

# COMPREHENSIVE GUIDE TO BEMS MONITORING PROGRAMS IN HEALTHCARE INSTITUTIONS

*Management and inspection of  
maintenance, testing and  
commissioning & disposal of  
Medical Devices.*

**28 & 29 August 2024**  
**Kuala Lumpur**



## Programme Objective



Establish a foundational understanding of regulatory requirements for medical devices in healthcare institutions.



Offer guidance on managing, monitoring, and inspecting hospital support services for medical devices, using WHO documentation and standards like IEC 62353:2014, MS2058:2019, MS2739:2021, and MS2650:2015.



Equip participants with the knowledge and tools for planning, executing, and reporting on maintenance, calibration, testing, commissioning, and disposal of medical devices.

## Speakers



**IR DR SASIKALA DEVI A/P  
THANGAVELU**

• Adjunct Professor & Consultant



**MRS NURMAZAINA MD ARIFFIN**

• Auditor, Medical Radiation  
Surveillance Division, MOH



**MR NASIR TALIB**

• Consultant



**MR IR GHANA SAKARAN A/L  
RAJAGOPAL**

• Auditor and consultant



**VIMALA RAGHAWAN**

• Health, Safety and Environment  
Consultant



# TOPICS

*Exclusive for technical personnel, managers, auditors, inspectors, and operation engineers from the Ministry of Health and Hospital Support Services(HSS) providers involved in the calibration, maintenance management, testing, commissioning, and inspection of medical devices in healthcare institutions.*



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## Regulatory compliance

- Medical Device Act 2012, Act 737
- Medical Device in Healthcare Institution, including Private Healthcare Act 586
- Atomic Energy Licensing Act, Act 304
- Occupational, Safety and Health Act, Act 514 Health & Safety in Healthcare Institution based on OSHA1994 & FMA1967
- Updates on WHO Medical Devices Technical Documentations

2

## Maintenance management of active medical device based on MS2058:2019 , International standards IEC 62353:2014 & WHO technical documents

3

## Management of installation, testing and commissioning, and acceptance of the medical device activities based on MS2739:2021, International standards & WHO technical documents

4

## Disposal management of medical devices based on in Healthcare Institutions, International standards & WHO technical documents and MS2650:2015

5

## Monitoring of BEMS & Implementation of QAP & KPI in MOH : Updates

6

## Case Study

- Monitoring and inspection of medical devices in healthcare institution
- Ventilator
  - Hemodialysis
  - X-Ray devices

## Training Duration : 2 days [28 & 29 August 2024]

This training program is suitable for technical personnel, managers, auditors, inspectors, and engineers from the Ministry of Health and hospital support service providers (HSS) who manage healthcare supportsuch as maintenance management, testing and commissioning of medical devices, and disposal of medical devices in healthcare institutions.

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HRDF CLAIMABLE & CPD POINTS AVAILABLE

RM1800  
RM900 ( MOH Employee)



# Training Schedule

## Day 1 : Regulatory compliance.

Basic understanding on the requirements of the Acts related to medical devices and activities in healthcare institution

Time	Topic	Speaker
9:00 – 9.45	Medical Device Act 2012(Act 737) <b>Synopsis of Topic:</b> Medical Devices in Healthcare Institutions: Ensuring Regulatory Compliance.	Dr. Ir. Sasikala
9.45-10.30	Atomic Energy Licensing Act 1984 (Act 304) <b>Synopsis of Topic:</b> Addressing Challenges and Ensuring Compliance Speaker:Ms. Nurmazaina Md Ariffin	Ms. Nurmazaina Md Ariffin
10.30-10.45	Tea break	
10.45-11.45	Health and Safety in Healthcare Institutions <b>Synopsis of Topic:</b> Adhering to the Occupational Safety and Health Act 1994 and Factories and Machinery Act 1967	Ms.Vimala
11.45-13.00	Effective Management and Monitoring of Medical Device Maintenance <b>Synopsis of Topic:</b> Adherence to MS 2058 and WHO Technical Guidelines	Dr. Ir. Sasikala
1300-1400	Lunch	
1400-1515	Comprehensive Management and Monitoring of Medical Device Installation, Testing, Commissioning, and Acceptance <b>Synopsis of Topic:</b> Adhering to MS 2739 and International Standards for Performance and Electrical Safety Testing Reports	Ir. Ghana
1515-15.30	Tea break	
15.30-16.30	Disposal Management of Medical Devices <b>Synopsis of Topic:</b> Adhering to MS 2650 and International Standards	Ir. Ghana
16.30-17.00	QUIZ	

# Training Schedule

## DAY 2 : Case Study: Monitoring and inspection of medical devices in healthcare Institution

Time	Topic	Speaker
9:00 – 10:00	Monitoring BEM Activities in Healthcare Institutions <b>Synopsis of Topic:</b> Latest MOH QAP & KPI Updates	MOH
10.00-10.15	Tea break	
	Case studies	
10.15-11.30	CASE STUDY 1 : X-Ray <b>Synopsis of Topic:</b> QAP : Introduction to X-Ray related activities, Inspection requirements, Findings & Reporting	Ms. Nurmazaina Md Ariffin
11.30-13.00	CASE STUDY 2 : Ventilators <b>Synopsis of Topic:</b> Inspection requirements, Findings & Reporting	En.Nasir
13.15-1400	Lunch	
1400-1530	CASE STUDY 3: Hemodialysis <b>Synopsis of Topic:</b> Introduction to Hemodialysisrelated activities: Inspection requirements, Findings & Reporting	Ir.Ghana
1530-1600	Tea break	
1600-1700	QUIZ	