Summary on Installation, Testing & Commissioning and Acceptance of Medical Device Guideline

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This guideline has been prepared under Medical Device Bureau Technical Committee, Ministry of Health Malaysia, with the intention to provide guidance to ensure the medical device is appropriately installed, tested and commissioned by the equipment specialists or competent personnel and accepted in accordance with manufacturer's specification, purchase agreement and statutory requirement.

The guideline applies to all products that fall within the definition of a medical device, as defined in Medical Device Act 737-2012 and applies to all medical devices which require installation, testing and commissioning (T&C) and acceptance in healthcare facility, aesthetic settings and premises for wellness programmes as well as related services.

PROCESS FLOW OF T&C AND ACCEPTANCE OF MEDICAL DEVICE

For a newly purchased medical device, the medical device establishment (i.e. vendor or supplier) shall be responsible for carrying out the installation and T&C of the medical device while the medical device owner (i.e. hospital, clinic, etc.) shall be responsible for the acceptance processes of the medical device.

Medical devices which are leased or on loan, trial evaluation and clinical investigation, transferred and undergone major upgrading, shall also be installed, tested and commissioned before use.

(Refer to flowchart Figure 1).

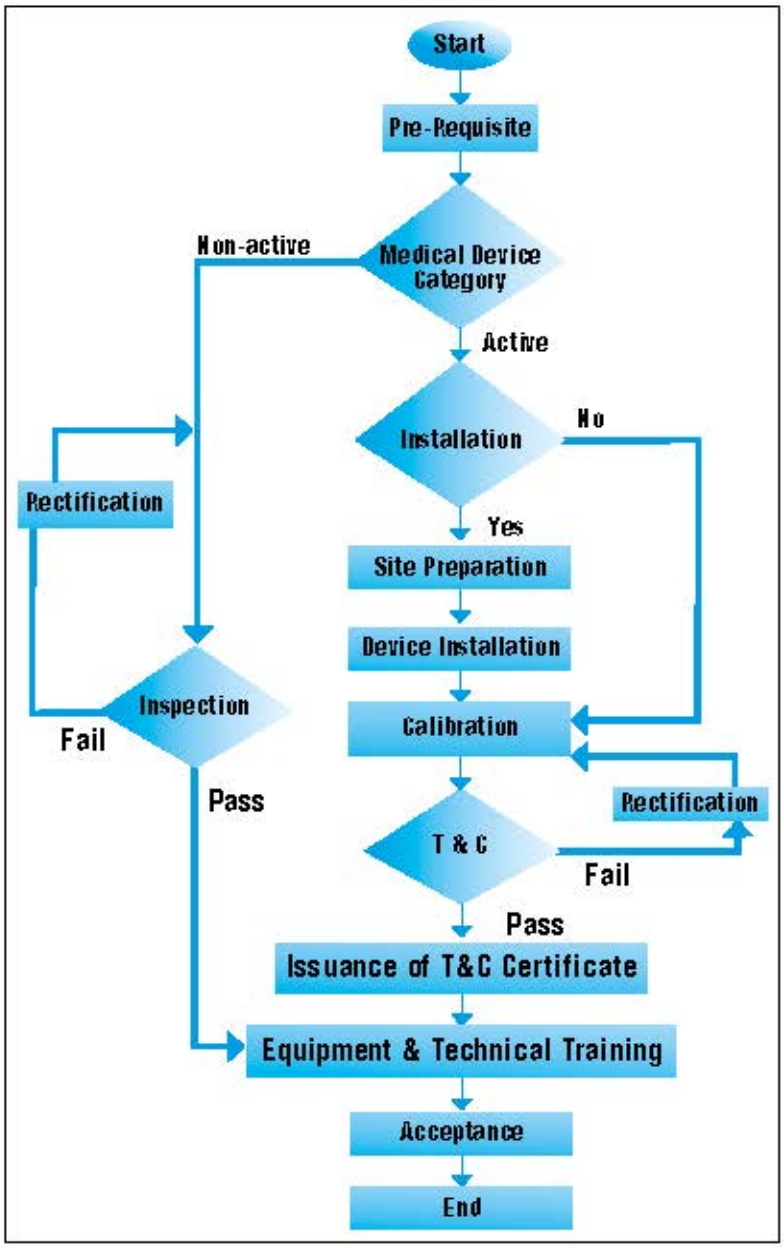

Figure 1: Flowchart of testing & commissioning and acceptance of medical device

PRE-REQUISITE

In any purchase of a new active medical device, documentation shall be made available to medical device owner by the medical device establishment prior to T&C. Example of documents are: Device registration certificate, Establishment Licence from Medical Device Authority (MDA), purchase agreement, relevant licences, test certificates, manuals (user/operation/service/maintenance) and build drawing of site and facility where relevant.

The medical device establishment shall provide written notification of any specific installation and T&C requirements to the medical device buyer.

Apart from new purchases, medical devices on lease, loan, trial evaluation, clinical investigation, transfers, donations and those that have undergone major upgrading, documentation shall also include maintenance history, a clear statement that the equipment is being resold or donated and proof of decontamination.

For a designated medical device, all drawings, safety requirements and installation plan shall be submitted for approval to the relevant regulatory authority. For management of radioactive source, the medical device owner shall refer to the medical device establishment and regulatory authority.

For non-active medical devices, only inspection, training and acceptance procedure are required.

MEDICAL DEVICE CATEGORY

Medical devices are categorised into active medical device and non-active medical devices. Active medical device refers to any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.

Medical devices intended to transmit energy, substance or other elements between an active medical device and the patient, without any significant change, is not considered active medical device.

INSTALLATION

a. For active medical device that requires installation

Installation usually applies when any of the following occurs:

1. Substantial assembly work will be required on-site;
2. There are dedicated plumbing, electrical and gas pipeline connections for the equipment
3. The device needs to be permanently fixed in place.

The medical device owner, with medical device establishment input or advice, shall ensure site preparation is in accordance to manufacturer and regulatory requirement. The medical device owner shall ensure that all technical drawings (medical device layout, mechanical and electrical, civil and structural) are submitted to the relevant authorities or departments for approval prior to installation.

Professional, competent technical personnel shall endorse the medical device installation layout. The medical device establishment shall install the medical device in accordance to the manufacturer's technical specification for installation work. All as-built drawings shall be made available and submitted to competent technical personnel of the medical device owner.

b. For active medical device which does not require installation

The medical device owner, with medical device establishment input or advice, shall perform a pre-check prior to T&C. The pre-check includes availability and sufficient utility such as medical gas, electrical supply (essential/non-essential), water supply, appropriate placement area i.e.; ventilation, humidity, room temperature.

SITE PREPARATION

a. Renovation

The medical device owner shall furnish the details of the renovation scope of work and a room data sheet recommended by medical device establishment. A room data sheet provides information on the minimum requirements for the room where the medical device is to be installed. The medical device owner shall prepare shop drawings that include:

1. Architectural drawings;
2. Structure drawing endorsed by the professional engineer if required
3. Layout and positioning details of the medical device and related systems as recommended by the establishment and local statutory and regulatory requirement and
4. Utilities details to support the installation of medical device and corresponding associated drawing.

Prior to installation, all shop drawings related to the installation of the medical device shall be verified by professional, competent technical personnel and agreed to by the medical device owner.

The medical device owner shall carry out the renovation and site preparation works according to the approved scope of work and shop drawings. Competent technical personnel shall supervise the renovation and site preparation works.

b. New building/ new building extension

If a new building or new extension building is to be constructed to accommodate the new medical device, the medical device owner shall appoint a team of consultants consisting of architects, civil and structural engineers, mechanical and electrical engineers, quantity surveyor and medical device planner. The consultants should be registered with their respective professional boards or other relevant bodies.

c. Mobile Healthcare Facilities

Mobile healthcare is a service that is provided on fixed routes and at a number of points, which are visited on a regular basis. Some visiting points may involve the use of a room in a building but the resources (equipment, stocks) are provided from the mobile when the service is available and are not maintained at the visiting point. The medical device

owner shall submit a technical report on the suitability of the proposed vehicle to the Road Transport Department.

The medical device owner shall prepare relevant document that includes drawings giving details of retrofitting works, layout and positioning details of the medical device and related systems, safety features and utilities details such as cold water supply, treated water supply, electrical supply, steam supply, medical gases and drain. The relevant authority shall approve all drawings.

The mobile medical device owner shall carry out the vehicle renovation and site preparation works according to the approved scope of work and drawings. Appointed consultants and competent technical personnel shall supervise the renovation/site preparation works.

DEVICE INSTALLATION

Site preparation works for the installation of the medical device shall be ready prior to installation. Competent technical personnel appointed by the medical device owner shall verify all relevant documents prior to device installation and ensure the facility is ready prior to installation. They will also ensure that the installation complies with the manufacturer's instructions and that all safety requirements are as required by the manufacturer and relevant authority. The medical device establishment shall ensure only equipment specialist(s) will carry out the installation.

CALIBRATION

The medical device establishment shall produce the manufacturer's calibration certificate or report for any medical device that does not require on-site calibration. The medical device establishment shall perform the calibration as per manufacturer's specification for any medical device that requires on-site calibration. A recognised and certified calibration laboratory shall do this for any medical device that requires certified calibration. The medical device establishment shall submit the calibration test report and calibration certificate of the medical device to the medical device owner. The medical device establishment shall rectify all faults that can cause calibration to fail and re-perform the calibration until it passes.

TESTING AND COMMISSIONING

The medical device owner shall verify that the medical device delivered is in good condition and complete, based on the purchase document. Physical evaluation or visual checks of the medical equipment include observations of chassis, mount/fasteners, castor/brakes, power cord, connectors, control/ switches, indicators/displays, accessories and labeling. T&C is best performed at the very location where the medical equipment will be placed for use.

The medical device establishment shall operate the medical device to ensure it is functional and ready to be tested. The competent technical personnel of the medical device owner shall ensure that all required documents are made available during T&C by the medical device establishment, such as a copy of delivery note (which specify separately between main system, subsystems, accessories and consumables), certificates, calibration report, manuals and backup copy of software, declaration of previous recalls/device alerts/end of life date, quality assurance, service engineer training certificate (manufacturer training), response time during warranty period and tentative date for equipment and technical training.

The medical device establishment is required to perform specific tasks during T&C on the medical device. These include confirmation of items delivered based on purchase document, validation of the specification/parameters using appropriate test equipment and all other relevant safety tests to the equipment which shall also be conducted and recorded accordingly.

The equipment specialist from the medical device establishment shall carry out performance and safety tests as required by the manufacturer, and witnessed by competent technical personnel.

A label indicating that the medical device has passed the electrical safety test, shall be affixed at a visible area on the device. All results shall be documented and the medical device establishment shall keep all documents according to retention period as specified by MDA. A copy is to be submitted to the medical device owner.

T&C shall be repeated upon rectification of all deficiencies by medical device establishment.

INSPECTION OF NON-ACTIVE MEDICAL DEVICE

The medical device owner accepting the device has the discretion to determine when and where the device should be inspected and sampled for conformance to specifications, depending upon the risk that failure of that device may pose. The non-active medical device shall be inspected by the medical device establishment, medical device owner (material/procurement warehouse) and medical device owner (user).

The medical device owner shall perform general acceptance inspection on random sampling basis for the non-active medical device against the purchase order. Inspection tasks shall include but not be limited to:

1. Checking and verifying that the product is exactly as ordered and corresponds with the delivery note
2. Verification of quantity, size, consumable items and accessories delivered as stated in the purchase agreement
3. Visual inspection of the device or equipment for physical damage, incompleteness, misassembling, void, wear and/ or abuse
4. Check relevant labelling on the device
5. Take note of batch number or lots in the event of a product recall
6. Contamination
7. Disseminate instructions and safety information when necessary.

Rejected medical devices shall be documented, rectified or replaced by the medical device establishment. The medical device establishment shall provide proof of compliance to the specification in purchase document and the medical device owner shall keep records of inspection.

ISSUANCE OF T&C CERTIFICATE

The medical device establishment shall issue a T&C certificate once the T&C process is successfully completed. The medical device establishment, medical device owner and competent technical personnel shall sign the T&C certificate.

TRAINING

EQUIPMENT TRAINING

The medical device establishment shall provide on-site, hands-on equipment training. The equipment training module shall include but not be limited to:

a) Safety precautions in operating the medical device
b) Proper operation/application
c) User maintenance
d) Cleanliness and decontamination
e) Operational verification procedures
f) Recognition and correction of common operational problems
g) Recognition of defective equipment and potential hazards
h) The risk associated with the device.

The medical device establishment shall issue a certificate of attendance to the user upon completion of the training.

TECHNICAL TRAINING

The medical device establishment shall conduct on-site technical training to the competent technical personnel of the medical device owner during and after the T&C. A certificate of attendance shall be issued upon completion of the training.

For the recognition of technical competency on that particular medical device, the medical device establishment shall offer detailed technical training according to maintenance competency level, with a reasonable fee. The medical device establishment shall issue a certificate of competency to the competent technical personnel upon completion of the training. The detailed technical training module shall include equipment training module and other module but not be limited to:

a) PPM according to manufacturers' specification
b) Maintenance competency as defined by MDA.

The medical device establishment shall issue a certificate of competency to the competent technical personnel upon completion of the training.

ACCEPTANCE

NON-ACTIVE MEDICAL DEVICE

Non-active medical device is accepted upon completion of successful inspection and training. The medical device establishment and medical device owner shall sign the records of acceptance.

ACTIVE MEDICAL DEVICE

Competent technical personnel shall perform the tasks that include, but not be limited to:

a) Ensuring the medical device is exactly as ordered and corresponds with the delivery note
b) Verifying the quantity, consumable item and accessories delivered as stated in the purchase agreement
c) Ensuring the equipment has successfully undergone performance and safety tests
d) Checking of relevant labelling on the device
e) Ensuring the medical device is delivered with a full set of documentation including user and operating manuals, spare parts list, schematic diagram, PPM manual and checklist as recommended by manufacturer.

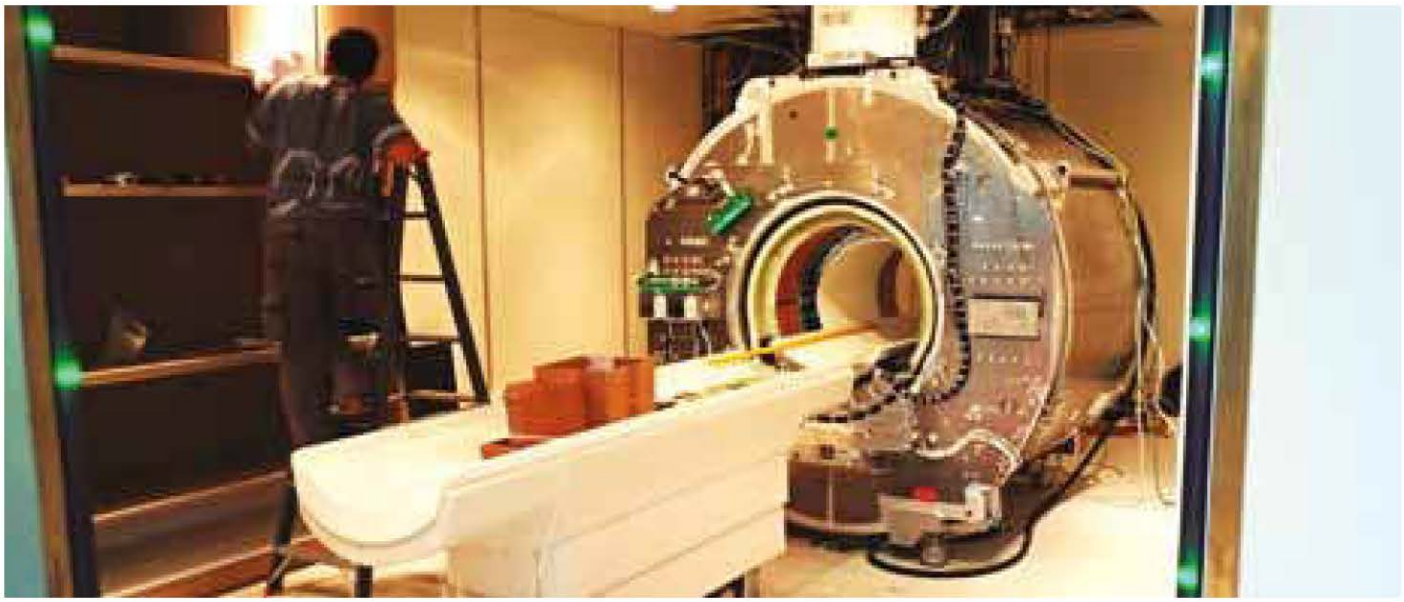

Figure 2: Magnetic Resonance Imaging (MRI) installation

validated T&C report and certificate, calibration certificate, training certificate and any other relevant document

f) Ensuring the medical device technical support information from the medical device establishment is submitted (address, person in-charge, telephone number, fax number, medical device registration number and any relevant information)

g) Ensuring the user and technical training on the medical device has been carried out.

Upon passing the acceptance testing, the medical device shall be labelled to indicate asset identification, warranty information, performance test pass label, electrical safety pass label (where applicable) and next PPM due date.

The medical device establishment shall issue an acceptance certificate once the acceptance process is successfully completed. The medical device establishment, medical device owner and competent technical personnel shall sign the certificate. The warranty period and PPM frequency (within the warranty period) shall be specified in the acceptance certificate.

CONCLUSION

This guideline aims to lay down the minimum installation, testing and commissioning and acceptance requirements to be carried out on all medical devices in Malaysia. ■

IEM DIARY OF EVENTS

Title: Talk on "Impact of Leadership and Teambuilding in Project Management"

7th March 2015

Organised by : Project Management Technical Division
Time : 5.30 p.m. – 7.30 p.m.
CPD/PDP : 2

Kindly note that the scheduled events below are subject to change. Please visit the IEM website at www.myiem.org.my for more information on the upcoming events.

Pengumuman yang ke-78

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Institusi mengucapkan terima kasih kepada semua yang telah memberikan sumbangan kepada tabung Bangunan Wisma IEM. Ahli-ahli IEM dan pembaca yang ingin memberikan sumbangan boleh berbuat demikian dengan memuat turun borang di laman web IEM http://www.iem.org.my atau menghubungi secretariat di +603-7968 4001/5518 untuk maklum,at lanjut. Senarai penyumbang untuk bulan Januari 2015 adalah seperti jadual di bawah:

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Thank you.

Chairman

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