Are spares readily available? What is the history of service support and competency of personnel?</td>
</tr>
</tbody>
</table>
What about end of service support?

<table>
<thead>
<tr>
<th>Maintenance Requirements</th>
<th>Intervals between inspection, frequency and complexity of checks and calibration requirements. Maintenance requirements in terms of personnel, tools and methodology.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety and Reliability</td>
<td>Evaluation of device performance and safety characteristics. Experiences of other users are important source of information.</td>
</tr>
<tr>
<td>Fitness for intended purpose</td>
<td>The device must meet fully the user specifications, other extra features must be viewed from the user’s perspective since these can be either a bonus or a problem.</td>
</tr>
<tr>
<td>Training</td>
<td>The nature and requirements of user and technical training may differ from one manufacturer to another. Will there be advance training program?</td>
</tr>
<tr>
<td>Manuals and Device Documentation</td>
<td>The completeness of manuals and documentation is an important factor. There should be user manuals as well as service/repair manuals which come complete with circuit diagrams, trouble-shooting and repair procedures, parts lists, and special tools list. The language in the manuals and documentation should be one that is easily understood by users and technical personnel. (English language)</td>
</tr>
</tbody>
</table>

Table. Medical Device Selection Criteria
3.3 Installation Stage

**Installation Work Flow Stage**

3.3.1 Prior to installation:

Certain devices, especially those in the major and complex category, may require site preparation work that should comply with all relevant statutory requirements such as uniform building by-laws, Environmental Quality and regulations and/or Atomic Energy Licensing and regulations. This work shall be performed or supervised by competent person and other relevant parties.

3.3.2 Upon receipt:

a) Verify package contents and do not attempt to use prior to proper installation.

When the site and associated work such as shielding, gas piping, electrical wiring and switchgear, piling and concrete work, has been duly approved by relevant authority, the device should be properly installed, tested and commissioned by
manufacturer person or trained person. All testing and commissioning results shall be documented for safekeeping, verification, auditing or any other purposes.

b) Acceptance testing shall be done to meet the following requirement:
   ➢ It has been delivered complete and is in good condition without visible defects.
   ➢ It is in full working order and performs within the specification as specified by the manufacturer.
   ➢ It passes all relevant standard safety and performance test such as electrical safety and gas safety.
   ➢ Compliance to operating environment in accordance with manufacturer’s specification.
   ➢ Accessories function properly with the device as intended by the manufacturer.
   ➢ User instruction manuals, maintenance and repair manuals, circuit diagrams, and other relevant manuals are complete and in the language as defined in the purchasing documents. (as required by the competent authority).

c) The acceptance test shall be performed by competent person. The competent person performing or supervising the acceptance test shall be responsible and accountable for it.

3.3.3 After installation:

a) The result of acceptance test shall be documented for safekeeping, verification, auditing or any other purposes. This can be kept in the device logbook or device inventory list or management medical device program which shall be established and maintained. The device logbook or medical device program list shall contain at least the following information:
   ➢ Initial configuration
- Supplier
- Dates of initial delivery, handover & first use
- Inventory number
- Changes to the initial configuration
- Category of medical device
- Product identification
- Service support contact

b) Acceptance test is applicable to all categories of devices. Once the device has been successfully tested, appropriate tagging or marks shall be attached to the device in such a way that it is noticeable yet does not interfere in the operation of the device. The tag or mark shall follow consist of one or more of the following:
  - Validity dates
  - Calibration and scheduled maintenance

c) Appropriate training in the operation and handling of the device shall be provided to users and if need it appropriate training in service shall be provided to technical/ Clinical engineers.

3.4 Acceptance Stage

Acceptance Work Flow Stage
The process should only be carried out by designated authorized person, Clinical Engineer and approved by the associated department. Acceptance testing shall be carried out for all newly introduced equipment before it is placed into clinical service and shall include visual inspection, electrical safety test and performance test-as specified in IFU by competent person.

Tests carried out to ensure its safety and performance is in accordance with manufacturer’s specifications, purchase agreement, and statutory requirements.

Equipment should not be used until the acceptance process is completed satisfactory.

The payment should not pay until everything complete.

3.5 Operation & Usage Stage

Users should perform operational checks daily to ensure that the device is operating as intended by the manufacturer. Users are also expected to perform the necessary shut down procedure if relevant. Devices found to be not operating in the intended use it shall be appropriately marked, and prevent from use, and corrective action taken.
• Devices that broke down during operation shall be appropriately marked and send it for correction. Causes of failure shall be identified and documented.

• Users are responsible for routine maintenance of the medical devices. Routine maintenance includes regular cleaning, preparation for use and checking of device.

Records of installation and verification performed by the dept. or authorized person shall be maintained.

3.6 Maintenance and Repair Stage
• All planned preventive maintenance and repair, whether performed by in house unit or third party service provider or manufacturer’s servicing facilities shall follow manufacturer’s guidelines or procedures. Any proposed changes shall be approved by the manufacturer or it can be demonstrated that performance and safety is not affected by a competent body or competent authority.

• If applicable devices due for planned preventive maintenance or repair shall be appropriately marked and should be isolated in a predetermined area. If necessary the device must be cleaned and decontaminated following appropriate standard before releasing it for planned preventive maintenance or repair whatever relevant.

• Planned preventive maintenance and repair shall only be undertaken or supervised by competent person. Planned preventive maintenance and repair activities shall make references to manufacturer’s documents, manuals and diagrams including any latest revision.

• Planned preventive maintenance and repair activities shall utilize adequate and appropriate tools and any special tools as prescribed by the manufacturer.

• Planned preventive maintenance and repair activities shall use spare parts approved by the manufacturer or equivalent that does not compromise safety and performance criteria of the device. Spare parts inventory list shall be updated correspondingly.

• The competent person shall verify that devices that pass planned preventive maintenance checks have met performance and safety criteria according to standards and manufacturers’ specifications. The devices that fail planned preventive maintenance checks shall be marked for corrective action.

• Devices that have been repaired must, if relevant, be recalibrated, and undergo appropriate performance and safety testing and verified by competent person before releasing it for clinical use.
All planned preventive maintenance and repair works on the devices shall be appropriately documented in the device logbook or device inventory or management medical devices program list or appropriate records for safekeeping, verification, auditing or any other purposes.

Devices that are deemed beyond economic repair by the competent person shall be appropriately marked for disposal.

**Particular requirement for active implantable medical devices and implantable medical devices**

The healthcare facility shall record the identity of personnel performing any inspection, testing and servicing for patient tracking.

### 3.7 Device Transfer and Storage of Medical Devices within the healthcare Facility

#### 3.7.1 Permanent Transfer

- When a permanent transfer of a medical device is made, the relevant documentation should be completed and a copy sent to the associated dept.

- All the medical device management information and documentation relating to the operation, safety and functioning of the medical device should be transferred with the medical device.

- The new owner takes responsibility for the medical device management from the time of transfer
3.7.2 Temporary Transfer

• Any relevant medical device management information and documentation relating to the operation, safety and functioning of the device should either be transferred with the medical device or made available to the borrower.

• The lender and the borrower retain shared responsibility for the device and its management.

• The borrower should assess the medical device management requirements and ensure that it can be used safely and according to any statutory guidance and best practice recommendations.

3.7.3 Storage of Medical Devices

• All medical devices, reusable and single use or single patient devices and their accessories must be stored in appropriate conditions in line with the manufacturer’s instructions/best practice.

• All medical devices must be stored in a state of readiness for use unless this is contrary to the instructions/best practice.

• All special storage considerations must be taken into account when storing the device i.e.:
  ✓ Battery removal
  ✓ Battery charging
  ✓ Use by dates
  ✓ Service
  ✓ Inspection and calibration requirements & Data storage.
3.8 Device Calibration

- Calibration of devices, whether performed by in-house unit or third party service provider or manufacturer facilities, shall be performed by competent person in accordance with appropriate procedures using appropriate tools and equipment.
- Test equipment, simulators or analyzers for device calibration must be calibrated to traceable standards recognized and approved by competent authority yearly. Devices that have been calibrated shall be appropriately tagged and calibration certificate issued competent body. Records in the device logbook or management of medical devices program list shall be updated correspondingly. The validity date on the devices must be clearly indicated.

3.9 Disposal Stage

**Disposal Work Flow Stage**

- The device is deemed no longer serviceable and must be disposed when any of the following criteria applies:
  - ✔️ Damage beyond economic repair
Unreliable (check service history)
Clinical or technically obsolete
Spare part no longer available
More cost-effective or clinically effective devices have become available
Statutory requirement revision which may render a device obsolete

- Devices that are meant for disposal shall be appropriately prepared to comply with relevant statutory requirement.

- Records in the device logbook or management of medical devices program list shall be updated correspondingly.

4. Training

4.1 Technical Personnel Training

- Maintenance management of medical devices shall be carried out by technical personnel/Engineer who are qualified, competent and appropriately trained. The personnel shall have undergone at least the following training programs:

  ✓ Preventive Maintenance and Device Repair training.
  ✓ Theoretical and Hands-on training
  ✓ Training on use of device as intended by the manufacturer including aspect on safety.

- The personnel shall be certified to handle appropriate class or category of devices by competent body based on qualification, experience and training. Manufacturer’s training on the device or appropriate level of experience shall be a necessary criterion to handle maintenance of that device.
4.2 User Training

- Effective operation of medical devices can only be achieved when users are properly trained to operate and handle the device as intended by the manufacturer. To this effect, whenever a new medical device is handed over to users after acceptance testing, appropriate training shall be provided to them by the supplier or send them to the mother manufacture for training. The person providing the training must be competent and certified by the manufacturer to do so.

- When the device is already in operation, users who are new to the device are required to attend user training program before they are allowed to handle the device. This shall also apply to newer models of particular device since the newer models may have new features or properties not present in the older one. Training shall be provided by competent person or persons certified by the manufacturer to do so or person approved by competent body.

5. Reporting of adverse events

Any user (including home user) and facility must report adverse events to the SFDA and the Vendor/manufacturer.

- What is an adverse event report?
It is the report of any event that lead or might lead to undesired or unexpected issues regarding safety of patients, users, janitors or any other person. This may include the following:

- Problems with the design of the device
- Untrained or unaware staff
- Carelessness in use
- Uninstructed modifications
- Inadequate maintenance
- Inappropriate conditions: storage, temperature and use
5.1 NCMDR Standard Operating Procedure for healthcare facilities:

5.1.1 Healthcare facilities are encouraged to nominate an officer as a contact point with SFDA.

5.1.2 In case of death or serious injury; or near miss Healthcare facilities must submit adverse event reports mandatorily online through National Center for Medical Devices Reporting (NCMDR) website: http://mdprc.sfda.gov.sa

5.1.3 NCMDR staff advice healthcare facilities to reserve the scene of the event as occurred as much as possible.

5.1.4 After submission of adverse event report; an acknowledge of receipt with a confirmation code must be sent to the reporter through supplied electronic mail according to “Personal Information” in the submitted form.

5.1.5 The reporter will be able to track the report status with the given confirmation code.

5.1.6 NCMDR staff will contact the reporter after report submission to verify the data supplied.

5.1.7 The reporter has the right to remain unidentified to the manufacturer or sponsor of the reported device(s) unless indicated in the report in “May we identify you to the manufacturer and/or supplier of the device(s) involve?” according to “Personal Information”.

5.1.8 During the investigation, the reporter shall reserve the associate medical device and provide required information, samples and documentations voluntarily (but mandatorily in case of death or serious injury or near miss) including: affected device(s) if available, service reports, evaluation reports, communication letters with manufacturers or sponsors, sketches, photographs, copies of portions of operating manuals or disposable accessories involved in an incident.
5.1.9 After the investigation, NCMDR is authorized to ask the reporter to send any required information, samples and documentations voluntarily (but mandatorily in case of death or serious injury).

5.1.10 At the end of the investigation; a notification letter with the output of the adverse event report (based on NCMDR staff’s recommendations) will be sent to the reporter through supplied electronic mail according to “Personal Information” in the submitted form.

5.1.11 In case of invalid, false, misleading reports no investigation will be carried out by NCMDR staff, but reports will be documented in NCMDR. However, misleading reports will be treated seriously and will be forwarded to compliance& enforcement department.

5.1.12 In case of isolated events, known complications or use errors; no investigation will be carried out by NCMDR staff, but reports will be documented in NCMDR.

5.1.13 Recommendations may include that NCMDR requests manufacturer or sponsor to initiate a voluntary recall.

5.1.14 For reporting criteria, refer to Guideline: *Adverse Event Reporting Guidance for Medical Device : A guide for healthcare facilities.(Appendix A)*

5.2 Healthcare Providers – Entering Adverse event report

Medical-device adverse event reports can be entered by healthcare providers. These users are unregistered. The Adverse event report entry page can be accessed by either clicking on the “Click here to report a device adverse event” link on the public home page or clicking on “Adverse event report” on the top menu bar.

After all three sections of the Adverse event report have been completed, click “Submit to SFDA” button at the bottom of the page. This will enter the item into the system for investigation as well as automatically send an e-mail to the reporter with the Confirmation Code and a link to access the Adverse event report.

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Page 25 of 54
5.2.1 Personal Information

The Personal Information section (Figure) allows the adverse event reporter to enter identifying information to allow NCMDR personal to contact the reporter if necessary. All fields marked with a red asterisks (*) are required.
Report Devices Adverse Event

Personal Information

Your personal and organization identities will not be revealed in any way without your permission.

Title: 
First Name: 
Last Name: 
Organization: 
Department: 
Address: 
City: 
State or Province: 
Postal Code: 
Phone: 
Fax: 
Email: 
Website URL: 
May we identify you to the manufacturer and/or supplier of the device(s) involved?: Yes [ ] No [ ]

Devices Information

Please be as specific as possible in identifying the devices involved. Please add any other information that might be helpful, and omit items that are not known or that appear to be irrelevant to this particular problem.

Type(s) of device(s) involved: 
Manufacturer: 
Local Supplier/Distributor: 
Model: 

(Figure.1): Adverse event report Personal Information

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Optional</td>
<td>Your title within your organization</td>
</tr>
</tbody>
</table>

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Page 27 of 54
<table>
<thead>
<tr>
<th>Field</th>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Required</td>
<td>First name or given name</td>
</tr>
<tr>
<td>Last Name</td>
<td>Required</td>
<td>Last name or family name</td>
</tr>
<tr>
<td>Organization</td>
<td>Required</td>
<td>Name of your organization or company</td>
</tr>
<tr>
<td>Department</td>
<td>Optional</td>
<td>Your department within you organization</td>
</tr>
<tr>
<td>Address</td>
<td>Required</td>
<td>The address of your organization or company. Only the first line is required.</td>
</tr>
<tr>
<td>City</td>
<td>Required</td>
<td>The city where your organization is located</td>
</tr>
<tr>
<td>State or Province</td>
<td>Optional</td>
<td>State or province where your organization is located</td>
</tr>
<tr>
<td>Postal Code</td>
<td>Required</td>
<td>Postal code of your organization location</td>
</tr>
<tr>
<td>Phone</td>
<td>Required</td>
<td>Your phone number including extension if necessary</td>
</tr>
<tr>
<td>Fax</td>
<td>Optional</td>
<td>Fax number</td>
</tr>
<tr>
<td>Email</td>
<td>Required</td>
<td>Your email address</td>
</tr>
<tr>
<td>Website URL</td>
<td>Optional</td>
<td>The web site of your organization</td>
</tr>
<tr>
<td>May we identify…</td>
<td>Required</td>
<td>If this is checked Yes, then SFDA may identify you to the manufacturer and/or supplier during the process of the investigation. If No is checked, then you will not be identified. The default value is No.</td>
</tr>
</tbody>
</table>
5.2.2 Device Information

The Device Information section (Error! Reference source not found.) provides NCMDR information about the device that is involved in the event. All fields should be entered as completely as possible. All fields marked with a red asterisks (*) are required.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type(s) of device(s) involved</td>
<td>Required</td>
<td>The type of devices that were involved in the event.</td>
</tr>
<tr>
<td>Manufacture</td>
<td>Required</td>
<td>The manufacture of the device.</td>
</tr>
<tr>
<td>Local Supplier/Distributor</td>
<td>Required</td>
<td>The local supplier or distributor of the device</td>
</tr>
<tr>
<td>Serial/Lot No</td>
<td>Required</td>
<td>The serial number or lot number of the device</td>
</tr>
<tr>
<td>Expiration/Used Before Date</td>
<td>Optional</td>
<td>If the device is a single-use device, enter the expiration or Use Before Date</td>
</tr>
<tr>
<td>How long in use</td>
<td>Optional</td>
<td>Enter how long the device was in use. Ex.: 4 years 3 months</td>
</tr>
<tr>
<td>Condition</td>
<td>Optional</td>
<td>The condition of the device at the time of the incident. Ex.: Brand new</td>
</tr>
<tr>
<td>Date event occurred</td>
<td>Required</td>
<td>The date the event occurred (this should be enter in Common Era year)</td>
</tr>
<tr>
<td>Date last inspected or serviced</td>
<td>Optional</td>
<td>Date the device was last inspected or serviced</td>
</tr>
<tr>
<td>Where other devices involved?</td>
<td>Optional</td>
<td>If other devices were involved in the incident, check Yes and enter the devices in the box below. If there were no other devices involved, check No.</td>
</tr>
<tr>
<td>If yes, please describe</td>
<td>Optional</td>
<td>If there were other devices involved in the event, enter the devices here.</td>
</tr>
<tr>
<td>Is the device available for inspection?</td>
<td>Optional Check Yes if SFDA is able to inspect the device. Check No, if the device is unavailable for inspection.</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>If a single-use device was involved, …</td>
<td>Optional If the device is a single-use device, indicate if the device was reprocessed.</td>
<td></td>
</tr>
<tr>
<td>Are other units of the same model similarly affected?</td>
<td>Optional Indicate if you are experiencing similar event with other units of the same model.</td>
<td></td>
</tr>
</tbody>
</table>

5.2.3 Event Description

Please use the text box (Figure) to describe the hazard or event in detail. Include how it was discovered, any action you took, and the response of any suppliers or manufacturers. Please also mail or fax any related correspondence when possible. Sketches, photographs, or copies of portions of operating manuals are often helpful in describing the event, especially if the affected device is not available for examination at SFDA. Retain all disposable accessories involved in an incident. Please do not send any devices to SFDA until requested. All fields marked with a red asterisks (*) are required.
(Figure.3): Event Description

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome of the event</td>
<td>Optional</td>
<td>If the event resulted in death, injury, or near miss, check the appropriate button. Otherwise, please click Other and briefly describe the outcome in the box immediately below.</td>
</tr>
<tr>
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<td>Please enter details of the event. The more relevant details you provide, the quicker SFDA can assess the event.</td>
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5.2.4 Viewing Existing Adverse event report

Users can access previously entered Adverse event reports by clicking on the “Click here to view Adverse event report you already entered” link on the public home page and entering the Confirmation Code.
Additional information can be appended to the original description by entering additional information at the button of the page and clicking “Save Changes”. These changes do not alter information entered initially.

SFDA personal may modify the original text to conform to industry standard nomenclature. If this occurs, an icon ( jó ) will appear next to the modified fields. Hovering over the icon with the mouse will display the original text entered by the submitter.
6. Technical Inspection Survey

**PURCHASING STAGE**

- Healthcare facility shall ensure all new devices to be purchased or planned for purchasing shall be evaluated against certain criteria.
- Input from clinical personnel, clinical engineer, and other relevant parties should be sought in the decision making process.
- The evaluation shall be documented and made readily available at later stages should the need arise.

**How the standards will be identified?**
- Document Review
- Interview

**Interview Questions: (Examples)**
- Explain the purchasing stage for any medical devices? Review the documents that explain the process
- Who make selection for the medical devices?
- Do you have any evaluation documents?
- When did you request new medical devices

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ACCEPTANCE STAGE

- The process should only be carried out by designated authorized person and clinical engineer/technician approved by the associated department.
- Equipment should not be used until the acceptance process is completed satisfactory.

How the standards will be identified?
- Document Review
- Interview

Interview Questions: (Examples)
- Who make acceptance for the medical devices?
- Do you have acceptance form? Show it
- Explain the acceptance stage?

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INSTALLATION STAGE

Prior to installation:

- Healthcare facility shall check all the requirements for medical devices installation.
- This work shall be performed or supervised by competent person and other relevant parties.
Upon receipt:

- Verify package contents and do not attempt to use prior to proper installation.
- Tested and commissioned by manufacturer person or trained person (ACCORDING TO THE MANUFACTURE INSTRUCTION).
- All testing and commissioning results shall be documented.
- Acceptance testing shall be done to meet the following requirement:

  ✓ It has been delivered complete and is in good condition without visible defects.
  ✓ It is in full working order and performs within the specification as specified by the manufacturer.
  ✓ It passes all relevant standard safety and performance test such as electrical safety and gas safety.
  ✓ Compliance to operating environment in accordance with manufacturer’s specification.
  ✓ Accessories function properly with the device as intended by the manufacturer.
  ✓ User instruction manuals, maintenance and repair manuals, circuit diagrams, and other relevant manuals are complete and in the language as defined in the purchasing documents. (as required by the competent authority).
- The acceptance test shall be performed by competent person. The competent person performing or supervising the acceptance test shall be responsible and accountable for it.
After installation:

- The result of acceptance test shall be documented.
- The device logbook or medical devices management system shall contain at least the following information:
  - Initial configuration
  - Supplier
  - Dates of initial delivery, handover & first use
  - Inventory number
  - Changes to the initial configuration
  - Category of medical device
  - Product identification
  - Service support contact

- Once the device has been successfully tested, appropriate tagging or marks shall be attached to the device in such a way that it is noticeable yet does not interfere in the operation of the device.
- The tag or mark shall follow consist of one or more of the following:
  - Validity dates
  - Calibration and scheduled maintenance
- Appropriate training in the operation and handling of the device shall be provided to users and if need it appropriate training in service shall be provided to technical/ Clinical engineers.

How the standards will be identified?

- Document Review
- Interview

Interview Questions: (Examples)

- Who make the installation for the medical devices?
• Explain the installation stage?
• Ask for any installation document?
• What happen during installation stage?

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OPERATION STAGE

• Users should perform operational checks daily.
• Users are also expected to perform the necessary shut down procedure if relevant. Devices found to be not operating in the intended use it shall be appropriately marked, and prevent from use, and corrective action taken.
• Devices that broke down during operation shall be appropriately marked and send it for correction. Causes of failure shall be identified and documented.
• Users are responsible for routine maintenance of the medical devices. Routine maintenance includes regular cleaning, preparation for use and checking of device.
• Records of installation and verification performed by the dept. or authorized person shall be maintained
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**How the standards will be identified?**
- Document Review
- Interview

**Interview Questions: (Examples)**
- Explain your daily work?
- What do you do if there is a medical device not working?
- Did you get any training on the devices you work on it?
- Do you have records about daily check?
• All planned preventive maintenance and repair, whether performed by in-house unit or third party service provider or manufacturer’s servicing facilities, shall follow manufacturer’s guidelines or procedures. Any proposed changes shall be approved by the manufacturer or it can be demonstrated that performance and safety is not affected by a competent body or competent authority.

• Devices due for planned preventive maintenance or repair shall be appropriately marked and should be isolated in a predetermined area. If necessary the device must be cleaned and decontaminated following appropriate standard before releasing it for planned preventive maintenance or repair whatever relevant.

• Planned preventive maintenance and repair shall only be undertaken or supervised by competent person. Planned preventive maintenance and repair activities shall make references to manufacturer’s documents, manuals and diagrams including any latest revision.

• Planned preventive maintenance and repair activities shall utilize adequate and appropriate tools and any special tools as prescribed by the manufacturer.

• Planned preventive maintenance and repair activities shall use genuine spare parts approved by the manufacturer or equivalent or similar or better part that does not compromise safety and performance criteria of the device. The use of cannibalized spare parts shall not be permitted. Spare parts inventory list shall be updated correspondingly.

• The competent person shall verify that devices that pass planned preventive maintenance checks have met performance and safety criteria according to standards and manufacturers’ specifications. The devices that fail planned preventive maintenance checks shall be marked for corrective action.

• Devices that have been repaired must, if relevant, be recalibrated, and undergo appropriate performance and safety testing and verified by competent person before releasing it for clinical use.
• All planned preventive maintenance and repair works on the devices shall be appropriately documented in the device logbook or asset records or device inventory list or appropriate records for safekeeping, verification, auditing or any other purposes.

• Devices that are deemed beyond economic repair by the competent person shall be appropriately marked for disposal.

Particular requirement for active implantable medical devices and implantable medical devices

The organization shall record the identity of personnel performing any inspection, testing and servicing and for patient tracking.

How the standards will be identified?
- Document Review
- Interview

Interview Questions: (Examples)
- Do you have medical devices management system? Explain it
- How do you schedule the preventive maintenance for medical devices?
- Based on what you schedule the preventive maintenance for medical devices?
- Who will do the preventive maintenance for medical devices? Is he trained?
- How do you repair the medical devices?
- Do you have history for any medical device?
- Are your engineers/technicians trained? Show me

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**TRANSFER & STORAGE**

**Permanent Transfer**

- When a permanent transfer of a medical device is made, the relevant documentation should be completed and a copy sent to the associated dept.

- All the medical device management information and documentation relating to the operation, safety and functioning of the medical device should be transferred with the medical device.

- The new owner takes responsibility for the medical device management from the time of transfer.

**Temporary Transfer**

- Any relevant medical device management information and documentation relating to the operation, safety and functioning of the device should either be transferred with the medical device or made available to the borrower.

- The lender and the borrower retain shared responsibility for the device and its management.

- The borrower should assess the medical device management requirements and
ensure that it can be used safely and according to any statutory guidance and best practice recommendations.

Storage of Medical Devices

- All medical devices, reusable and single use or single patient devices and their accessories must be stored in appropriate conditions in line with the manufacturer’s instructions/best practice.

- All medical devices must be stored in a state of readiness for use unless this is contrary to the instructions/best practice.

- All special storage considerations must be taken into account when storing the device i.e.
  - Battery removal
  - Battery charging
  - Use by dates
  - Service
  - Inspection and calibration requirements & Data storage

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**Interview Questions:** (Examples)

- What do you do if there is permanent transfer?
- What do you do if there is temporary transfer?
- How do you store the medical devices?

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Page 43 of 54
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**DEVICE CALIBRATION STAGE**

- Calibration of devices, whether performed by in-house unit or third party service provider or manufacturer facilities, shall be performed by competent person in accordance with appropriate procedures using appropriate tools and equipment.
- Test equipment, simulators or analyzers for device calibration must be calibrated to traceable standards recognized and approved by competent authority. Calibration certificate issued by competent person or competent body. Records in the device logbook or asset records or device inventory list shall be updated correspondingly. The validity date on the devices must be clearly indicated.

**How the standards will be identified:**
- Document Review
- Interview

**Interview Questions (Examples):**
- Who calibrate the medical devices? When
- Who calibrate the test equipment? When
- Ask for any document for that calibration

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**DISPOSAL STAGE**

- The device is deemed no longer serviceable and must be disposed when any of the following criteria applies:
  - Damage beyond economic repair
  - Unreliable (check service history)
  - Clinical or technically obsolete
  - Spare part no longer available
  - More cost-effective or clinically effective devices have become available
  - Statutory requirement revision which may render a device obsolete

- Devices that are meant for disposal shall be appropriately prepared to comply with relevant statutory requirement.

- Records in the device logbook or asset records or device inventory list shall be updated correspondingly.

**How the standards will be identified?**
- Document Review
- Interview

**Interview Questions:(Examples)**
- When do you dispose the medical devices?
- Ask for disposal form
- Who make the disposal for medical devices
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**TRAINING STAGE**

**Technical Personnel Training**

- Maintenance management of medical devices shall be carried out by technical personnel who are qualified, competent and appropriately trained. The personnel shall have undergone at least the following training programs:
  - Preventive Maintenance and Device Repair training.
  - Theoretical and Hands-on training
  - Training on use of device as intended by the manufacturer including aspect on safety.

- The personnel shall be certified to handle appropriate class or category of devices by competent body based on qualification, experience and training. Manufacturer’s training on the device or appropriate level of experience shall be a necessary criterion to handle maintenance of that device.
### User Training

- Effective operation of medical devices can only be achieved when users are properly trained to operate and handle the device as intended by the manufacturer. To this effect, whenever a new medical device is handed over to users after acceptance testing, appropriate training shall be provided to them by the supplier or by sending them to the mother manufacture for training. The person providing the training must be competent and certified by the manufacturer to do so.

- When the device is already in operation, users who are new to the device are required to attend user training program before they are allowed to handle the device. This shall also apply to newer models of particular device since the newer models may have new features or properties not present in the older one. Training shall be provided by competent person or persons certified by the manufacturer to do so or person approved by competent body.

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**REPORTING OF ADVERSE EVENTS**

How the standards will be identified?
- Document Review
- Interview

**Interview Questions:**
How do you make an adverse event report?

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**Total Scoring**

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Appendix A

Adverse event reporting criteria for the NCMDR (Guidance for Healthcare Facilities)
Reporting Criteria

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. Thus, this document will explain what should be reported to SFDA.

The main criteria for submitting adverse event report to NCMDR are:

1. An Event has Occurred

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 on the labeling, in the instructions and/or in promotional materials.

b) An inadequate design or manufacture.

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

c) An inaccuracy in the labeling, instructions for use and/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 of significant and unexpected nature such that it becomes alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

e) Use Error

   o Use Error Resulting in Death or Serious Injury/ Serious Public Health Concern

Use error related to medical devices, which did result in death or serious injury or serious public health concern, should be reported to the SFDA.

   o Use errors becoming reportable

Use errors become reportable to the SFDA when you:

   - notes a change in trend (usually an increase in frequency), or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern.; or
   - initiates corrective action to prevent death or serious injury or serious public health concern.

2. The Event Led to One of the Following Outcomes:

   - Death of a Patient, User or Other Person.

   - Serious Injury of a Patient, User or Other Person.

Serious injury (also known as serious deterioration in state of health) is either:

   - Life threatening illness or injury.
- Permanent impairment of a body function or permanent damage to a body structure.
- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

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

The term “permanent” means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

Medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess the reportability of an event.

- 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.

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.

Include relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in this report.
Exemption Rules

Whenever exemption rules are met, the adverse event does not need to be reported to the SFDA.

1. Deficiency of a Device Found by the User prior to patient use

Deficiencies of devices that would always be detected by the user and where no serious injury has occurred do not need to be reported.

Based on the information stated, these are examples of non-reportable adverse events:

- User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. A malfunction on inflation is detected. Another balloon is used. Patient is not injured.
- Packaging of a sterile single use device is labeled with the caution ‘do not use if package is opened or damaged’ but damage to the packaging was obvious and discovered, and the device was not used.”

2. Adverse Event Caused by Patient Conditions

Due to a patient’s condition, the event does not need to be reported. These conditions could be preexisting or occurring during device use.

Examples of non-reportable adverse events:

- 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.
- The death of a patient that is unrelated to any implanted device or device used to treat the patient.

3. Service Life or shelf life of the Medical Device

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

The service life or shelf life must be specified by the device manufacturer in the medical device labeling or instructions for use. Service life or shelf life is defined as: the time or usage that a device is intended to remain functional after it is manufactured, placed into use, maintained as specified.

Examples of non-reportable adverse events:

- Loss of sensing after a pacemaker has reached its expected end of life as indicated in the instructions for use. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.
- Surgical glove was used after expiry date. User was exposed to infected blood due to glove failure.

4. Protection against a fault function Correctly

Adverse events which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard do not need to be reported. The protection against malfunction used needs to comply with relevant standards or documented design inputs for that type of device and take due account of technology and practice in existence. The risk has to be reduced to an acceptable level.

Examples of non-reportable adverse events:

- During radiation treatment, the automatic exposure control is engaged. Treatment stops. In accordance with the relevant standards the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

5. Negligible Likelihood of Occurrence of Death or Serious Injury

Adverse events which could lead, but have not yet led, to death or serious injury, but have a negligible 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.

Example of non-reportable adverse events:
- 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 negligible. No patients experienced adverse health effects.

6. Expected and Foreseeable Side Effects
Expected and foreseeable side effects which meet all the following criteria:
- clearly identified in the manufacturer's labeling;
- clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended;
- documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the adverse event; and
- clinically acceptable in terms of the patient benefit are ordinarily not reportable.

Examples of non-reportable adverse events
- A patient who is known to have claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured.
- 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.