Jabatan Pembangunan Kemahiran
Kementerian Sumber Manusia, Malaysia

STANDARD KEMAHIRAN PEKERJAAN KEBANGSAAN
(*NATIONAL OCCUPATIONAL SKILLS STANDARD*)

C331-006-3:2019

MEDICAL DEVICES MAINTENANCE
PENYELENGGARAAN PERANTI PERUBATAN

LEVEL 3

Department of Skills Development (DSD)
Federal Government Administrative Centre
62530 PUTRAJAYA, MALAYSIA

NATIONAL OCCUPATIONAL SKILLS STANDARD

MEDICAL DEVICES MAINTENANCE

PENYELENGGARAAN PERANTI PERUBATAN

LEVEL 3

TABLE OF CONTENTS

Abbreviation

1.	AC	Alternating Current
2.	BM	Breakdown Maintenance
3.	BMD	Basic Medical Devices
4.	BES	Biomedical Engineering Services
5.	CT/CAT	Computerised Tomography/Cardiac Axial Tomography
6.	CPM	Continuous Passive Range of Motion
7.	CM	Corrective Maintenance
8.	CP	Competency Profile
9.	CPC	Competency Profile Chart
10.	CU	Competency Unit
11.	CoCU	Curriculum of Competency Unit
12.	DC	Direct Current
13.	DOSH	Department of Occupational Safety and Health
14.	DSD	Department of Skills Development
15.	EST	Electrical Safety Test
16.	ECG	Electrocardiogram
17.	EEG	Electroencephalogram
18.	FT	Functional Test
19.	IEC	International Electrotechnical Commission
20.	IMD	Intermediate Medical Devices
21.	MD	Medical Devices
22.	MDM	Medical Devices Maintenance

23. MDMT	Medical Devices Maintenance Technicians
24. MRI	Magnetic Resonance Imaging
25. MS	Malaysian Standard
26. MDA	Medical Device Authority
27. MOSTI	Ministry of Sciences, Technology and Innovations
28. MSC	Malaysian Skills Certificate
29. MMIS	Maintenance Management Information System
30. NSDC	National Skills Development Council
31. NOSS	National Occupational Skills Standard
32. OS	Occupational Structure
33. OAS	Occupational Area Structure
34. OSH	Occupational Safety and Health
35. PE	Performance Test
36. PET	Positron Emission Tomography
37. PM	Preventive Maintenance
38. PPM	Planned Preventive Maintenance
39. PPE	Personal Protective Equipment
40. QMS	Quality Management Systems
41. SME	Subject Matter Experts
42. SDC	Standard Development Committee
43. SIRIM	Standard and Industrial Research Institute of Malaysia
44. STC	Standard Technical Committee
45. STEC	Standard Technical Evaluation Committee

46. SM Scheduled Maintenance

47. TEM Tools, Equipment and Materials

48. TE Test Equipment

49. UM Unscheduled Maintenance

Glossary

1.	Active Medical Devices	Any medical device operations 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, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices[1].
2.	Basic Medical Devices (BMD)	Basic designed device to aid in the diagnosis, monitoring or treatment of medical conditions. BMD includes Basic Diagnostic Device, Basic Therapeutic Device, Basic Laboratory Device and Basic Radiology and Imaging Device. Please refer to Annex A for the list of Active/ Non-active Medical Devices/ Biomedical Equipment Required Maintenance.
3.	Breakdown Maintenance (BM)	Any in-house or third-party personnel or organisation recognised by an authorised agency responsible to carry out, implement and/or manage Biomedical Engineering activities[2].
4.	Calibration	Calibration is the measurement or adjustment of various devise parameters to ensure its accuracy within prescribed standards[3].
5.	Corrective Maintenance (CM)	The action performed to restore the defective active Medical Devices back to the specified conditions. The defect is detected by the user or staff of Bioengineering Services during operations or SM[4].
6.	Disposal	Process whereby a medical device is to be discontinued from use and removed from healthcare facility[5].
7.	Decontamination	A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response[6].
8.	Intermediate Medical Devices (IMD)	Intermediate designed device to aid in the diagnosis, monitoring or treatment of medical conditions. IMD includes Intermediate Diagnostic Device, Intermediate Therapeutic Device, Intermediate Laboratory Device and Intermediate Radiology and Imaging Device. Please refer to Annex A for the list of Active/ Non-active Medical Devices/ Biomedical

[1] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp2/Medical Devices Regulations 2012.
[2] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp2.
[3] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp8.
[4] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp2.
[5] MS 2650 - Guidance on Disposal of Medical Devices pp2.
[6] MS 2650 - Guidance on Disposal of Medical Devices pp2.

Equipment Required Maintenance.

9. Medical Devices (MD)	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of; (a) diagnosis, prevention, monitoring, treatment or alleviation of diseases; (b) diagnosis, monitoring, treatment, alleviation of or compensation for injury; (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; (d) supporting or sustaining life; (e) control of conception; (f) disinfection of medical devices; (g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and 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 function by such means[7]. BD divided into 3 main categories, i.e. Basic BD, Intermediate BD and Advanced BD. Please refer to Annex A for the list of Active/ Non-active Medical Devices/ Biomedical Equipment Required Maintenance.
10. Medical Device Electrical Safety Test (EST)	The medical device electrical safety test shall conform to MS IEC 62353. It describes electro-medical device according to the type of protection provided against electric shock (defined as Class I, II, or III), and the degree of protection provided against electric shock (defined as Type B, BF, or CF). During PPM inspections, the Biomedical Engineering Services personnel shall perform a general safety inspection on all device and an electrical safety test, if applicable. In addition to pass or fail, numerical results of the electrical safety inspections shall be recorded[8].
11. Non-active Medical Devices	Medical devices, without an integral power source, e.g. cardiovascular stents, cardiac valves, surgical instrument, injection, etc[9]. Please refer to Annex A for the list of Active/Non-active Medical Devices/ Biomedical Equipment Required Maintenance.
12. Functional Test (FT)	Functional tests are processes designed to confirm that all of the components of a piece of code or software operate correctly. Functional testing focuses on testing the interface of the application to ensure that all user requirements for a properly working application are met.

[7] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp4.
[8] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp10.
[9] MS 2650 - Guidance on Disposal of Medical Devices pp3.

13. Planned Preventive Maintenance (PPM)	Planned maintenance of device that is designed to improve device life and avoid any unplanned maintenance activity. PPM include lubrications, cleaning, adjusting, and PPM kit replacement (if applicable) to extend the life of active Medical Devices and facilities[10].
14. Scheduled Maintenance (SM)	The SM program consists of a series of planned maintenance requirement and inspections. The program is designed to ensure that medical device is maintained in the highest possible state of operational throughout its life cycle[11].
15. Storage	Specifically designed and suitably equipped location for effective storage of segregated materials for disposal[12].
16. Scheduled Waste	Any waste falling within the categories of waste listed in the First Schedule of Regulation 2, Environmental Quality (Scheduled Waste) Regulation 2005.
17. Unscheduled Maintenance (UM)	UM involves those actions necessary to restore normal function, safety, performance, and reliability to malfunctioning device[13].
18. Troubleshooting	Troubleshooting is a systematic approach to problem solving that is often used to find and correct issues with complex machines, electronics, computers and software systems[14].
19. Test Equipment (TE)	TE is used to create signals and capture responses from electronic devices under test. In this way, the proper operation of the devices under test can be proven or faults in the device can be traced. Use of TE is essential to any serious work on electronics systems[15].
20. Performance Test (PE)	Tests as recommended by the manufacturer or as recommended by standard practices using appropriate TE as specified by the manufacturer[16].
21. Quantitative Tasks	The measurable tasks in specific values or ranges as specified by the manufacturer to determine the device functionality, safety and performances[17].

[10] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).
[11] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).
[12] MS 2650 - Guidance on Disposal of Medical Devices pp3.
[13] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).
[14] https://whatis.techtarget.com/definition/troubleshooting.
[15] https://en.wikipedia.org/wiki/Electronic_test_equipment.
[16] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).

22. Qualitative Tasks	The non-measurable tasks to ensure the quality of the equipment component or fixtures are in good conditions[18].

[17] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).
[18] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision).

Acknowledgement

The Director General of DSD would like to extend his gratitude to the organisations and individuals who have been involved in developing this Standard including National Skills Development Council (NSDC), Standard Technical Committee (STC), Standard Technical Evaluation Committee (STEC), Standard Development Committee (SDC), Facilitator, Secretariat, and Medical Device Authority (MDA), Ministry of Health Malaysia.

STANDARD PRACTICE

NATIONAL OCCUPATIONAL SKILLS STANDARD (NOSS) FOR:

MEDICAL DEVICES MAINTENANCE

LEVEL 3

1. Introduction

1.1. Occupation Overview

Medical Devices (MD) are defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of; (a) diagnosis, prevention, monitoring, treatment or alleviation of diseases; (b) diagnosis, monitoring, treatment, alleviation of or compensation for injury; (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; (d) supporting or sustaining life; (e) control of conception; (f) disinfection of medical devices; (g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and 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 function by such means[19].

MD are also known as Armamentarium. It's designed to aid in the diagnosis, monitoring or treatment of medical conditions. MD helps a patient to easily recover from their disease. Some of the most commonly used pieces of MD includes Magnetic Resonance Imaging (MRI), Ultrasound Machines, Positron Emission Tomography (PET) Scanners (which use cameras and tracer fluid to produce images of a patient's internal organs in order to detect signs of cancer or other diseases), Computerised Tomography (CT) Scanners (which use x-ray sand dye to do the same job as PET scanner)[20].

MD are divided into several types such as Diagnostic Device (may also be used in the home for certain purposes, e.g. for the control of diabetes mellitus), Therapeutic Device (physical therapy machines like Continuous Passive Range of Motion (CPM) machines), Laboratory Device (automates or helps analyse blood, urine, genes, and dissolved gases in the blood) and Radiology & Imaging Device (allow medical staff to measure a patient's medical state)[21]. For the list of Active/ Non-active MD/ Biomedical Equipment Required Maintenance, please refer to Annex A.

Medical Device Maintenance Technicians (MDMT) is a vital component of the Healthcare Delivery System. Employed primarily by hospitals, MDMT's are the people responsible for maintaining a facility's MD. MDMT mainly act as an interface between doctor and device[22].

MDMT, maintain, adjust, calibrate, and repair a wide variety of electronic, electromechanical, and hydraulic device used in hospitals and other medical environments, including health practitioners' offices. They may work on patient

[19] MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) pp4.
[20] https://www.medventura.com/healthaffairs/types-medical-equipment/.
[21] https://www.medventura.com/healthaffairs/types-medical-equipment/.
[22] https://www.medventura.com/healthaffairs/types-medical-equipment/.

monitors, defibrillators, medical imaging equipment (X-rays, Computed Tomography (CAT) Scanners, and Ultrasound Equipment), Voice-controlled Operating Tables, as well as other sophisticated Dental, Optometric, and Ophthalmic Equipment[23] .

MDMT use a wide variety of tools to conduct their work, including multimeters, specialised software, and computers added designed to communicate with specific pieces of hardware. They may also use hand tools, soldering irons, and other electronic tools to fix or adjust malfunctioning device. If a machine is not functioning to its potential, the MDMT may have to adjust the mechanical or hydraulic components or adjust the software to bring the device back into calibration. Most BD is powered by electricity, but because many also have mechanical and hydraulic components, being familiar with all of these systems is critical[24].

MDMT perform Routine Scheduled Maintenance as well as Unscheduled Maintenance to ensure that all device is in good working order. Since many doctors, particularly specialty practitioners, regularly use complex MD to run tests and diagnose patients, they must be guaranteed that the readings are accurate[25].

In a hospital setting, specialists must be comfortable working around patients because repairs occasionally must take place while device is being used. When this is the case, the MDMT must take great care to ensure that repairs do not disturb patients.

Many MDMT are employed in hospitals. Some, however, work for electronic device repair and maintenance companies that service medical device used by other health practitioners, including gynaecologists, orthodontists, veterinarians, and other diagnostic medical professionals. Whereas some MDMT are trained to fix a wide variety of device, others specialise and become proficient at repairing one or a small number of machines.

MDMT are problem solvers, diagnosing and repairing equipment, often under time constraints, therefore, being able to work under pressure is critical. As in most repair occupations, having mechanical and technical aptitude, as well as manual dexterity, is important[26].

1.2. Rationale of NOSS Development

In facing of the rapid growth and increasingly-demanded MD Industry, Malaysia needs to enhance and improve in many areas especially in Human Resource Development. Globalisation had resulted in various new technologies, applications and methods of practices in MD Industry nationwide and globally. Therefore, the primary need of the industry is Knowledge-Workers (K-Workers) and Skilled Workers to enable them to serve higher-end clients by introducing new services and bringing innovative solutions. To this end, it is very important for the industry players to pay attention to invest in

[23] http://hospital.com.my/medic_equipment.htm.
[24] http://hospital.com.my/medic_equipment.htm.
[25] http://hospital.com.my/medic_equipment.htm.
[26] http://hospital.com.my/medic_equipment.htm.

Human Resource Development as one of the key areas in their business expansion. To attract the best minds and skilled talents, the level of professionalism in the industry should be enhanced.

The government and the industry observe that one of the critical job areas in MD Industry is Medical Device Maintenance (MDM). Therefore, in order to accommodate skilled workers in this increasingly-demanded industry, development of National Occupational Skills Standard (NOSS) for MDM job area becomes intensely crucial.

1.3. Rationale of Occupational Structure and Occupational Area Structure

MDM's OS and OAS starts at Level 3 because the Subject Matter Experts (SME) of this industry agreed that an employee who has competent at Level 1 and Level 2 in this field has limited prospects for career advancement. The limited competency at Level 1and 2 will also provide limited investment returns to employers. So much so, these factors will contribute to the marketability of workers. MDM's OS and OAS starts at Level 3 is in line with Medical Device Authority (MDA) Malaysia requirements which the minimum qualification to enter MDM's job area is Level 3 Certificate with 2 years experiences in the related field.

1.4. Regulatory/ Statutory Body Requirements Related to Occupation

MDM's job area is governed or related by Labour Act 1955 (Act 265), Medical Devices Act 2012 (Act 737), Occupational Safety and Health Act 1994 (Act 514), Factories and Machinery Act 1967 (Act 139), Environmental Quality (Scheduled Waste) Regulations 2005, Solid Waste and Public Cleansing Management Act 2007, MS 2058 - Code of Practice for Good Engineering Maintenance Management of Active Medical Devices, MS 2650 - Guidance on Disposal of Medical Devices, MS 838 - Radiation Protection for Medical Diagnostic X-ray - Code of Practice, MS ISO 13485 - Medical Devices Quality Management Systems (QMS), MS IEC 60601 - The Technical Standards for the Safety and Effectiveness of Medical Electrical Device, MS IEC 61010 - The Safety Standard for Measurement, Control and Laboratory Device and MS IEC 62353 - Medical Electrical Device - Recurrent Test and Test After Repair of Medical Electrical Device.

The authorised and regulatory body to enforce the act are Ministry of Health Malaysia, Medical Devices Authority (MDA) Malaysia, Ministry of Sciences, Technology and Innovations (MOSTI) Malaysia, Department of Occupational Safety and Health (DOSH), Ministry of Human Resources Malaysia, Department of Environment, Ministry of Energy, Technology, Science, Environment & Climate Change and Standard and Industrial Research Institute of Malaysia (SIRIM) Berhad.

1.5. Occupational Prerequisite

Although education requirements vary depending on a worker's experience and area of specialisation, the most common education path for MDMT is diploma/ degree in MD Technology or Engineering or Others or Malaysian Skills Certificate (MSC) Level 3 in

MDM, particularly those who work on more sophisticated device such as CAT scanners and defibrillators, may need a bachelor's degree. New workers generally start by observing and assisting experienced maintainers over a period of 2 years, learning a single piece of device at a time. Gradually, they begin working more independently, while still under close supervision. Each piece of device is different, and MDMT must learn each one separately. In some cases, this requires careful study of a Machine's Technical Specifications and Manuals. Medical Device Manufacturers also may provide training courses in a classroom or online.

Because MD's technology is rapidly evolving and new devices are frequently introduced, MDMT must constantly update their skills and knowledge of device. As a result, they must constantly learn new technologies and device through seminars, self-study, and certification exams.

Due to the high risk of infections, workers must have vaccination before entering this job area and have regular medical check-up to ensure that they are healthy and in good medical conditions at all times.

1.6. General Training Prerequisite for Malaysian Skills Certification System

i. Aged 18 years old and above;
ii. Holding Malaysian Certificate of Education (Sijil Pelajaran Malaysia - SPM) or equivalence with at least pass in Malay Language, English Languages, Mathematics and all Science subjects;
iii. Physically and mentally fit;
iv. Pass the health screening/tests and vaccinated; and
v. Not colour blind.

2. Occupational Structure (OS)

Section	(C) Manufacturing
Group	(331) Repair and Installation of Machinery and Equipment
Area	Medical Devices Engineering Services (MDES)
Level 5	Medical Devices Maintenance Specialist
Level 4	Medical Devices Maintenance Senior Technician
Level 3	Medical Devices Maintenance Technician
Level 2	No Level
Level 1	No Level

Figure 1: Occupational Structure

3. Occupational Area Structure (OAS)

Section	(C) Manufacturing
Group	(331) Repair and Installation of Machinery and Equipment
Area	Medical Devices Engineering Services (MDES)
Level 5	Medical Devices Maintenance Management
Level 4	Medical Devices Maintenance Coordination
Level 3	Medical Devices Maintenance
Level 2	Embedded to L3
Level 1	Embedded to L3

Figure 2: Occupational Area Structure

4. Definition of Competency Levels

The NOSS is developed for various occupational areas. Below is a guideline of each NOSS Level as defined by the Department of Skills Development, Ministry of Human Resources, Malaysia.

Level 1: Competent in performing a range of varied work activities, most of which are routine and predictable.

Level 2: Competent in performing a significant range of varied work activities, performed in a variety of contexts. Some of the activities are non-routine and require individual responsibility and autonomy.

Level 3: Competent in performing a broad range of varied work activities, performed in a variety of contexts, most of which are complex and non-routine. There is considerable responsibility and autonomy and control or guidance of others is often required.

Level 4: Competent in performing a broad range of complex technical or professional work activities performed in a wide variety of contexts and with a substantial degree of personal responsibility and autonomy. Responsibility for the work of others and allocation of resources is often present.

Level 5: Competent in applying a significant range of fundamental principles and complex techniques across a wide and often unpredictable variety of contexts. Very substantial personal autonomy and often significant responsibility for the work of others and for the allocation of substantial resources features strongly, as do personal accountabilities for analysis, diagnosis, planning, execution and evaluation.

5. Award of Certificate

The Director General may award, to any person upon conforming to the Standards the following skills qualifications as stipulated under the National Skills Development Act 2006 (Act 652):

5.1. Malaysian Skills Certificate (MSC)
5.2. Statements of Achievement

6. Occupational Competencies

The MDM Level 3 personnel are competent in performing the following Core Competencies:

6.1. Basic Medical Devices (BMD) Scheduled Maintenance (SM)
6.2. Basic Medical Devices (BMD) Unscheduled Maintenance (UM)
6.3. Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)
6.4. Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)
6.5. Medical Devices (MD) Disposal and Waste Administration
6.6. Medical Devices Maintenance (MDM) Administrative Coordination

There are no Elective Competencies for the MDM Level 3 personnel.

7. Work Conditions

MDMT usually work daytime hours but are often expected to be on call. Still, like other hospital employees, some MDMT work irregular hours and may be required to work overtime if an important piece of MD malfunctions. MDMT often must work in a patient environment, which has the potential to expose them to diseases and other health risks. Because MD is often used in life-saving therapies, troubleshooting and repairing device can be urgent. Although this may be gratifying, it can also be very stressful. Those who work as contractors often have to travel, sometimes long distances, to perform needed maintenance or repairs[27].

8. Employment Prospects

Over the next five years (2019 to 2024) opportunities in MDM job area are expected to be good. There is excellent prospect in private sectors due to shortage of hands-on expert in MDM. In public sector, there is lacking of professional and well experience MDM experts. This area has a very good job market potential abroad for skilled personnel due to shortage of such highly skilled personnel in this region.

The greater use of MD in Malaysia is expected to continue to provide good employment prospects for workers in this job area. The increase in MDM sophisticated reliable technologies, will require MDMT to possess higher credentials in this job area. So much so,

[27] http://www.careerprofiles.info/medical-technician-career.html.

those who possess higher credentials and with experience in latest technology will have best job prospects.

9. Up Skilling Opportunities

MDMT assists biological and medical scientists by making sure the laboratory and other health care device are in good working order. They install, maintain, test, calibrate, and repair different types of devices, and also teach others how to operate them.[28]

Similar occupations are in a General Maintenance or Technician Field, though these can span through various work environments. Maintenance workers usually repair machines or fixtures in device, as well as conduct regular inspections to ensure mechanical device are working properly. Another similar career would be becoming An Industry Machinery Mechanic. In this field, workers are responsible for replacing, repairing, and maintaining the equipment in manufacturing plants or factories[29]. They also may have opportunity to work in the Waste Management Industries particularly in disposal of MD.

10. Organisation Reference for Sources of Additional Information

The following organisations can be referred as sources of additional information which can assist in defining the document's contents.

10.1. Ministry of Sciences, Technology and Innovations Malaysia
Aras 1-7, Blok C4 & C5
Kompleks C, Federal Government Administrative Centre
62662, PUTRAJAYA, Malaysia
+603 - 8000 8000
www.mosti.gov.my/

10.2. Ministry of Health Malaysia
Block E1, E3, E6, E7 & E10
Parcel E, Federal Government Administration Centre,
62590, PUTRAJAYA Malaysia
+603 8000 8000
www.moh.gov.my/

10.3. Medical Devices Authority (MDA) Malaysia
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 CYBERJAYA, Selangor, Malaysia
+603 - 8230 0300
www.mdb.gov.my/mdb/

[28] http://www.careerprofiles.info/biomedical-technician-career.html.
[29] http://www.careerprofiles.info/medical-technician-career.html.

10.4. Standard and Industrial Research Institute of Malaysia (SIRIM) Berhad
Ministry of Sciences, Technology and Innovations (MOSTI) Malaysia
1, Persiaran Dato' Menteri
P.O. Box 7035, Section 2
40700 SHAH ALAM, Selangor, Malaysia
1-300-88-7035, +603 - 5544 6000
www.sirim.my/

10.5. Department of Occupational Safety and Health (DOSH)
Ministry of Human Resources Malaysia
Level 1, 3, 4 & 5 Block D4
Complex D, Federal Government Administrative Centre
62530 PUTRAJAYA, Malaysia
+603 - 8000 8000
www.dosh.gov.my/

10.6. Department of Standards Malaysia
Century Square, Level 1 & 2
Block 2300, Jalan Usahawan
63000 CYBERJAYA
Selangor, Malaysia
+603 - 8318 0002
www.standardsmalaysia.gov.my

10.7. Department of Environment
Ministry of Energy, Technology, Science, Environment & Climate Change
Level 1 - 4, Podium 2 & 3
Wisma Sumber Asli
No.25, Persiaran Perdana, Presint 4
Pusat Pentadbiran Kerajaan Persekutuan
62574 Putrajaya, Malaysia
+603 - 8871 2000/2200
www.doe.gov.my

11. Standard Technical Evaluation Committee

NO	NAME	POSITION & ORGANISATION
1.	Ir T. Sasikala Devi	Director Policy, Code and Standards Division Medical Device Authority (MDA) Malaysia Ministry of Health Malaysia
2.	Raziah Binti Esa	Assistant Director (Biomedical Engineer) Policy, Code and Standards Division Medical Device Authority (MDA) Malaysia Ministry of Health Malaysia
3.	Mas Syamsiah Binti Noor Mazlan	Senior Engineer University Malaya Medical Centre
4.	Mohd Hanafi Iskandar Bin Asnawee	Technical Manager Zone Radicare (M) Sdn. Bhd.
5.	Elman Mustafa ElBakri	Senior Consultant Healthcare Technical Services Sdn. Bhd.

12. Standard Development Committee

MEDICAL DEVICES MAINTENANCE

LEVEL 3

NO	NAME	POSITION & ORGANISATION
1.	Mohd Shahrezza Bin Sirun	Assistant Director (Biomedical Engineer) Policy, Code and Standards Division Medical Device Authority (MDA) Malaysia Ministry of Health Malaysia
2.	Azim Fauza Bin Md Khair	Biomedical Engineer Hospital Kuala Lumpur Ministry of Health Malaysia
3.	Mohamed Fadzli Bin Ismail	Vocational Training Officer Kolej Kemahiran Tinggi MARA Ledang
4.	Ganesan s/o Satimuti	Director/ HRDF Certified Trainer Asia Synergy Training and Consultancy
5.	Mohd Saifudin Bin Saad	Head of Biomedical Equipment Maintenance Edgenta Mediserve Sdn. Bhd.
6.	Khairul Azwan Bin Kamarudin	Technical Manager Radibems Sdn. Bhd.
7.	Ainna Amalina Binti Abdul Aziz	Asset Maintenance Executive Edgenta Healthcare Management Sdn. Bhd.
8.	Shahlan Bin Shafiee	Senior Service Engineer Pacific Biomedical Engineering
9.	Ismadi Bin Hj Ismail	Certified Trainer/ Technical Manager Service Centre Radicare (M) Sdn. Bhd.
10.	Zulkifli Bin Mahmoodin	Senior Lecturer Medical Engineering Technology Universiti Kuala Lumpur British Malaysian Institute
11.	Sabrina Binti Mohamad	Assistant Lecturer Electronic Medical Engineering Department Universiti Kuala Lumpur British Malaysian Institute

FACILITATOR		
1.	Commander Mohamed Salleh Bin Hj Shahadan RMN (Rtd)	CIAST/PPL/KD/12/2014/0330 Total Oracle Sdn. Bhd.

STANDARD CONTENT

NATIONAL OCCUPATIONAL SKILLS STANDARD (NOSS) FOR:

MEDICAL DEVICES MAINTENANCE

LEVEL 3

13. Competency Profile Chart (CPC)

SECTION	(C) MANUFACTURING		
GROUP	(331) REPAIR AND INSTALLATION OF MACHINERY AND EQUIPMENT		
AREA	MEDICAL DEVICES ENGINEERING SERVICES (MDES)		
NOSS TITLE	MEDICAL DEVICES MAINTENANCE		
NOSS LEVEL	THREE (3)	NOSS CODE	C331-006-3:2019

	COMPETENCY UNIT			
CORE COMPETENCY	BASIC MEDICAL DEVICES (BMD) SCHEDULED MAINTENANCE (SM) C331-006-3:2019-C01	BASIC MEDICAL DEVICES (BMD) UNSCHEDULED MAINTENANCE (UM) C331-006-3:2019-C02	INTERMEDIATE MEDICAL DEVICES (IMD) SCHEDULED MAINTENANCE (SM) C331-006-3:2019-C03	INTERMEDIATE MEDICAL DEVICES (IMD) UNSCHEDULED MAINTENANCE (UM) C331-006-3:2019-C04
	MEDICAL DEVICES (MD) DISPOSAL AND WASTE ADMINISTRATION C331-006-3:2019-C05	MEDICAL DEVICES MAINTENANCE (MDM) ADMINISTRATIVE COORDINATION C331-006-3:2019-C06		

14. Competency Profile (CP)

SECTION	(C) MANUFACTURING		
GROUP	(331) REPAIR AND INSTALLATION OF MACHINERY AND EQUIPMENT		
AREA	MEDICAL DEVICES ENGINEERING SERVICES (MDES)		
NOSS TITLE	MEDICAL DEVICES MAINTENANCE		
NOSS LEVEL	THREE (3)	NOSS CODE	C331-006-3:2019

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
1. Basic Medical Devices (BMD) Scheduled Maintenance (SM) C331-006-3:2019-C01	Basic Medical Devices (BMD) Scheduled Maintenance (SM) describes a process of servicing for the purpose of maintaining BMD as well as their associated equipment in satisfactory operating condition by providing a systematic check, detection, and correction of incipient/ initial failures either before they occur or before they develop into major defects. SM Programme will ensure optimum performance and safe operations of BMD. It is also important in minimising downtime while extending BMD clinical application life. This CU is important because it can determine factors that contributes towards ensuring BMD are functioning in the highest possible state of operations throughout its	1. Prepare BMD SM Activities	1.1 Appropriate BMD SM activities and information interpreted based on BMD Planned Maintenance Schedule, Work Instructions, Manufacturer's Reference Documents and PPM Forms/ Checklists. 1.2 BMD selected based on categories and types. 1.3 BMD functionality interpreted based on clinical application and operations specifications. 1.4 Appropriate Test Equipment (TE) and Tools operations and safety inspected based on Occupational Safety and Health (OSH) Procedures/ Guidelines. 1.5 Appropriate Personal Protective Equipment (PPE) operations and safety inspected based on OSH Procedures/ Guidelines. 1.6 Immediate workplace surrounding safety and hazards-free established in line with OSH Procedures. 1.7 BMD infection risks and decontamination methods/ process

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	clinical application. Through this CU, it also provides means to detect impending BMD failures, forecast manpower and material requirements and eliminating the need of premature replacement of device. The person who is competent in this CU shall be able to Prepare BMD SM Activities, Perform BMD Qualitative Tasks, Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks), Perform BMD Quantitative Tasks (Performance Tests), Perform BMD Quantitative Tasks (Electrical Safety Test-EST), Perform BMD Parameters Setting-up/ Calibration and Perform BMD Routine Inspection (RI). The outcome of this CU is person that shall be able to perform BMD SM to ensure the BMD can be performed smoothly and avoid downtimes according to Manufacturer's Reference Document, MS IEC60601/ MS IEC61010/ MS IEC62353 and relevant PPM Forms/ Checklists.		carried out based on situations and infections/ contaminations symptoms.
		2. Perform BMD Qualitative Tasks	2.1 BMD Qualitative Tasks Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 2.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 2.3 BMD components, sub-components, accessories and other related features physical condition tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.4 BMD components, sub-components, accessories and other related features functional conditions tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.5 BMD fittings, connectors, alarms, interlocks, label and cables conditions inspected and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.6 BMD Qualitative Tasks results recorded and PPM Forms/ Checklists updated. 2.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007. 2.8 BMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists.
		3. Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3.1 BMD Quantitative Tasks (PM Tasks) Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 3.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.3 BMD interior and exterior, blowers, filters, fans and coils (where applicable) cleaned from corrosion, dirt, solutions, dust, lint or deposits based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.4 BMD motors, gears, bearings, casters and other moving components (where applicable) lubricated based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.5 BMD battery compartments (where applicable) inspected and battery replaced (if necessary) based on Manufacturer's Recommendations,

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Standard Practices and relevant PPM Forms/ Checklists. 3.6 BMD maintenance consumables serviced/ replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.7 BMD PPM Kit (where applicable) replaced based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.8 BMD Quantitative Tasks (PM Tasks) results recorded and PPM Forms/ Checklists updated. 3.9 BMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		4. Perform BMD Quantitative Tasks (Performance Tests)	4.1 BMD Quantitative Tasks (Performance Tests) Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.2 Designated PPE and Tools utilised

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			based on OSH Procedures/ Guidelines. 4.3 BMD Quantitative Tasks (Performance Tests) carried out based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.4 BMD Quantitative Tasks (Performance Tests) results recorded and PPM Forms/ Checklists updated. 4.5 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		5. Perform BMD Quantitative Tasks (Electrical Safety Test-EST)	5.1 BMD Quantitative Tasks (EST) Procedures interpreted based on Manufacturer's Reference Documents, MS IEC 60601, MS IEC 61010, MS IEC 62353 and relevant PPM Forms/ Checklists. 5.2 BMD type of protection provided against electrical shock determined and confirmed based on classes. 5.3 BMD degree of protection against electrical shock determined and confirmed based on Types. 5.4 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.5 BMD general safety inspection carried

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			out and results confirmed against Manufacturer's Reference Documents and PPM Requirements. 5.6 BMD Quantitative Tasks (EST) results (pass or fail)/numerical results (if applicable) recorded and PPM Forms/ Checklists updated. 5.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		6. Perform BMD Parameters Setting-up/ Calibration	6.1 BMD Setting-up/ Calibration Requirements/ Procedures determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.2 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 6.3 BMD accuracy within the prescribed standard determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.4 BMD Setting-up/ Calibration carried out through built-in self-calibration or manual calibration using appropriate calibration equipment.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			6.5 BMD Setting-up/ Calibration results recorded and PPM Forms/ Checklists/ device log (manually/ attaching printed results) updated. 6.6 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		7. Perform BMD Routine Inspection (RI)	7.1 BMD (not included in the PPM list and PPM Procedures) determined based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.2 BMD List and RI Schedule determined based on location and RI Frequency Requirements. 7.3 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 7.4 BMD physical condition visually inspected for flaws, cracks, deformities, tears or any other apparent defects based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.5 BMD label, sticker, notices compliance inspected based on Manufacturer Recommendations, Standard Practices

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			and Relevant RI Forms/ Checklists. 7.6 BMD general performance (display, lights and tones) inspected based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.7 BMD (malfunction/ problems) isolated and tagged based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.8 BMD RI results recorded and Relevant RI Forms/ Checklists updated. 7.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
2. Basic Medical Devices (BMD) Unscheduled Maintenance (UM) C331-006-3:2019-C02	Basic Medical Devices (BMD) Unscheduled Maintenance (UM) describes the requirements to respond, check, troubleshoot and repair minor defect related to BMD so that it can be restored to an operational condition within the established limits and tolerances. UM includes breakdown maintenance, corrective maintenance and emergency	1. Prepare BMD UM Activities	1.1 BMD UM activities determined based on User Breakdown Request Form/ Breakdown Report (during SM). 1.2 Appropriate Reference Documents and Forms/ Checklists interpreted based on BMD Troubleshooting and Rectification Procedures/ Requirements. 1.3 BMD maintenance and components repaired/ replace history confirmed against BMD Service Records. 1.4 BMD functionality interpreted based on

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	maintenance. This CU is important to ensure malfunctioned BMD are restored to its normal function, achieving its desired safety and performance standards and maintain reliability within the shortest time possible. Through this CU, the maximum target of uptime for a BMD can be achieved. The person who is competent in this CU shall be able to Prepare BMD UM Activities, Perform BMD Resetting, General Checking and Rectification, Perform BMD Power Section Troubleshooting and Rectification, Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification and Perform BMD Electro-Mechanical Trouble-shooting and Rectification. The outcome of this CU is person that shall be able to perform BMD UM according to MS 2058 and Test Standard/Protocol.		clinical application and operations specifications. 1.5 Appropriate PPE, TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.6 Immediate workplace surrounding safety and hazards-free established in line with OSH Procedures. 1.7 BMD infection risks and decontamination methods/ process determined based on related reference documents.
		2. Perform BMD Resetting, General Checking and Rectification	2.1 BMD Resetting, General Checking and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 2.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 2.3 BMD components, sub-components, accessories and other related features physical condition and functioning inspected based on Manufacturer's Reference Documents. 2.4 BMD common repair carried out based on Manufacturer's Requirements. 2.5 BMD light bulbs, batteries, probes, electrode, tubing/ consumables replaced (if necessary) based on Manufacturer's Requirements. 2.6 BMD resetting (to its original setting)

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			carried out based on Manufacturer's Requirements. 2.7 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 2.8 BMD Performance and Calibration Test carried out Manufacturer's Requirements. 2.9 BMD Resetting, General Checking and Rectification results recorded and appropriate Forms/ Checklists updated. 2.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		3. Perform BMD Power Section Troubleshooting and Rectification	3.1 BMD Power Section Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 3.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.3 BMD Power Supply functionality checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.4 BMD AC/ DC Output Voltage checked and confirmed against Voltage Reference, Manufacturer's Reference

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Documents and Forms/ Checklists. 3.5 BMD Battery Assembly functionality (Off Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.6 BMD Battery Charger Assembly functionality (On Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.7 BMD Power Section repair carried out based on Manufacturer's Requirements. 3.8 BMD consumables replaced (if necessary) based on Manufacturer's Requirements. 3.9 BMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 3.10 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 3.11 BMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 3.12 BMD Power Section Troubleshooting and Rectification results recorded and Appropriate Forms/ Checklists updated. 3.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		4. Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification	4.1 BMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 4.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 4.3 BMD Input Signal Status (Applied Part) functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 4.4 BMD Input Signal Status (Applied Part) repair carried out based on Manufacturer's Requirements. 4.5 BMD consumables replaced (if necessary) based on Manufacturer's Requirements. 4.6 BMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 4.7 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 4.8 BMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 4.9 BMD Input Signal Status (Applied Part) Troubleshooting and Rectification

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			results recorded and Appropriate Forms/ Checklists updated. 4.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		5. Perform BMD Electro-Mechanical Trouble-shooting and Rectification	5.1 BMD Electro-Mechanical Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 5.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.3 DC/ AC Bulbs functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.4 DC/ AC Motor Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.5 Heater Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.6 BMD reassembled and reset to its original setting as per the

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Manufacturer's Requirements. 5.7 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 5.8 BMD Performance and Calibration Test carried out using appropriate TE according to Manufacturer's Requirements. 5.9 BMD Electro-Mechanical Troubleshooting and Rectification results recorded. 5.10 Appropriate Forms/ Records updated. 5.11 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
3. Intermediate Medical Devices (IMD) Scheduled Maintenance (SM) C331-006-3:2019-C03	Intermediate Medical Devices (IMD) Scheduled Maintenance (SM) describes a process of servicing for the purpose of maintaining IMD as well as their associated equipment in satisfactory operating condition by providing a systematic check, detection, and correction of incipient/initial failures either before they occur or before they develop into major defects. SM	1. Prepare IMD SM Activities	1.1 Appropriate IMD SM activities and information interpreted based on IMD Planned Maintenance Schedule, Work Instructions, Manufacturer's Reference Documents and PPM Forms/ Checklists. 1.2 IMD selected based on categories and types. 1.3 IMD functionality interpreted based on clinical application and operations specifications. 1.4 Appropriate TE and Tools operations and safety inspected based on OSH

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	Programme will ensure optimum performance and safe operations of IMD. It is also important in minimising downtime while extending IMD clinical application life. This CU is important because it can determine factors that contributes towards ensuring IMD are functioning in the highest possible state of operations throughout its clinical application. Through this CU, it also provides means to detect impending IMD failures, forecast manpower and material requirements and eliminating the need of premature replacement of device. The person who is competent in this CU shall be able to Prepare IMD SM Activities, Perform IMD Qualitative Tasks, Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks), Perform IMD Quantitative Tasks (Performance Tests), Perform IMD Quantitative Tasks (Electrical Safety Test-EST), Perform IMD Parameters Setting-up/ Calibration		Procedures/ Guidelines. 1.5 Appropriate PPE operations and safety inspected based on OSH Procedures/ Guidelines. 1.6 Immediate workplace surrounding safety and hazards-free established in line with OSH Procedures. 1.7 IMD infection risks and decontamination methods/ process carried out based on situations and infections/ contaminations symptoms.
		2. Perform IMD Qualitative Tasks	2.1 BMD Qualitative Tasks Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 2.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 2.3 IMD components, sub-components, accessories and other related features physical condition tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.4 IMD components, sub-components, accessories and other related features functional conditions tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.5 IMD fittings, connectors, alarms, interlocks, label and cables conditions

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	and Perform IMD Routine Inspection (RI). The outcome of this CU is person that shall be able to perform IMD SM to ensure the IMD can be performed smoothly and avoid downtimes according to Manufacturer's Reference Document, MS IEC 60601/ MS IEC 61010/ MS IEC 62353 and relevant PPM Forms/ Checklists.		inspected and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.6 IMD Qualitative Tasks results recorded and PPM Forms/ Checklists updated. 2.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007. 2.8 IMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists.
		3. Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3.1 IMD Quantitative Tasks (PM Tasks) Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 3.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.3 IMD interior and exterior, blowers, filters, fans and coils (where applicable) cleaned from corrosion, dirt, solutions, dust, lint or deposits based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.4 IMD motors, gears, bearings, casters

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			and other moving components (where applicable) lubricated based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.5 IMD battery compartments (where applicable) inspected and battery replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.6 IMD maintenance consumables serviced/replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.7 IMD PPM Kit (where applicable) replaced based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.8 IMD Quantitative Tasks (PM Tasks) results recorded and PPM Forms/ Checklists updated. 3.9 IMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		4. Perform IMD Quantitative Tasks (Performance Tests)	4.1 IMD Quantitative Tasks (Performance Tests) Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 4.3 IMD Quantitative Tasks (Performance Tests) carried out based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.4 IMD Quantitative Tasks (Performance Tests) results recorded and PPM Forms/ Checklists updated. 4.5 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		5. Perform IMD Quantitative Tasks (Electrical Safety Test-EST)	5.1 IMD Quantitative Tasks (EST) Procedures interpreted based on Manufacturer's Reference Documents, MS IEC 60601, MS IEC 61010, MS IEC 62353 and relevant PPM Forms/ Checklists.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			5.2 IMD type of protection provided against electrical shock determined and confirmed based on Classes. 5.3 IMD degree of protection against electrical shock determined and confirmed based on Types. 5.4 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.5 IMD general safety inspection carried out and results confirmed against Manufacturer's Reference Documents and PPM Requirements. 5.6 IMD Quantitative Tasks (EST) results (pass or fail)/ numerical results (if applicable) recorded and PPM Forms/ Checklists updated. 5.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		6. Perform IMD Parameters Setting-up/ Calibration	6.1 IMD Setting-up/ Calibration Requirements/ Procedures determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.2 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			6.3 IMD accuracy within the prescribed standard determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.4 IMD Setting-up/ Calibration carried out through built-in self-calibration or manual calibration using appropriate calibration equipment. 6.5 IMD Setting-up/ Calibration results recorded and PPM Forms/ Checklists/ device log (manually/ attaching printed results) updated. 6.6 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		7. Perform IMD Routine Inspection (RI)	7.1 IMD (not included in the PPM list and PPM Procedures) determined based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.2 IMD List and RI Schedule determined based on location and RI Frequency Requirements. 7.3 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			7.4 IMD physical condition visually inspected for flaws, cracks, deformities, tears or any other apparent defects based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.5 IMD label, sticker, notices compliance inspected based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.6 IMD general performance (display, lights and tones) inspected based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.7 IMD (malfunction/problems) isolated and tagged based on Manufacturer Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.8 IMD RI results recorded and Relevant RI Forms/ Checklists updated. 7.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
4. Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM) C331-006-3:2019-C04	Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM) describes the requirements to respond, check, troubleshoot and repair minor defect related to IMD so that it can be restored to an operational condition within the established limits and tolerances. UM includes breakdown maintenance, corrective maintenance and emergency maintenance. This CU is important to ensure malfunctioned IMD are restored to its normal function, achieving its desired safety and performance standards and maintain reliability within the shortest time possible. Through this CU, the maximum target of uptime for IMD can be achieved. The person who is competent in this CU shall be able to Prepare IMD UM Activities, Perform IMD Resetting, General Checking and Rectification, Perform IMD Power Section Troubleshooting and Rectification, Perform IMD Input Signal Status (Applied Part)	1. Prepare IMD UM Activities	1.1 IMD UM activities determined based on User Breakdown Request Form/ Breakdown Report (during SM). 1.2 Appropriate Reference Documents and Forms/ Checklists interpreted based on IMD Troubleshooting and Rectification Procedures/ Requirements. 1.3 IMD maintenance and components repaired/ replace history confirmed against IMD Service Records. 1.4 IMD functionality interpreted based on clinical application and operations specifications. 1.5 Appropriate PPE, TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.6 Immediate workplace surrounding safety and hazards-free established in line with OSH Procedures. 1.7 IMD infection risks and decontamination methods/ process determined based on related reference documents.
		2. Perform IMD Resetting, General Checking and Rectification	2.1 IMD Resetting, General Checking and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 2.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 2.3 IMD components, sub-components,

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	Troubleshooting and Rectification and Perform IMD Electro-Mechanical Troubleshooting and Rectification. The outcome of this CU is person that shall be able to perform IMD UM according to MS 2058 and Test Standard/Protocol.		accessories and other related features physical condition and functioning inspected based on Manufacturer's Reference Documents. 2.4 IMD common repair carried out based on Manufacturer's Requirements. 2.5 IMD light bulbs, batteries, probes, electrode, tubing/ consumables replaced (if necessary) based on Manufacturer's Requirements. 2.6 IMD resetting (to its original setting) carried out based on Manufacturer's Requirements. 2.7 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 2.8 IMD Performance and Calibration Test carried out Manufacturer's Requirements. 2.9 IMD Resetting, General Checking and Rectification results recorded and appropriate Forms/ Checklists updated. 2.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
		3. Perform IMD Power Section Troubleshooting and Rectification	3.1 IMD Power Section Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 3.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.3 IMD Power Supply functionality checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.4 IMD AC/ DC Output Voltage checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.5 IMD Battery Assembly functionality (Off Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.6 IMD Battery Charger Assembly functionality (On Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and Forms/ Checklists. 3.7 IMD Power Section repair carried out based on Manufacturer's Requirements. 3.8 IMD consumables replaced (if necessary) based on Manufacturer's Requirements. 3.9 IMD reassembled and reset (to its original setting) based on

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			Manufacturer's Requirements. 3.10 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 3.11 IMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 3.12 IMD Power Section Troubleshooting and Rectification results recorded and Appropriate Forms/ Checklists updated. 3.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		4. Perform IMD Input Signal Status (Applied Part) Troubleshooting and Rectification	4.1 IMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 4.2 Designated PPE and Tools utilised based on OSH Procedures/Guidelines. 4.3 IMD Input Signal Status (Applied Part) functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 4.4 IMD Input Signal Status (Applied Part) repair carried out based on Manufacturer's Requirements.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			4.5 IMD consumables replaced (if necessary) based on Manufacturer's Requirements. 4.6 IMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 4.7 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 4.8 IMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 4.9 IMD Input Signal Status (Applied Part) Troubleshooting and Rectification results recorded and Appropriate Forms/ Checklists updated. 4.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		5. Perform IMD Electro-Mechanical Troubleshooting and Rectification	5.1 IMD Electro-Mechanical Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 5.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.3 DC/ AC Bulbs functionality checked

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.4 DC/ AC Motor Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.5 Heater Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.6 IMD reassembled and reset to its original setting as per the Manufacturer's Requirements. 5.7 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 5.8 IMD Performance and Calibration Test carried out using appropriate TE according to Manufacturer's Requirements. 5.9 IMD Electro-Mechanical Troubleshooting and Rectification results recorded. 5.10 Appropriate Forms/ Records updated. 5.11 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
5. Medical Devices (MD) Disposal and Waste Administration C331-006-3:2019-C05	Medical Devices (MD) Disposal and Waste Administration describes the process whereby medical devices is to be discontinued from use and removed from healthcare facility for decontamination and disposal processes. This CU is important to ensure all MD are properly removed, transported, decontaminated and disposed as required by the authorities as to avoid illegally reused and fatal contaminations. The person who is competent in this CU shall be able to Prepare MD Disposal, Perform Waste Identification, Perform MD Collection and Transportation, Perform MD Storage, Perform MD Decontamination, Perform MD Disposal Processes, Handle Spillage Waste and Handle MD Disposal Documentations and Records. The outcome of this CU is person that shall be able to perform MD Disposal and Waste Administration according to MS 2650/ MS 2058/	1. Prepare MD Disposal	1.1 MD Disposal Requirements/ Procedures interpreted based on MS 2650/ Related Reference Documents. 1.2 MD due for disposal determined based on Work Order Requirements. 1.3 MD disposal workflow determined based on MS 2650/ Related Reference Documents. 1.4 MD removal and dedicated decontamination area/ storage arrangements carried out. 1.5 MD decontamination and disposal arrangements carried out. 1.6 Appropriate PPE and Tools/ Decontamination Kits operations and safety inspected based on OSH Procedures/ Guidelines. 1.7 Immediate workplace surrounding safety and hazards-free established in line with OSH Procedures.
		2. Perform Waste Identification	2.1 Designated PPE and Tools/ Decontamination Kits utilised based on OSH Procedures/ Guidelines. 2.2 MD status determined based on its usage. 2.3 Used active MD determined and isolated for decontamination process. 2.4 Used non-active MD determined and handled in accordance with Environmental Quality (Scheduled

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
	Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007 Recommended Practises/ Other Related Regulations.		Waste) Regulations 2005. 2.5 Unused non-active MD determined and handled in accordance with Solid Waste and Public Cleansing Management Act 2007. 2.6 Scheduled waste determined and handled in accordance with Environmental Quality (Scheduled Waste) Regulation 2005. 2.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		3. Perform MD Collection and Transportation	3.1 Designated PPE and Tools/ Decontamination Kits utilised based on OSH Procedures/ Guidelines. 3.2 Fixed MD dismantled in accordance with Manufacturer's Instructions. 3.3 Collected MD cleaned and labelled with appropriate notifications. 3.4 Appropriate transport vehicles utilised based on Environmental Quality Act 1974 (Act 127). 3.5 MD for disposal transported to suitable storage facility in safe manner. 3.6 MD being transported documented with user department information, period of

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			storage and scheduled date for decontamination. 3.7 Transport vehicles cleaned/ decontaminated after each transportation based on Environmental Quality Act 1974 (Act 127). 3.8 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		4. Perform MD Storage	4.1 MD Storage Requirements/ Procedures determined based on Handling and Management of Clinical Waste Guidelines. 4.2 Designated PPE and Tools/ Decontamination Kits utilised based on OSH Procedures/ Guidelines. 4.3 Dedicated MD storage/holding facility water-resistant floor shelving cleaned. 4.4 MD storage/ holding facility secured and accessible to only authorised personnel. 4.5 Dedicated hand decontamination facility (hand wash basin) prepared. 4.6 MD properly placed and arranged at storage area. 4.7 Trolleys and other equipment to assist

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			loading/ unloading MD prepared and cleaned. 4.8 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		5. Perform MD Decontamination	5.1 MD to be decontaminated determined based on its status. 5.2 MD decontamination methods/ processes determined based on MS 2650/ MS 2058/ Other Related Regulations. 5.3 Designated PPE and Tool/ Decontamination Kits utilised based on OSH Procedures/ Guidelines. 5.4 Appropriate MD decontamination procedures/ process carried out in accordance with MS 2058 Recommended Practises/ Other Related Regulations. 5.5 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
		6. Perform MD Disposal Processes	6.1 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 6.2 Scheduled Waste disposed-off in accordance with Environmental Quality (Scheduled Waste) Regulation 2005. 6.3 Non-scheduled Waste disposed-off in accordance with Solid Waste and Public Cleansing Management Act 2007. 6.4 Clinical Waste disposed-off in accordance with Environmental Quality (Scheduled Waste) Regulations 2005. 6.5 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		7. Handle Spillage Waste	7.1 Hazardous material spillage handling requirements/ procedures determined based on MS 2058 Recommended Practises/ Other Related Regulations. 7.2 Designated PPE and Tools/ Spillage Kits utilised based on OSH Procedures/ Guidelines. 7.3 Scheduled Waste spillage immediately reported for investigation, in accordance with relevant regulatory requirements, policies and procedures. 7.4 Spillage waste area made safe in

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			accordance with spillage procedures/ relevant regulatory requirements, policies and procedures. 7.5 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
		8. Handle MD Disposal Documentations and Records	8.1 MD Disposal Documentations and Records Handling Requirements/ Procedures determined based on Environment Quality (Scheduled Waste) Regulations 2005 and Other Related Regulations. 8.2 MD Disposal Documentations and Records compiled and updated based on Related Regulations. 8.3 MD Disposal Documentations and Records maintained and retained based on Related Regulations.
6. Medical Devices Maintenance (MDM) Administrative Coordination C331-006-	Medical Devices Maintenance (MDM) Administrative Coordination describes the requirement to assist and manage related MDM technical documentations. This includes inventory of parts and	1. Maintain MD Parts and Inventory Database and Technical Documentations	1.1 MD Parts Inventory Database and Technical Documentations Requirements interpreted based on Manufacturer's Manual and Related Reference Documents. 1.2 MD parts consumption projected based on Manufacturer's Recommendations

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
3:2019-C06	consumables, management of warranty and updating of any device alert or recall. This CU is important to ensure that the MDM services policies and procedures are well implemented and maintained. The person who is competent in this CU shall be able to Maintain MD Parts and Inventory Database and Technical Documentations, Coordinate MD Warranty Maintenance Activities and Coordinate MD Recalls. The outcome of this CU is person that shall be able to perform MDM Administrative Coordination according to Manufacturer's Manual and Related Reference Documents.		and/ or Historic Consumption, Manual and History Records. 1.3 MD parts and inventory stock taking carried out Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records. 1.4 MD parts and inventory list audited to confirm availability based on Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records. 1.5 MD Technical Documentations checked to the latest version. 1.6 MD Technical Documentation and Inventory List updated based on Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records.
		2. Coordinate MD Warranty Maintenance Activities	2.1 MD Warranty Maintenance activities and Schedule Requirements interpreted based on Manufacturer's Manual and Related Reference Documents. 2.2 MD Registration carried out base on Manufacturer's Manual and Related Reference Documents. 2.3 MD Maintenance Schedule coordinated based on Manufacturer's Recommendations, Risks, Ages, Usage Frequency and Location.

CU TITLE & CU CODE	CU DESCRIPTION	WORK ACTIVITIES	PERFORMANCE CRITERIA
			2.4 MD Maintenance Schedule updated according to Department's Administrative Procedures. 2.5 MD Warranty controlled in accordance with the Manufacturer's Recommendation and Department's Regulations.
		3. Coordinate MD Recalls	3.1 Alerts and MD recall notices determined and confirmed against MD Inventory List. 3.2 MD dismantled/ collected and segregated to quarantine area. 3.3 Recalled MD isolated, tagged and labelled. 3.4 MD recall cases reported/ referred to appropriate personal for further actions. 3.5 Related Forms/ Reports/ Inventory List updated.

CURRICULUM OF COMPETENCY UNIT

NATIONAL OCCUPATIONAL SKILLS STANDARD (NOSS) FOR:

MEDICAL DEVICES MAINTENANCE

LEVEL 3

15. Curriculum of Competency Unit

15.1. Basic Medical Devices (BMD) Scheduled Maintenance (SM)

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Basic Medical Devices (BMD) Scheduled Maintenance (SM)		
LEARNING OUTCOMES	The outcome of this CU is to ensure the BMD can be performed smoothly and avoid downtimes according to Manufacturer's Reference Document, MS IEC 60601/MS IEC 61010/ MS IEC 62353 and relevant PPM Forms/ Checklists. Upon completion of this competency unit, trainees shall be able to: 1. Prepare BMD SM Activities 2. Perform BMD Qualitative Tasks 3. Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks) 4. Perform BMD Quantitative Tasks (Performance Tests) 5. Perform BMD Quantitative Tasks (Electrical Safety Test-EST) 6. Perform BMD Parameters Setting-up/ Calibration 7. Perform BMD Routine Inspection (RI)		
TRAINING PRE-REQUISITE (SPECIFIC)	Not Available		
CU CODE	C331-006-3:2019-C01	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Prepare BMD SM Activities	1.1 MD Technology, includes: • MD Design, Purpose and Performance • MD Maintenance and Repair 1.2 Electronics, includes:	1.1 Interpret appropriate BMD SM activities and information. 1.2 Select BMD categories and types. 1.3 Interpret BMD functionality. 1.4 Inspect appropriate	ATTITUDE • Focus and attentive in Preparing BMD Activities. • Apply work ethics. SAFETY • Establish immediate	1.1 MD Design, Purpose and Performance explained. 1.2 MD Maintenance and Repair Requirements/ Procedures explained. 1.3 Electronics Principles of Electronic Components, Circuits and Instruments

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Principles of Electronic Components, Circuits and Instruments • Troubleshooting and Repairing of Electronic Device 1.3 Electric Foundations and Fundamentals. 1.4 Information Technology, includes: • Principles of Computers, Peripherals, Networks and Software Related to MD 1.5 Mathematics for Technician, includes: • Ohm's Law • Kirchhoff's Law • Algebra 1.6 SM Reference Documents, includes: • Manufacturer's Service Manuals • BMD Service Records/ MMIS • BMD Maintenance	TE and Tools operations and safety. 1.5 Inspect appropriate PPE operations and safety. 1.6 Carry out BMD infection risks and decontamination methods/ process.	workplace surrounding safety and hazards-free. • Eliminate infection risks. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	described. 1.4 Troubleshooting and Repairing of Electronic Device described. 1.5 Electric Fundamentals described. 1.6 Principles of Computers, Peripherals, Networks and Software Related to MD described. 1.7 Ohm's Law, Kirchhoff's Law and Algebra calculated. 1.8 SM Reference Documents described. 1.9 TE Types and Functions/ Usage explained. 1.10 PPE and Tools Types and Functions/ Usage explained. 1.11 BMD Types and Functions/ Usage explained. 1.12 Basic Structures and Functions of Human Body and Interaction of BMD with Human Body explained. 1.13 Medical Device Regulations explained. 1.14 Healthcare for Biomedical Technical Personnel explained. 1.15 Medical Devices Safety explained.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Schedule/ Planned Maintenance Schedule • Work Instructions. • BMD PPM Forms/ Checklist • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 1.7 TE Types and Functions/ Usage, includes: • Function Generator • Electrical Safety Analysers • Oscilloscopes • Digital Multimetres • Pressure Gauges • Pressure Meter • Digital Tachometer • DC Power Supply			1.16 Act/ Standard Requirements and Compliance explained. 1.17 Appropriate BMD SM activities/ information interpreted based on BMD PM Schedule, Work Instructions, Manufacturer's Reference Documents and PPM Forms/ Checklists. 1.18 BMD selected based on categories and types. 1.19 BMD functionality interpreted based on clinical application and operations specifications. 1.20 Appropriate TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.21 Appropriate Personal PPE operations and safety inspected based on OSH Procedures/ Guidelines. 1.22 BMD infection risks and decontamination methods/ process carried out based on situations and infections/ contaminations symptoms. 1.23 Work area cleaned, all waste removed and disposed-off in accordance with Workplace

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Calibrated Weights • Digital Luxmeter • Irradiant Meter 1.8 PPE and Tools Types and Functions/ Usage, includes: • Surgical Masks • Gloves • Safety Shoes • Hand Tools 1.9 Types and Functions/ Usage of **Basic Medical Diagnostic Devices**, includes: • Scales • Laryngoscopes • Eye Charts • Ophthalmoscopes • Light Sources • Meters Aneroid 1.10 Types and functions/ Usage of **Basic Medical Therapeutic Devices**, includes: • Baths, Paraffin, Physical Therapy, Water • Cast Cutters			Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Lights - Headlights, Dental, Infrared, Surgical • Mattress Systems • Nebulizers • Phototherapy Units • Pumps - Breast • Warming blanket • Enteral Pump • Nerve Stimulator 1.11 Types and Functions/ Usage of **Basic Medical Laboratory Devices**, includes: • Balances • Baths, Water • Hot Plates • Mixers • pH Meters • Rotators • Separators • Shakers • Slide Strainers • Stirrers 1.12 Medical Device Authority (MDA) Malaysia, Ministry of Health (MOH)			

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	regulatory requirements (Compulsory Competency Module-CCM 2), includes: • Basic Anatomy and Physiology (Structures and Functions of Human Body and Interaction of BMD with Human Body) • Medical Device Regulations • Introduction to Healthcare for Biomedical Technical Personnel • Medical Devices Safety 1.13 Act/ Standard Requirements and Compliance, includes: • Occupational Safety and Health Act 1994 (Act 514) • MS 2058 - Code			

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	of Practice for Good Engineering Maintenance Management of Active Medical Devices (First Revision) • International Electrotechnical Commission (IEC) 60601, 62353, 61010 - Technical Standards for the Safety and Effectiveness of Medical Electrical Device • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007			
2. Perform BMD Qualitative Tasks	2.1 BMD Qualitative Tasks Requirements/ Procedures, includes: • Manufacturer's Reference	2.1 Interpret BMD Qualitative Tasks Requirements/ Procedures. 2.2 Utilise designated	<u>ATTITUDE</u> • Focus and attentive in performing BMD Qualitative Tasks.	2.1 BMD Qualitative Tasks Requirements/ Procedures explained. 2.2 PPE, TE and Tools Utilisation explained.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Documents • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 2.2 PPE, TE and Tools Utilisation 2.3 BMD Qualitative Tasks (Involving the Checking of), includes: • Chassis/ Housing • Mount/ Fastener • Caster/ Brakes • AC Plugs • Line Cords • Strain Relief • Fuses • Cables • Fitting/ Connectors	PPE, TE and Tools. 2.3 Test BMD components, sub-components, accessories and other related features physical condition. 2.4 Test BMD components, sub-components, accessories and other related features functional conditions. 2.5 Inspect BMD fittings, connectors, alarms, interlocks, label and cables conditions. 2.6 Record BMD Qualitative Tasks results. 2.7 Update PPM Forms/ Checklists. 2.8 Isolate and tag malfunction/ problems BMD.	<u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	2.3 BMD Qualitative Tasks explained. 2.4 PPM Records Updating Procedures explained. 2.5 BMD Tagging and Labelling Procedures explained. 2.6 BMD Qualitative Tasks Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 2.7 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 2.8 BMD components, sub-components, accessories and other related features physical condition tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.9 BMD components, sub-components, accessories and other related features functional conditions tested and confirmed against Manufacturer's Reference Documents and PPM Requirements.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Electrodes • Control/ Switches • Indicators • Labels • Other related features 2.4 PPM Records Updating Procedures, includes: • PPM Forms • PPM Checklist 2.5 BMD Tagging and Labelling Procedures			2.10 BMD fittings, connectors, alarms, interlocks, label and cables conditions inspected and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.11 BMD Qualitative Tasks results recorded and PPM Forms/ Checklists updated. 2.12 BMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 2.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
3. Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3.1 BMD Quantitative Tasks (Preventive Maintenance-PM Tasks) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 3.1 BMD Quantitative Tasks (PM Tasks), includes: • Cleaning • Lubricating • Replacing • Servicing 3.2 BMD Consumables, includes:	3.1 Interpret BMD Quantitative Tasks (PM Tasks) Requirements/ Procedures. 3.2 Utilise designated PPE, TE and Tools. 3.3 Clean BMD interior and exterior, blowers, filters, fans and coils (where applicable). 3.4 Lubricate BMD motors, gears, bearings, casters and other moving components (where applicable). 3.5 Inspect BMD battery compartments (where applicable) and replace battery (if necessary). 3.6 Service BMD maintenance consumables and replace (if necessary). 3.7 Replace BMD PPM Kit (where applicable).	<u>ATTITUDE</u> • Focus and attentive in performing BMD Quantitative Tasks (Preventive Maintenance-PM Tasks). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping	3.1 BMD Quantitative Tasks (Preventive Maintenance-PM Tasks) Requirements/ Procedures explained. 3.2 BMD Quantitative Tasks (PM Tasks) explained. 3.3 BMD Consumables explained. 3.4 BMD Quantitative Tasks (PM Tasks) Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 3.5 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.6 BMD interior and exterior, blowers, filters, fans and coils (where applicable) cleaned from corrosion, dirt, solutions, dust, lint or deposits based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.7 BMD motors, gears, bearings, casters and other moving components (where applicable) lubricated based

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Tubing. • Filters.	3.8 Record BMD Quantitative Tasks (PM Tasks) results. 3.9 Update PPM Forms/ Checklists. 3.10 Isolate and tag malfunction/ problems BMD.	Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.8 BMD battery compartments (where applicable) inspected and battery replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.9 BMD maintenance consumables serviced/ replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.10 BMD PPM Kit (where applicable) replaced based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.11 BMD Quantitative Tasks (PM Tasks) results recorded and PPM Forms/ Checklists updated. 3.12 BMD (malfunction/ problems) isolated and

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
4. Perform BMD Quantitative Tasks (Performance Tests)	4.1 BMD Quantitative Tasks (Performance Tests) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste)	4.1 Interpret BMD Quantitative Tasks (Performance Tests) Requirements/ Procedures. 4.2 Utilise designated PPE, TE and Tools. 4.3 Carry out BMD Quantitative Tasks (Performance Tests). 4.4 Record BMD Quantitative Tasks (Performance Tests) results. 4.5 Update PPM Forms/	<u>ATTITUDE</u> • Focus and attentive in performing BMD Quantitative Tasks (Performance Tests). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety.	4.1 BMD Quantitative Tasks (Performance Tests) Requirements/ Procedures explained. 4.2 BMD Quantitative Tasks (Performance Tests) explained. 4.3 BMD Quantitative Tasks (Performance Tests) Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.4 Designated PPE, TE and

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 4.2 BMD Quantitative Tasks (Performance Tests), includes: • Parameter Operational Specifications • Output Measurement	Checklists.	ENVIRONMENT • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Tools utilised based on OSH Procedures/ Guidelines. 4.5 BMD Quantitative Tasks (Performance Tests) carried out based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.6 BMD Quantitative Tasks (Performance Tests) results recorded and PPM Forms/ Checklists updated. 4.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
5. Perform BMD Quantitative Tasks (Electrical Safety Test-EST)	5.1 BMD Quantitative Tasks (EST) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS IEC 60601 • MS IEC 61010 • MS IEC 62353 • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 5.2 BMD Quantitative Tasks (EST), includes: • Types of Protection Against Electrical Shock (Class I, Class II or Internal Power	5.1 Interpret BID Quantitative Tasks (EST) Requirements/ Procedures. 5.2 Determine BMD protection types provided against electrical shock. 5.3 Determine BMD protection degree against electrical shock. 5.4 Utilise designated PPE and Tools. 5.5 Carry out BMD general safety inspection. 5.6 Record BMD Quantitative Tasks (EST) results. 5.7 Update PPM Forms/ Checklists.	<u>ATTITUDE</u> • Focus and attentive in performing BMD Quantitative Tasks (Electrical Safety Test-EST). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA	5.1 BMD Quantitative Tasks (EST) Requirements/ Procedures explained. 5.2 BMD Quantitative Tasks (EST) explained. 5.3 BMD Quantitative Tasks (EST) Requirements/ Procedures interpreted based on Manufacturer's Reference Documents, MS IEC 60601, MS IEC 61010, MS IEC 62353 and relevant PPM Forms/ Checklists. 5.4 BMD protection types provided against electrical shock determined and confirmed based on Classes. 5.5 BMD protection degree against electrical shock determined and confirmed based on Types. 5.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.7 BMD general safety inspection carried out and results confirmed against Manufacturer's Reference Documents and PPM Requirements. 5.8 BMD Quantitative Tasks

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	(IP) • Degree of Protection Against Electrical Shock (Type B (Body), Type BF (Body Floating), Type CF (Cardiac Floating), Type BF- Defibrillator Proof or Type CF-Defibrillator Proof) • General Safety Inspection		Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	(EST) results recorded and PPM Forms/ Checklists updated. 5.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
6. Perform BMD Parameters Setting-up/ Calibration (Adjustment)	6.1 BMD Setting-up/ Calibration (Adjustment) Requirements/ Procedures, includes: • Manufacturer's Prescribed Standards • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005	6.1 Interpret BMD Setting-up/ Calibration Requirements/ Procedures. 6.2 Utilise designated PPE, Calibration Equipment and Tools. 6.3 Determine BMD accuracy. 6.4 Carry out BMD Setting-up/ Calibration. 6.5 Record BMD	<u>ATTITUDE</u> • Focus and attentive in performing BMD Parameters Setting-up/ Calibration (Adjustment). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety.	6.1 BMD Setting-up/ Calibration (Adjustment) Requirements/ Procedures explained. 6.2 BMD Setting-up/ Calibration (Adjustment) explained. 6.3 Types and Usage of Calibration Equipment explained. 6.4 BMD Setting-up/ Calibration Requirements/ Procedures interpreted based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Solid Waste and Public Cleansing Management Act 2007 6.2 BMD Setting-up/ Calibration (Adjustment), includes: • Built-In Self-Calibrations • Manual Calibrations 6.3 Types and Usage of Calibration Equipment, includes: • Digital Multimeter • Electrical Safety Analyser • Calibrated Mass	Setting-up/ Calibration results. 6.6 Update PPM Forms/ Checklists/ Device Log.	<u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	6.5 Designated PPE, Calibration Equipment and Tools utilised based on OSH Procedures/ Guidelines. 6.6 BMD accuracy within the prescribed standard determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.7 BMD Setting-up/ Calibration carried out through built-in self-calibration or manual calibration using appropriate calibration equipment. 6.8 BMD Setting-up/ Calibration results recorded and PPM Forms/ Checklists/ Device Log (manually/ attaching printed results) updated. 6.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
7. Perform BMD Routine Inspection (RI)	7.1 BMD RI Requirements/ Procedures, includes: • Manufacturer's Recommendations • Standard Practices • Relevant BMD RI Forms/ Checklists • RI Schedules • Locations • Frequency Requirements • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 7.2 BMD Physical Conditions, includes: • Flaws • Cracks • Deformities • Tears 7.3 BMD Compliance, which includes: • Label	7.1 Interpret BMD RI Requirements/ Procedures. 7.2 Determine BMD (not included in the PPM list and PPM Procedures. 7.3 Determine BMD List and RI Schedule. 7.4 Utilise designated PPE, TE and Tools. 7.5 Inspect BMD physical condition visually. 7.6 Inspect BMD label, sticker, notices compliance. 7.7 Inspect BMD general performance. 7.8 Isolate and tag malfunction/ problems BMD. 7.9 Record BMD RI results. 7.10 Update Relevant RI Forms/ Checklists.	<u>ATTITUDE</u> • Focus and attentive in performing BMD Routine Inspection (RI). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/	7.1 BMD RI Requirements/ Procedures explained. 7.2 BMD Physical Conditions explained. 7.3 BMD Compliance explained. 7.4 BMD General Performance explained. 7.5 BMD RI Requirements/ Procedures interpreted based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.6 BMD (not included in the PPM list and PPM Procedures) determined based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.7 BMD List and RI Schedule determined based on location and RI Frequency Requirements. 7.8 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 7.9 BMD physical condition visually inspected based on Manufacturer's Recommendations, Standard

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Sticker • Notices 7.4 BMD General Performance, includes: • Display • Lights • Tones		Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Practices and Relevant RI Forms/ Checklists. 7.10 BMD label, sticker, notices compliance inspected based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.11 BMD general performance inspected based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.12 BMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.13 BMD RI results recorded and Relevant RI Forms/ Checklists updated. 7.14 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

1 Chan, Anthony Charles C. Thomas. 2008. Biomedical Device Technology-Principles and Design. ISBN 978-0-398-07699-3.
2 Khandpur, R.S. McGraw Hill. 2005. Biomedical Instrumentation, Technology and Applications. ISBN 0-07-144-784-9.
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7 Ananda Natarajan, R. 2015. Biomedical Instrumentation and Measurements, 2nd Ed. PHI Learning Pvt. Ltd. ISBN 8120352157, 9788120352155.
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9 Andrew G. Webb. 2018. Principles of Biomedical Instrumentation. Cambridge Texts in Biomedical Engineering. Cambridge University Press. ISBN 110711313X, 9781107113138.
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12 C. Raja Rao, Sujoy K. Guha. 2001. Principles of Medical Electronics and Biomedical Instrumentation. Biomedical Engineering Universities Press. ISBN 8173712573, 9788173712579.
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14 Anthony Y. K. Chan. 2016. Biomedical Device Technology: Principles and Design - Illustration Resources for Instructors. Charles C. Thomas Publisher, Limited. ISBN 0398091250, 9780398091255.
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15.2. Basic Medical Devices (BMD) Unscheduled Maintenance (UM)

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Basic Medical Devices (BMD) Unscheduled Maintenance (UM)		
LEARNING OUTCOMES	The outcome of this competency unit is to perform BMD UM according to MS 2058 and Test Standard/ Protocol. Upon completion of this competency unit, trainees shall be able to: 1. Prepare BMD UM Activities 2. Perform BMD Resetting, General Checking and Rectification 3. Perform BMD Power Section Troubleshooting and Rectification 4. Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification 5. Perform BMD Electro-Mechanical Trouble-shooting and Rectification		
TRAINING PRE-REQUISITE (SPECIFIC)	Completed and Passed C331-006-3:2019-C01 - Basic Medical Devices (BMD) Scheduled Maintenance (SM).		
CU CODE	C331-006-3:2019-C02	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Prepare BMD UM Activities	1.1 BMD UM Activities Requirements, includes: • User Breakdown Request Form • Breakdown Report (During SM) • BMD Maintenance and Components Repaired/ Replace History	1.1 Determine BMD UM Activities Requirements. 1.2 Interpret appropriate BMD UM Reference Documents and Forms/ Checklists. 1.3 Confirm BMD maintenance and components repaired/ replace	ATTITUDE • Focus and attentive in Preparing BMD UM Activities. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks.	1.1 BMD UM Activities Requirements explained. 1.2 BMD Troubles-hooting and Rectification Procedures/ Requirements explained. 1.3 BMD Clinical Application and Operations Specifications explained. 1.4 BMD UM activities determined based on User Breakdown Request Form/

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• BMD Service Records • CM Forms • CM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 1.2 BMD Troubles-hooting and Rectification Procedures/ Requirements 1.3 BMD Clinical Application and Operations Specifications	history. 1.4 Interpret BMD functionality. 1.5 Inspect appropriate PPE, TE and Tools operations and safety. 1.6 Carry out BMD infection risks and decontamination methods/ process.	• Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Breakdown Report (during SM). 1.5 Appropriate Reference Documents and Forms/ Checklists interpreted based on BMD Troubleshooting and Rectification Procedures/ Requirements. 1.6 BMD maintenance and components repaired/ replace history confirmed against BMD Service Records. 1.7 BMD functionality interpreted based on clinical application and operations specifications. 1.8 Appropriate PPE, TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.9 BMD infection risks and decontamination methods/ process determined based on related reference documents. 1.10 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
2. Perform BMD Resetting, General Checking and Rectification	2.1 BMD Resetting, General Checking and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • MS IEC 62353 and MS IEC 61010 • OSHA Guidelines. • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 2.2 BMD Resetting, General Checking and Rectification, includes: • Physical	2.1 Interpret BMD Resetting, General Checking and Rectification Requirements/ Procedures. 2.2 Utilise designated PPE, TE and Tools utilised. 2.3 Inspect BMD components, sub-components, accessories and other related features physical condition and functioning. 2.4 Carry out BMD common repair. 2.5 Replace BMD light bulbs, batteries, probes, electrode, tubing/ consumables (if necessary). 2.6 Carry out BMD resetting (to its original setting). 2.7 Carry out BMD EST.	<u>ATTITUDE</u> • Focus and attentive in performing BMD Resetting, General Checking and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in	2.1 BMD Resetting, General Checking and Rectification Requirements/ Procedures explained. 2.2 BMD Resetting, General Checking and Rectification explained. 2.3 Common Repair/ Replacement Procedures explained. 2.4 BMD Resetting Procedures explained. 2.5 BMD EST Procedures explained. 2.6 BMD Resetting, General Checking and Rectification Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists. 2.7 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 2.8 BMD components, sub-components, accessories and other related features

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Conditions • Functioning • Components • Sub-components • Accessories • Other Related Features 2.3 Common Repair/ Replacement Procedures, includes: • Batteries • Probes • Electrodes • Tubing • BMD Consumables 2.4 BMD Resetting Procedures 2.5 Performance and Calibration Test Procedures 2.6 BMD EST Procedures	2.8 Carry out BMD Performance and Calibration Test. 2.9 Record BMD Resetting, General Checking and Rectification results. 2.10 Update CM Forms/ Checklists.	accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	physical condition and functioning inspected based on Manufacturer's Reference Documents. 2.9 BMD common repair carried out based on Manufacturer's Requirements. 2.10 BMD light bulbs, batteries, probes, electrode, tubing/ consumables replaced (if necessary) based on Manufacturer's Requirements. 2.11 BMD resetting (to its original setting) carried out based on Manufacturer's Requirements. 2.12 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 2.13 BMD Performance and Calibration Test carried out Manufacturer's Requirements. 2.14 BMD Resetting, General Checking and Rectification results recorded and appropriate Forms/ Checklists updated. 2.15 Work area cleaned, all waste removed and disposed-off in

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
3. Perform BMD Power Section Troubleshooting and Rectification	3.1 BMD Power Section Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • Voltage Reference • BMD Service Manual • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007	3.1 Interpret BMD Power Section Troubles-hooting and Rectification Requirements/ Procedures. 3.2 Utilise designated PPE, TE and Tools. 3.3 Check and confirm BMD Power Supply functionality. 3.4 Check and confirm BMD AC/ DC Output. 3.5 Check and confirm BMD Battery Assembly functionality (Off Position). 3.6 Check and confirm BMD Battery Charger Assembly	<u>ATTITUDE</u> • Focus and attentive in performing BMD Power Section Trouble-shooting and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce,	3.1 BMD Power Section Troubleshooting and Rectification Requirements/ Procedures explained. 3.2 BMD Power Section Rectification Procedures explained. 3.3 Power Supply Checking Procedures explained. 3.4 Output DC Voltage Checking Procedures explained. 3.5 Battery Assembly Checking (Off Position) Procedures explained. 3.6 Battery Charger Assembly (On Position) Checking Procedures explained. 3.7 BMD Reassemble and Reset Procedures explained. 3.8 BMD Power Section Troubleshooting and Rectification Requirements/

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	3.2 BMD Power Section Rectification Procedures, includes: • Power Supply • Battery Charger • Battery Assembly 3.3 Power Supply Checking Procedures, includes: • Connection of input voltage supply between live terminal and neutral terminal of input power supply 3.4 Output DC Voltage Checking Procedures, includes: • Voltage between positive terminal connection and negative terminal connection of power supply assembly 3.5 Battery Assembly Checking (Off Position) Procedures, includes: • Connection of	functionality (On Position). 3.7 Carry out BMD Power Section repair. 3.8 Replace BMD consumables (if necessary). 3.9 Reassemble and reset BMD (to its original setting). 3.10 Carry out BMD EST. 3.11 Carry out BMD Performance and Calibration Test. 3.12 Record BMD Power Section Trouble-shooting and Rectification results. 3.13 Update CM Forms/ Checklists.	Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists. 3.9 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.10 BMD Power Supply functionality checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.11 BMD AC/ DC Output Voltage checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.12 BMD Battery Assembly functionality (Off Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.13 BMD Battery Charger Assembly functionality (On Position) checked and confirmed against Voltage Reference, Manufacturer's

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Battery Voltage Output between the positive terminal connection and the negative terminal connection of the battery assembly 3.6 Battery Charger Assembly (On Position) Checking Procedures, includes: • Connection of battery charger output between positive terminal connection and negative terminal connection of battery assembly 3.7 BMD Reassemble and Reset Procedures			Reference Documents and CM Forms/ Checklists. 3.14 BMD Power Section repair carried out based on Manufacturer's Requirements. 3.15 BMD consumables replaced (if necessary) based on Manufacturer's Requirements. 3.16 BMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 3.17 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 3.18 BMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 3.19 BMD Power Section Troubleshooting and Rectification results recorded and CM Forms/ Checklists updated. 3.20 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
4. Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification	4.1 BMD Input Signal Input Status (Applied Part) Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • Voltage Reference • BMD Service Manual • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 4.2 Applied Part Functionality	4.1 Interpret BMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures. 4.2 Utilise designated PPE, TE and Tools. 4.3 Check and confirm BMD Input Signal Status (Applied Part) functionality. 4.4 Carry out BMD Input Signal Status (Applied Part) repair. 4.5 Replace BMD consumables replaced (if necessary). 4.6 Reassemble and reset BMD (to its original setting). 4.7 Carry out BMD EST. 4.8 Carry out BMD Performance and Calibration Test.	<u>ATTITUDE</u> • Focus and attentive in performing BMD Input Signal Status (Applied Part) Troubleshooting and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace	4.1 BMD Input Signal Input Status (Applied Part) Troubleshooting and Rectification Requirements/ Procedures explained. 4.2 Applied Part Functionality Checking Procedures explained. 4.3 BMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists. 4.4 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 4.5 BMD Input Signal Status (Applied Part) functionality checked and confirmed against Manufacturer's Reference Documents and CM Forms/ Checklists. 4.6 BMD Input Signal Status

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Checking Procedures, includes: • Plug-in to BMD • Using Appropriate TE	4.9 Record BMD Input Signal Status (Applied Part) Troubleshooting and Rectification results. 4.10 Update CM Forms/ Checklists.	Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	(Applied Part) repair carried out based on Manufacturer's Requirements. 4.7 BMD consumables replaced (if necessary) based on Manufacturer's Requirements. 4.8 BMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 4.9 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 4.10 BMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 4.11 BMD Input Signal Status (Applied Part) Troubleshooting and Rectification results recorded and Appropriate Forms/ Checklists updated. 4.12 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
5. Perform BMD Electro-Mechanical Trouble-shooting and Rectification	5.1 BMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • Forms/ Checklists • MS IEC 62353 • MS IEC 61010 • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 5.2 DC/ AC Bulbs Functionality Check Procedures, includes: • Supplying Appropriate DC/ AC Voltage & Current to DC/	5.1 Interpret BMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures. 5.2 Utilise designated PPE and Tools. 5.3 Check and confirm DC/ AC Bulbs functionality. 5.4 Check and confirm DC/ AC Motor Assembly functionality. 5.5 Check and confirm Heater Assembly functionality. 5.6 Reassemble and reset BMD to its original setting. 5.7 Carry out BMD EST. 5.8 Carry out BMD Performance and Calibration Test. 5.9 Record BMD Electro-Mechanical	<u>ATTITUDE</u> • Focus and attentive in performing BMD Electro-Mechanical Troubleshooting and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in	5.1 BMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 5.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.3 DC/AC Bulbs functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.4 DC/AC Motor Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.5 Heater Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	AC Bulbs 5.3 DC/AC Motor Assembly Functionality Check Procedures, includes: • Supply Appropriate DC/ AC Voltage & Current to DC/ AC Motor 5.4 Heater Assembly Functionality Check Procedures, includes: • Dismantle Heater Assembly from BMD • Check Resistance of Heater Assembly Between Live, Neutral and Earth Terminal 5.5 BMD Reassemble and Reset Procedures 5.6 BMD EST Procedures 5.7 BMD Performance and Calibration Test Procedures 5.8 BMD Electro-Mechanical	Troubleshooting and Rectification results. 5.10 Update appropriate Forms/ Records.	accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	5.6 BMD reassembled and reset to its original setting as per the Manufacturer's Requirements. 5.7 BMD EST carried out based on MS IEC 62353 and MS IEC 61010. 5.8 BMD Performance and Calibration Test carried out using appropriate TE according to Manufacturer's Requirements. 5.9 BMD Electro-Mechanical Troubleshooting and Rectification results recorded. 5.10 Appropriate Forms/ Records updated. 5.11 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Troubleshooting and Rectification Results Recording/ Updating Procedures			

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

1 Chan, Anthony Charles C. Thomas. 2008. Biomedical Device Technology-Principles and Design. ISBN 978-0-398-07699-3.
2 Khandpur, R.S. McGraw Hill. 2005. Biomedical Instrumentation, Technology and Applications. ISBN 0-07-144-784-9.
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4 Richard Aston. 1999. Electrical Circuit Analysis Using the TI-85 Or TI-86, Volumes 1-86. Prentice Hall. Pennsylvania State University ISBN 0138486980, 9780138486983.
5 Andrew G. Webb. 2018. Principles of Biomedical Instrumentation. Cambridge Texts in Biomedical Engineering. Cambridge University Press. ISBN 110711313X, 9781107113138.
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15.3. Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)		
LEARNING OUTCOMES	The outcome of this CU is to ensure the IMD can be performed smoothly and avoid downtimes according to Manufacturer's Reference Document, MS IEC 60601/ MS IEC 61010/ MS IEC 62353 and relevant PPM Forms/ Checklists. Upon completion of this competency unit, trainees shall be able to: 1. Prepare IMD SM Activities 2. Perform IMD Qualitative Tasks 3. Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks) 4. Perform IMD Quantitative Tasks (Performance Tests) 5. Perform IMD Quantitative Tasks (Electrical Safety Test-EST) 6. Perform IMD Parameters Setting-up/ Calibration 7. Perform IMD Routine Inspection (RI)		
TRAINING PRE-REQUISITE (SPECIFIC)	Completed and Passed C331-006-3:2019-C02 - Basic Medical Devices (BMD) Unscheduled Maintenance (UM).		
CU CODE	C331-006-3:2019-C03	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Prepare IMD SM Activities	1.1 IMD SM Reference Documents, includes: • Manufacturer's Service Manuals • IMD Service Records/ MMIS • IMD Maintenance	1.1 Interpret appropriate IMD SM activities and information. 1.2 Select IMD categories and types. 1.3 Interpret IMD functionality.	ATTITUDE • Focus and attentive in Preparing IMD Activities. • Apply work ethics. SAFETY	1.1 IMD SM Reference Documents explained. 1.2 Types and Functions/ Usage of Intermediate Medical Diagnostic Devices explained. 1.3 Types and functions/ Usage

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Schedule/ Planned Maintenance Schedule • Work Instructions • IMD PPM Forms/ Checklist • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 1.2 Types and Functions/ Usage of **Intermediate Medical Diagnostic Devices**, includes: • Audiometers • Cardiographs • Cardiotocographs • ECG Monitors • Electrocardio-graphs • Pulse Oximeters • Microscopes • Patient Monitors • Non-Invasive	1.4 Inspect appropriate TE and Tools operations and safety. 1.5 Inspect appropriate PPE operations and safety. 1.6 Carry out BMD infection risks and decontamination methods/ process.	• Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	of Intermediate Medical Therapeutic Devices explained. 1.4 Types and Functions/ Usage of Intermediate Medical Laboratory Devices explained. 1.5 Types and Functions/ Usage of Intermediate Biomedical Radiology and Imaging Equipment explained. 1.6 Appropriate IMD SM activities/ information interpreted based on IMD PM Schedule, Work Instructions, Manufacturer's Reference Documents and PPM Forms/ Checklists. 1.7 IMD selected based on categories and types. 1.8 IMD functionality interpreted based on clinical application and operations specifications. 1.9 Appropriate TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.10 Appropriate Personal PPE operations and safety inspected based on OSH Procedures/ Guidelines.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Blood Pressure, Electronics • Foetal Heart Detectors/ Doppler • Slit Lamp 1.3 Types and functions/ Usage of **Intermediate Medical Therapeutic Devices**, includes: • Analgesia Units • Baths • Defibrillators • Dental Equipment - Endodontic, Chairs, Examination/ Treatment, Delivery Units • Dynamometer • Humidifiers • Incubators • Infusion Devices • Microwave Therapy Systems • Diathermy • Oxygen Concentrators			1.11 IMD infection risks and decontamination methods/ process carried out based on situations and infections/ contaminations symptoms.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Stimulators, Electrical Neuromuscular/ Peripheral. • Warming/ Cooling Units • Traction Units • Electrosurgical Units • Aspirator • Tourniquets 1.4 Types and Functions/ Usage of **Intermediate Medical Laboratory Devices**, includes: • Centrifuges • Incubators, Laboratory • Incubators- Aerobic, Anaerobic, Thermocycling • Microscope, Light 1.5 Types and Functions/ Usage of **Intermediate Biomedical Radiology and Imaging Equipment**,			

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	includes: • Cameras - Multi-Image, Video • Film Digitisers • Film Processor • Printers			
2. Perform IMD Qualitative Tasks	2.1 IMD Qualitative Tasks Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 2.2 PPE, TE and Tools Utilisation 2.3 IMD Qualitative Tasks (Involving the Checking of)	2.1 Interpret IMD Qualitative Tasks Requirements/ Procedures. 2.2 Utilise designated PPE, TE and Tools. 2.3 Test IMD components, sub-components, accessories and other related features physical condition. 2.4 Test IMD components, sub-components, accessories and other related features functional conditions. 2.5 Inspect IMD fittings, connectors, alarms, interlocks, label and cables conditions. 2.6 Record IMD	<u>ATTITUDE</u> • Focus and attentive in performing IMD Qualitative Tasks. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace	2.1 IMD Qualitative Tasks Requirements/Procedures explained. 2.2 PPE, TE and Tools Utilisation explained. 2.3 IMD Qualitative Tasks explained. 2.4 PPM Records Updating Procedures explained. 2.5 IMD Tagging and Labelling Procedures explained. 2.6 IMD Qualitative Tasks Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 2.7 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 2.8 IMD components, sub-components, accessories and other related features physical condition tested and

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	includes: • Chassis/ Housing • Mount/ Fastener • Caster/ Brakes • AC Plugs • Line Cords • Strain Relief • Fuses • Cables • Fitting/ Connectors • Electrodes • Control/ Switches • Indicators • Labels • Other related features. 2.4 PPM Records Updating Procedures, includes: • PPM Forms • PPM Checklist 2.5 IMD Tagging and Labelling Procedures	Qualitative Tasks results. 2.7 Update PPM Forms/ Checklists. 2.8 Isolate and tag malfunction/ problems IMD.	Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.9 IMD components, sub-components, accessories and other related features functional conditions tested and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.10 IMD fittings, connectors, alarms, interlocks, label and cables conditions inspected and confirmed against Manufacturer's Reference Documents and PPM Requirements. 2.11 IMD Qualitative Tasks results recorded and PPM Forms/ Checklists updated. 2.12 IMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 2.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.
3. Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3.1 IMD Quantitative Tasks (Preventive Maintenance-PM Tasks) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 3.2 IMD Quantitative Tasks (PM Tasks),	3.1 Interpret IMD Quantitative Tasks (PM Tasks) Requirements/ Procedures. 3.2 Utilise designated PPE, TE and Tools. 3.3 Clean IMD interior and exterior, blowers, filters, fans and coils (where applicable). 3.4 Lubricate IMD motors, gears, bearings, casters and other moving components (where applicable). 3.5 Inspect IMD battery compartments (where applicable) and replace battery (if necessary).	<u>ATTITUDE</u> • Focus and attentive in performing IMD Quantitative Tasks (Preventive Maintenance-PM Tasks). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce,	3.1 IMD Quantitative Tasks (Preventive Maintenance-PM Tasks) Requirements/ Procedures explained. 3.2 IMD Quantitative Tasks (PM Tasks) explained. 3.3 IMD Consumables explained. 3.4 IMD Quantitative Tasks (PM Tasks) Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 3.5 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.6 IMD interior and exterior, blowers, filters, fans and coils (where applicable) cleaned from corrosion, dirt, solutions, dust, lint or deposits based on

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	includes: • Cleaning • Lubricating • Replacing • Servicing 3.3 IMD Consumables, includes: • Tubing • Filters	3.6 Service IMD maintenance consumables and replace (if necessary). 3.7 Replace IMD PPM Kit (where applicable). 3.8 Record IMD Quantitative Tasks (PM Tasks) results. 3.9 Update PPM Forms/ Checklists. 3.10 Isolate and tag malfunction/ problems IMD.	Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.7 IMD motors, gears, bearings, casters and other moving components (where applicable) lubricated based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.8 IMD battery compartments (where applicable) inspected and battery replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.9 IMD maintenance consumables serviced/ replaced (if necessary) based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.10 IMD PPM Kit (where applicable) replaced based on Manufacturer's Recommendations, Standard

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Practices and relevant PPM Forms/ Checklists. 3.11 IMD Quantitative Tasks (PM Tasks) results recorded and PPM Forms/ Checklists updated. 3.12 IMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and relevant PPM Forms/ Checklists. 3.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
4. Perform IMD Quantitative Tasks (Performance Tests)	4.1 IMD Quantitative Tasks (Performance Tests) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS 2058	4.1 Interpret IMD Quantitative Tasks (Performance Tests) Requirements/ Procedures. 4.2 Utilise designated PPE, TE and Tools. 4.3 Carry out IMD	ATTITUDE • Focus and attentive in performing IMD Quantitative Tasks (Performance Tests). SAFETY • Establish immediate	4.1 IMD Quantitative Tasks (Performance Tests) Requirements/ Procedures explained. 4.2 IMD Quantitative Tasks (Performance Tests) explained. 4.3 IMD Quantitative Tasks

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 4.2 IMD Quantitative Tasks (Performance Tests), includes: • Parameter Operational Specifications • Output Measurement	Quantitative Tasks (Performance Tests). 4.4 Record IMD Quantitative Tasks (Performance Tests) results. 4.5 Update PPM Forms/ Checklists.	workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	(Performance Tests) Requirements/Procedures interpreted based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.4 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 4.5 IMD Quantitative Tasks (Performance Tests) carried out based on Manufacturer's Reference Documents and PPM Forms/ Checklists. 4.6 IMD Quantitative Tasks (Performance Tests) results recorded and PPM Forms/ Checklists updated. 4.7 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
5. Perform IMD Quantitative Tasks (Electrical Safety Test-EST)	5.1 IMD Quantitative Tasks (EST) Requirements/ Procedures, includes: • Manufacturer's Reference Documents • MS IEC 60601 • MS IEC 61010 • MS IEC 62353 • MS 2058 • HEPPM • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 5.2 IMD Quantitative Tasks (EST), includes: • Types of Protection Against Electrical Shock (Class I, Class II or Internal Power	5.1 Interpret IMD Quantitative Tasks (EST) Requirements/ Procedures. 5.2 Determine IMD protection types provided against electrical shock. 5.3 Determine IMD protection degree against electrical shock. 5.4 Utilise designated PPE and Tools. 5.5 Carry out IMD general safety inspection. 5.6 Record IMD Quantitative Tasks (EST) results. 5.7 Update PPM Forms/ Checklists.	<u>ATTITUDE</u> • Focus and attentive in performing IMD Quantitative Tasks (Electrical Safety Test-EST). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/OSHA	5.1 IMD Quantitative Tasks (EST) Requirements/ Procedures explained. 5.2 IMD Quantitative Tasks (EST) explained. 5.3 IMD Quantitative Tasks (EST) Requirements/ Procedures interpreted based on Manufacturer's Reference Documents, MS IEC 60601, MS IEC 61010, MS IEC 62353 and relevant PPM Forms/ Checklists. 5.4 IMD protection types provided against electrical shock determined and confirmed based on Classes. 5.5 IMD protection degree against electrical shock determined and confirmed based on Types. 5.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.7 IMD general safety inspection carried out and results confirmed against Manufacturer's Reference Documents and PPM Requirements. 5.8 IMD Quantitative Tasks

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	(IP) • Degree of Protection Against Electrical Shock (Type B (Body), Type BF (Body Floating), Type CF (Cardiac Floating), Type BF- Defibrillator Proof or Type CF-Defibrillator Proof) • General Safety Inspection		Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	(EST) results recorded and PPM Forms/ Checklists updated. 5.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.
6. Perform IMD Parameters Setting-up/ Calibration	6.1 IMD Setting-up/ Calibration (Adjustment) Requirements/ Procedures, includes: • Manufacturer's Prescribed Standards • PPM Forms • PPM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005	6.1 Interpret IMD Setting-up/ Calibration Requirements/ Procedures. 6.2 Utilise designated PPE, Calibration Equipment and Tools. 6.3 Determine IMD accuracy. 6.4 Carry out IMD Setting-up/ Calibration. 6.5 Record IMD Setting-	<u>ATTITUDE</u> • Focus and attentive in performing IMD Parameters Setting-up/ Calibration (Adjustment). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety.	6.1 IMD Setting-up/ Calibration (Adjustment) Requirements/ Procedures explained. 6.2 IMD Setting-up/ Calibration (Adjustment) explained. 6.3 Types and Usage of Calibration Equipment explained. 6.4 IMD Setting-up/ Calibration Requirements/ Procedures interpreted based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Solid Waste and Public Cleansing Management Act 2007 6.2 IMD Setting-up/ Calibration (Adjustment), includes: • Built-In Self-Calibrations • Manual Calibrations 6.3 Types and Usage of Calibration Equipment, includes: • Digital Multimeter • Electrical Safety Analyser • Calibrated Mass	up/ Calibration results. 6.6 Update PPM Forms/ Checklists/ Device Log.	<u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	6.5 Designated PPE, Calibration Equipment and Tools utilised based on OSH Procedures/ Guidelines. 6.6 IMD accuracy within the prescribed standard determined based on recommended device parameters set by the manufacturer and relevant PPM Forms/ Checklists. 6.7 BMD Setting-up/Calibration carried out through built-in self-calibration or manual calibration using appropriate calibration equipment. 6.8 BMD Setting-up/ Calibration results recorded and PPM Forms/ Checklists/ Device Log (manually/ attaching printed results) updated. 6.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
7. Perform IMD Routine Inspection (RI)	7.1 IMD RI Requirements/ Procedures, includes: • Manufacturer's Recommendations • Standard Practices • Relevant IMD RI Forms/ Checklists • RI Schedules • Locations. • Frequency Requirements • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 7.2 IMD Physical Conditions, includes: • Flaws • Cracks • Deformities • Tears 7.3 IMD Compliance, includes: • Label	7.1 Interpret IMD RI Requirements/ Procedures. 7.2 Determine IMD (not included in the PPM list and PPM Procedures. 7.3 Determine IMD List and RI Schedule. 7.4 Utilise designated PPE, TE and Tools. 7.5 Inspect IMD physical condition visually. 7.6 Inspect IMD label, sticker, notices compliance. 7.7 Inspect IMD general performance. 7.8 Isolate and tag malfunction/ problems IMD. 7.9 Record IMD RI results. 7.10 Update Relevant RI Forms/ Checklists.	<u>ATTITUDE</u> • Focus and attentive in performing IMD Routine Inspection (RI). <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/	7.1 IMD RI Requirements/ Procedures explained. 7.2 IMD Physical Conditions explained. 7.3 IMD Compliance explained. 7.4 IMD General Performance explained. 7.5 IMD RI Requirements/ Procedures interpreted based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.6 IMD (not included in the PPM list and PPM Procedures) determined based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.7 IMD List and RI Schedule determined based on location and RI Frequency Requirements. 7.8 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 7.9 IMD physical condition visually inspected based on Manufacturer's Recommendations, Standard

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Sticker • Notices 7.4 IMD General Performance, includes: • Display • Lights • Tones		Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Practices and Relevant RI Forms/ Checklists. 7.10 IMD label, sticker, notices compliance inspected based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.11 IMD general performance inspected based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.12 IMD (malfunction/ problems) isolated and tagged based on Manufacturer's Recommendations, Standard Practices and Relevant RI Forms/ Checklists. 7.13 IMD RI results recorded and Relevant RI Forms/ Checklists updated. 7.14 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				and Public Cleansing Management Act 2007.

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

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6 Richard Aston. 1990. Principles of Biomedical Instrumentation and Measurement, Merrill's International Series in Engineering Technology, Merrill's international series in electrical and electronics technology, Merrill Publishing Company, The University of Michigan. ISBN 0675209439, 9780675209434.
7 Ananda Natarajan, R. 2015. Biomedical Instrumentation and Measurements, 2nd Ed. PHI Learning Pvt. Ltd. ISBN 8120352157, 9788120352155.
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12 C. Raja Rao, Sujoy K. Guha. 2001. Principles of Medical Electronics and Biomedical Instrumentation. Biomedical Engineering Universities Press. ISBN 8173712573, 9788173712579.
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15 Kevin T. Patton. 2015. Anatomy and Physiology - E-Book. Elsevier Health Sciences. ISBN 0323316875, 9780323316873.

15.4. Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)		
LEARNING OUTCOMES	The outcome of this competency unit is to perform IMD UM according to MS 2058 and Test Standard/ Protocol. Upon completion of this competency unit, trainees shall be able to: 1. Prepare IMD UM Activities 2. Perform IMD Resetting, General Checking and Rectification 3. Perform IMD Power Section Troubleshooting and Rectification 4. Perform IMD Input Signal Status (Applied Part) Troubleshooting and Rectification 5. Perform IMD Electro-Mechanical Troubleshooting and Rectification		
TRAINING PRE-REQUISITE (SPECIFIC)	Completed and Passed C331-006-3:2019-C03 - Intermediate Medical Devices (IMD) Scheduled Maintenance (SM).		
CU CODE	C331-006-3:2019-C04	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Prepare IMD UM Activities	1.1 IMD UM Activities Requirements, includes: • User Breakdown Request Form • Breakdown Report (During SM) • IMD Maintenance and Components Repaired/ Replace History	1.1 Determine IMD UM Activities Requirements. 1.2 Interpret appropriate IMD UM Reference Documents and Forms/ Checklists. 1.3 Confirm IMD maintenance and components repaired/ replace	ATTITUDE • Focus and attentive in Preparing IMD UM Activities. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks.	1.1 IMD UM Activities Requirements explained. 1.2 IMD Troubles-hooting and Rectification Procedures/ Requirements explained. 1.3 IMD Clinical Application and Operations Specifications explained. 1.4 IMD UM activities determined based on User Breakdown Request Form/

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• IMD Service Records • CM Forms • CM Checklists • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 1.2 IMD Troubles-hooting and Rectification Procedures/ Requirements 1.3 IMD Clinical Application and Operations Specifications	history. 1.4 Interpret IMD functionality. 1.5 Inspect appropriate PPE, TE and Tools operations and safety. 1.6 Carry out IMD infection risks and decontamination methods/ process.	• Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	Breakdown Report (during SM). 1.5 Appropriate Reference Documents and Forms/ Checklists interpreted based on IMD Troubleshooting and Rectification Procedures/ Requirements. 1.6 IMD maintenance and components repaired/replace history confirmed against IMD Service Records. 1.7 BMD functionality interpreted based on clinical application and operations specifications. 1.8 Appropriate PPE, TE and Tools operations and safety inspected based on OSH Procedures/ Guidelines. 1.9 IMD infection risks and decontamination methods/ process determined based on related reference documents.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
2. Perform IMD Resetting, General Checking and Rectification	2.1 IMD Resetting, General Checking and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • MS IEC 62353 and MS IEC 61010 • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 2.2 IMD Resetting, General Checking and Rectification, includes: • Physical Conditions • Functioning • Components • Sub-components	2.1 Interpret IMD Resetting, General Checking and Rectification Requirements/ Procedures. 2.2 Utilise designated PPE, TE and Tools utilised. 2.3 Inspect IMD components, sub-components, accessories and other related features physical condition and functioning. 2.4 Carry out IMD common repair. 2.5 Replace IMD light bulbs, batteries, probes, electrode, tubing/ consumables (if necessary). 2.6 Carry out IMD resetting (to its original setting). 2.7 Carry out IMD EST. 2.8 Carry out IMD Performance and Calibration Test. 2.9 Record IMD	<u>ATTITUDE</u> • Focus and attentive in performing IMD Resetting, General Checking and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA	2.1 IMD Resetting, General Checking and Rectification Requirements/ Procedures explained. 2.2 IMD Resetting, General Checking and Rectification explained. 2.3 Common Repair/ Replacement Procedures explained. 2.4 IMD Resetting Procedures explained. 2.5 IMD EST Procedures explained. 2.6 IMD Resetting, General Checking and Rectification Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists. 2.7 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 2.8 IMD components, sub-components, accessories and other related features physical condition and functioning inspected based on Manufacturer's Reference Documents.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Accessories • Other Related Features 2.3 Common Repair/ Replacement Procedures, includes: • Batteries • Probes • Electrodes • Tubing • IMD Consumables 2.4 IMD Resetting Procedures 2.5 Performance and Calibration Test Procedures 2.6 IMD EST Procedures	Resetting, General Checking and Rectification results. 2.10 Update CM Forms/ Checklists.	Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	2.9 IMD common repair carried out based on Manufacturer's Requirements. 2.10 IMD light bulbs, batteries, probes, electrode, tubing/ consumables replaced (if necessary) based on Manufacturer's Requirements. 2.11 IMD resetting (to its original setting) carried out based on Manufacturer's Requirements. 2.12 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 2.13 IMD Performance and Calibration Test carried out Manufacturer's Requirements. 2.14 IMD Resetting, General Checking and Rectification results recorded and appropriate Forms/ Checklists updated. 2.15 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				(Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
3. Perform IMD Power Section Troubleshooting and Rectification	3.1 IMD Power Section Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • Voltage Reference • IMD Service Manual • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 3.2 IMD Power Section Rectification Procedures, includes: • Power Supply	3.1 Interpret IMD Power Section Troubles-hooting and Rectification Requirements/ Procedures. 3.2 Utilise designated PPE, TE and Tools. 3.3 Check and confirm IMD Power Supply functionality. 3.4 Check and confirm IMD AC/ DC Output. 3.5 Check and confirm IMD Battery Assembly functionality (Off Position). 3.6 Check and confirm IMD Battery Charger Assembly functionality (On Position). 3.7 Carry out IMD Power Section	ATTITUDE • Focus and attentive in performing IMD Power Section Trouble-shooting and Rectification. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. ENVIRONMENT • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping	3.1 IMD Power Section Troubleshooting and Rectification Requirements/ Procedures explained. 3.2 IMD Power Section Rectification Procedures explained. 3.3 Power Supply Checking Procedures explained. 3.4 Output DC Voltage Checking Procedures explained. 3.5 Battery Assembly Checking (Off Position) Procedures explained. 3.6 Battery Charger Assembly (On Position) Checking Procedures explained. 3.7 IMD Reassemble and Reset Procedures explained. 3.8 IMD Power Section Troubleshooting and Rectification Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	• Battery Charger • Battery Assembly 3.3 Power Supply Checking Procedures, includes: • Connection of input voltage supply between live terminal and neutral terminal of input power supply 3.4 Output DC Voltage Checking Procedures, includes: • Voltage between positive terminal connection and negative terminal connection of power supply assembly 3.5 Battery Assembly Checking (Off Position) Procedures, includes: • Connection of Battery Voltage Output between the positive terminal	repair. 3.8 Replace IMD consumables (if necessary). 3.9 Reassemble and reset IMD (to its original setting). 3.10 Carry out IMD EST. 3.11 Carry out IMD Performance and Calibration Test. 3.12 Record IMD Power Section Trouble-shooting and Rectification results. 3.13 Update CM Forms/ Checklists.	Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	3.9 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.10 IMD Power Supply functionality checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.11 IMD AC/ DC Output Voltage checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.12 IMD Battery Assembly functionality (Off Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.13 IMD Battery Charger Assembly functionality (On Position) checked and confirmed against Voltage Reference, Manufacturer's Reference Documents and CM Forms/ Checklists. 3.14 IMD Power Section repair carried out based on

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	connection and the negative terminal connection of the battery assembly 3.6 Battery Charger Assembly (On Position) Checking Procedures, includes: • Connection of battery charger output between positive terminal connection and negative terminal connection of battery assembly 3.7 IMD Reassemble and Reset Procedures			Manufacturer's Requirements. 3.15 IMD consumables replaced (if necessary) based on Manufacturer's Requirements. 3.16 IMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 3.17 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 3.18 IMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 3.19 IMD Power Section Troubleshooting and Rectification results recorded and CM Forms/ Checklists updated. 3.20 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Management Act 2007.
4. Perform IMD Input Signal Status (Applied Part) Troubleshooting and Rectification	4.1 IMD Input Signal Input Status (Applied Part) Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • CM Forms • CM Checklists • Voltage Reference • IMD Service Manual • OSHA Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 4.2 Applied Part Functionality Checking Procedures, includes: • Plug-in to IMD • Using Appropriate	4.1 Interpret IMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures. 4.2 Utilise designated PPE, TE and Tools. 4.3 Check and confirm IMD Input Signal Status (Applied Part) functionality. 4.4 Carry out IMD Input Signal Status (Applied Part) repair. 4.5 Replace IMD consumables replaced (if necessary). 4.6 Reassemble and reset IMD (to its original setting). 4.7 Carry out IMD EST. 4.8 Carry out IMD Performance and Calibration Test. 4.9 Record IMD Input Signal Status (Applied Part) Troubleshooting and	<u>ATTITUDE</u> • Focus and attentive in performing IMD Input Signal Status (Applied Part) Troubleshooting and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace	4.1 IMD Input Signal Input Status (Applied Part) Troubleshooting and Rectification Requirements/ Procedures explained. 4.2 Applied Part Functionality Checking Procedures explained. 4.3 IMD Input Signal (Applied Part) Troubleshooting and Rectification Procedures interpreted based on Manufacturer's Reference Documents and CM Forms/ Checklists. 4.4 Designated PPE, TE and Tools utilised based on OSH Procedures/ Guidelines. 4.5 IMD Input Signal Status (Applied Part) functionality checked and confirmed against Manufacturer's Reference Documents and CM Forms/ Checklists. 4.6 IMD Input Signal Status (Applied Part) repair carried out based on Manufacturer's Requirements. 4.7 IMD consumables replaced

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	TE	Rectification results. 4.10 Update CM Forms/ Checklists.	Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	(if necessary) based on Manufacturer's Requirements. 4.8 IMD reassembled and reset (to its original setting) based on Manufacturer's Requirements. 4.9 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 4.10 IMD Performance and Calibration Test carried out based on Manufacturer's Requirements. 4.11 IMD Input Signal Status (Applied Part) Troubleshooting and Rectification results recorded and Appropriate Forms/ Checklists updated. 4.12 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
5. Perform IMD Electro-Mechanical Troubleshooting and Rectification	5.1 IMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures, includes: • Manufacturer's Reference Documents • Forms/ Checklists • MS IEC 62353 • MS IEC 61010 • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 5.2 DC/ AC Bulbs Functionality Check Procedures, includes: • Supplying Appropriate DC/ AC Voltage & Current to DC/ AC Bulbs 5.3 DC/ AC Motor Assembly Functionality Check	5.1 Interpret IMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures. 5.2 Utilise designated PPE and Tools. 5.3 Check and confirm DC/ AC Bulbs functionality. 5.4 Check and confirm DC/ AC Motor Assembly functionality. 5.5 Check and confirm Heater Assembly functionality. 5.6 Reassemble and reset IMD to its original setting. 5.7 Carry out IMD EST. 5.8 Carry out IMD Performance and Calibration Test. 5.9 Record IMD Electro-Mechanical Troubleshooting and Rectification results. 5.10 Update appropriate Forms/ Records.	<u>ATTITUDE</u> • Focus and attentive in performing IMD Electro-Mechanical Troubleshooting and Rectification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA	5.1 IMD Electro-Mechanical Troubleshooting and Rectification Requirements/ Procedures interpreted based on Manufacturer's Reference Documents and Forms/ Checklists. 5.2 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.3 DC/ AC Bulbs functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.4 DC/ AC Motor Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.5 Heater Assembly functionality checked and confirmed against Manufacturer's Reference Documents and Forms/ Checklists. 5.6 IMD reassembled and reset to its original setting as per the Manufacturer's Requirements.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Procedures, includes: • Supply Appropriate DC/ AC Voltage & Current to DC/ AC Motor 5.4 Heater Assembly Functionality Check Procedures, includes: • Dismantle Heater Assembly from IMD • Check Resistance of Heater Assembly Between Live, Neutral and Earth Terminal 5.5 IMD Reassemble and Reset Procedures 5.6 IMD EST Procedures 5.7 IMD Performance and Calibration Test Procedures 5.8 IMD Electro-Mechanical Troubleshooting and Rectification Results Recording/ Updating Procedures		Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	5.7 IMD EST carried out based on MS IEC 62353 and MS IEC 61010. 5.8 IMD Performance and Calibration Test carried out using appropriate TE according to Manufacturer's Requirements. 5.9 IMD Electro-Mechanical Troubleshooting and Rectification results recorded. 5.10 Appropriate Forms/ Records updated. 5.11 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

1 Chan, Anthony Charles C. Thomas. 2008. Biomedical Device Technology-Principles and Design. ISBN 978-0-398-07699-3.
2 Khandpur, R.S. McGraw Hill. 2005. Biomedical Instrumentation, Technology and Applications. ISBN 0-07-144-784-9.
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4 Richard Aston. 1999. Electrical Circuit Analysis Using the TI-85 Or TI-86, Volumes 1-86. Prentice Hall. Pennsylvania State University ISBN 0138486980, 9780138486983.
5 Andrew G. Webb. 2018. Principles of Biomedical Instrumentation. Cambridge Texts in Biomedical Engineering. Cambridge University Press. ISBN 110711313X, 9781107113138.
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12 Ernesto Iadanza, Joseph F. Dyro. 2004. Clinical Engineering Handbook. Academic Press. ISBN 012226570X, 9780122265709.
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15.5. Medical Devices (MD) Disposal and Waste Administration

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Medical Devices (MD) Disposal and Waste Administration		
LEARNING OUTCOMES	The outcome of this competency unit is to perform MD Disposal and Waste Administration according to MS 2650/MS 2058/Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007 Recommended Practises/ Other Related Regulations. Upon completion of this competency unit, trainees shall be able to: 1. Prepare MD Disposal 2. Perform Waste Identification 3. Perform MD Collection and Transportation 4. Perform MD Storage 5. Perform MD Decontamination 6. Perform MD Disposal Processes 7. Handle Spillage Waste 8. Handle MD Disposal Documentations and Records		
TRAINING PRE-REQUISITE (SPECIFIC)	Completed and Passed C331-006-3:2019-C04 - Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM).		
CU CODE	C331-006-3:2019-C05	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Prepare MD Disposal	1.1 MD Disposal Requirements/ Procedures, includes: • MS 2650 • Work Order • Workplace Housekeeping Procedures/ OSHA Guidelines • Other Related Reference Documents. • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 1.2 MD Disposal Workflow 1.3 MD Removal, Decontamination Area and Storage Arrangements 1.4 MD Decontamination and Disposal Arrangements	1.1 Interpret MD Disposal Requirements/ Procedures. 1.2 Determine MD due for disposal. 1.3 Determine MD disposal workflow. 1.4 Carry out MD removal and dedicated decontamination area storage arrangements. 1.5 Carry out MD decontamination and disposal arrangements. 1.6 Inspect appropriate PPE and Tools operations and safety.	<u>ATTITUDE</u> • Focus and attentive in Preparing MD Disposal. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality	1.1 MD Disposal Requirements/ Procedures explained based on Related Reference Documents. 1.2 MD Disposal Workflow explained based on MS 2650/ Related Reference Documents. 1.3 MD Removal, Decontamination Area and Storage Arrangements explained based on MS 2650/Related Reference Documents. 1.4 MD Decontamination and Disposal Arrangements explained based on MS 2650/ Related Reference Documents. 1.5 MD Disposal Requirements/Procedures interpreted based on MS 2650/ Related Reference Documents. 1.6 MD due for disposal determined based on Work Order Requirements. 1.7 MD disposal workflow determined based on MS 2650/ Related Reference Documents.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			(Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	1.8 MD removal and dedicated decontamination area storage arrangements carried out. 1.9 MD decontamination and disposal arrangements carried out. 1.10 Appropriate PPE and Tools operations and safety inspected based on OSH Procedures/ Guidelines.
2. Perform Waste Identification	2.1 Waste Identification Requirements/ Procedures, includes: • Environmental Quality (Scheduled Waste) Regulations 2005 • Solid Waste and Public Cleansing Management Act 2007 2.2 Types of Waste and Handling/ Decontamination Processes, includes: • Active and Non-active Devices • Used Non-active MD • Unused Non-	2.1 Utilise designated PPE and Tools. 2.2 Determine MD status. 2.3 Isolate used active MD. 2.4 Determine and handle used non-active MD. 2.5 Determine and handle unused non-active MD. 2.6 Determine and handle scheduled waste. 2.7 Label and tag MD	<u>ATTITUDE</u> • Focus and attentive in Performing Waste Identification. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce,	2.1 Waste Identification Requirements/Procedures explained based on Environmental Quality (Scheduled Waste) Regulations 2005/ Solid Waste and Public Cleansing Management Act 2007. 2.2 Types of Waste and Handling/ Decontamination Processes explained based on Environmental Quality (Scheduled Waste) Regulations 2005/ Solid Waste and Public Cleansing Management Act 2007. 2.3 Labelling and tagging procedure explained based on MS 2650/ Related Reference Documents.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	active MD • Scheduled Waste • Un-scheduled Waste • Clinical Waste 2.3 Labelling and Tagging Procedure		Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	2.4 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 2.5 MD status determined based on its usage (active/ non-active devices). 2.6 Used active MD determined and isolated for disinfections process. 2.7 MD Labelled and Tagged based on its status. 2.8 Used non-active MD determined and handled in accordance with Environmental Quality (Scheduled Waste) Regulations 2005. 2.9 Unused non-active MD determined and handled in accordance with Solid Waste and Public Cleansing Management Act 2007. 2.10 Scheduled waste determined and handled in accordance with Environmental Quality (Scheduled Waste) Regulation 2005.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
3. Perform MD Collection and Transportation	3.1 MD Collection and Transportation Requirements/ Procedures, includes: • OSH Procedures/ Guidelines • Manufacturer's Instructions • Environmental Quality Act 1974 (Act 127) 3.2 Fixed MD Dismantling Procedures 3.3 MD Cleaning and Labelling Procedures 3.4 MD Transport Vehicles Safety Requirements 3.5 Transported MD Documentations	3.1 Utilise designated PPE and Tools. 3.2 Dismantled fixed MD. 3.3 Clean and label collected MD. 3.4 Utilise appropriate transport vehicles. 3.5 Transport MD for disposal to suitable storage facility. 3.6 Document MD being transported. 3.7 Clean/ decontaminate transport vehicles.	<u>ATTITUDE</u> • Focus and attentive in Performing MD Collection and Transportation. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/	3.1 MD Collection and Transportation Requirements/ Procedures explained based on Related Reference Documents. 3.2 Fixed MD Dismantling Procedures explained based on Manufacturer's Recommendations. 3.3 MD Cleaning and Labelling Procedures explained based on Related Reference Documents. 3.4 MD Transport Vehicles Safety Requirements explained based on Environmental Quality Act 1974 (Act 127). 3.5 Transported MD Documentations explained based on Environmental Quality Act 1974 (Act 127). 3.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 3.7 Fixed MD dismantled in accordance with Manufacturer's Instructions. 3.8 Collected MD cleaned and labelled with appropriate notifications.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	3.9 Appropriate transport vehicles utilised based on Environmental Quality Act 1974 (Act 127). 3.10 MD for disposal transported to suitable storage facility in a safe manner. 3.11 MD being transported documented with user department information, period of storage and scheduled date for decontamination and decommissioning. 3.12 Transport vehicles cleaned/ decontaminate after each transportation based on Environmental Quality Act 1974 (Act 127). 3.13 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
4. Perform MD Storage	4.1 MD Storage Requirements/ Procedures, includes: • Handling and Management of Clinical Waste Guidelines • OSH Procedures/ Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 4.2 MD Storage/ Holding Facility Management 4.3 MD Storage and Arrangement Procedures 4.4 MD Loading/ Unloading Management	4.1 Interpret MD Storage Requirements/ Procedures. 4.2 Utilise designated PPE and Tools. 4.3 Clean dedicated MD storage/ holding facility water-resistant floor shelving. 4.4 Secure MD storage/ holding facility and accessible to only authorised personnel. 4.5 Prepare dedicated hand decontamination facility (hand wash basin). 4.6 Place and arrange MD properly at storage area. 4.7 Prepare and clean trolleys and other equipment to assist in loading/ unloading MD.	ATTITUDE • Focus and attentive in Performing MD Storage. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. ENVIRONMENT • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality	4.1 MD Storage Requirements/ Procedures explained based on Related Reference Documents. 4.2 MD Storage/ Holding Facility Management explained based on Related Reference Documents. 4.3 MD Storage and Arrangement Procedures explained based on Related Reference Documents. 4.4 MD Loading/ Unloading Management explained based on Related Reference Documents. 4.5 MD Storage Requirements/ Procedures interpreted based on Handling and Management of Clinical Waste Guidelines. 4.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 4.7 Dedicated MD storage/ holding facility water-resistant floor shelving cleaned. 4.8 MD storage/ holding facility secured and accessible to only authorised personnel.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			(Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	4.9 Dedicated hand decontamination facility (hand wash basin) prepared. 4.10 MD properly placed and arranged at storage area. 4.11 Trolleys and other equipment to assist in loading/ unloading MD prepared and cleaned. 4.12 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.
5. Perform MD Decontamination	5.1 MD Decontamination Requirements/ Procedures, includes: • MS 2650 • MS 2058 • OSH Procedures/ Guidelines • Environmental Quality (Scheduled Waste)	5.1 Determine decontaminated MD status. 5.2 Determine MD decontamination methods/ processes. 5.3 Utilise designated PPE and Tools. 5.4 Carry out appropriate MD decontamination procedures/ process.	<u>ATTITUDE</u> • Focus and attentive in Performing MD Decontamination. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks.	5.1 MD Decontamination Requirements/ Procedures explained based on Related Reference Documents. 5.2 Decontaminated MD Status explained based on MS 2650/ MS 2058. 5.3 MD Decontamination Methods/ Processes explained based on MS 2650/ MS 2058/ Related Reference

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Regulation 2005. • Solid Waste and Public Cleansing Management Act 2007 • Other Related Regulations 5.2 Decontaminated MD Status 5.3 MD Decontamination Methods/ Processes		• Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	Documents. 5.4 MD to be decontaminated determined based on its status. 5.5 MD decontamination methods/ processes determined based on MS 2650/ MS 2058/ Other Related Regulations. 5.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 5.7 Appropriate MD decontamination procedures/ process carried out in accordance with MS 2058 Recommended Practises/ Other Related Regulations. 5.8 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
6. Perform MD Disposal Processes	6.1 MD Disposal Requirements/ Procedures, includes: • OSH Procedures/ Guidelines • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 6.2 Scheduled Waste Disposal Methods/ Processes 6.3 Non-scheduled Waste Disposal Methods/ Processes 6.4 Clinical Waste Disposal Methods/ Processes	6.1 Utilise designated PPE and Tools. 6.2 Dispose-off Scheduled Waste. 6.3 Dispose-off Non-scheduled Waste. 6.4 Dispose-off Clinical Waste.	<u>ATTITUDE</u> • Focus and attentive in Performing MD Disposal Processes. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality	6.1 MD Disposal Requirements/ Procedures explained based on OSH Procedures/ Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007. 6.2 Scheduled Waste Disposal Methods/ Processes explained based on Environmental Quality (Scheduled Waste) Regulation 2005. 6.3 Non-scheduled Waste Disposal Methods/Processes explained based on Solid Waste and Public Cleansing Management Act 2007. 6.4 Clinical Waste Disposal Methods/ Processes explained based on Environmental Quality (Scheduled Waste) Regulations 2005. 6.5 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 6.6 Scheduled Waste disposed-off in accordance with Environmental Quality

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			(Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	(Scheduled Waste) Regulation 2005. 6.7 Non-scheduled Waste disposed-off in accordance with Solid Waste and Public Cleansing Management Act 2007. 6.8 Clinical Waste disposed-off in accordance with Environmental Quality (Scheduled Waste) Regulations 2005. 6.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.
7. Handle Spillage Waste	7.1 Spillage Waste Handling Requirements/ Procedures, includes: • MS 2058 • Recommended Practises • OSH Procedures/	7.1 Interpret hazardous material spillage handling requirements/ procedures. 7.2 Utilise designated PPE and Tools/ spillage kit.	<u>ATTITUDE</u> • Focus and attentive in Handling Spillage Waste. <u>SAFETY</u> • Establish immediate workplace surrounding	7.1 Spillage Waste Handling Requirements/Procedures based on MS 2058/ Recommended Practises/ OSH Procedures/ Guidelines/ Regulatory Requirements, Policies and Procedures/ Other Related Regulations.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Guidelines • Regulatory Requirements, Policies and Procedures • Environmental Quality (Scheduled Waste) Regulation 2005 • Solid Waste and Public Cleansing Management Act 2007 • Other Related Regulations 7.2 Types and Handling of Hazardous Material Spillage, includes: • Mercury • Body Liquids • Drugs • Chemical materials 7.3 Scheduled Waste Spillage Reporting Procedures 7.4 Spillage Waste Area Cleansing Methods/ Procedures	7.3 Report Scheduled Waste spillage for investigation. 7.4 Make safe spillage waste area.	safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.	7.2 Types and Handling of Hazardous Material Spillage explained based on MS 2058/ Recommended Practises/ OSH Procedures/ Guidelines/ Regulatory Requirements, Policies and Procedures/ Other Related Regulations. 7.3 Scheduled Waste Spillage Reporting Procedures based on MS 2058/ Recommended Practises/ OSH Procedures/ Guidelines/ Regulatory Requirements, Policies and Procedures/ Other Related Regulations. 7.4 Spillage Waste Area Cleansing Methods/ Procedures explained based on MS 2058/ Recommended Practises/ OSH Procedures/ Guidelines/ Regulatory Requirements, Policies and Procedures/ Other Related Regulations. 7.5 Hazardous material spillage handling requirements/ procedures interpreted based on MS 2058/ Recommended Practises/ Other Related Regulations.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				7.6 Designated PPE and Tools utilised based on OSH Procedures/ Guidelines. 7.7 Scheduled Waste spillage immediately reported for investigation, in accordance with relevant regulatory requirements, policies and procedures. 7.8 Spillage waste area made safe in accordance with spillage procedures/ relevant regulatory requirements, policies and procedures. 7.9 Work area cleaned, all waste removed and disposed-off in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid Waste and Public Cleansing Management Act 2007.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
8. Handle MD Disposal Documentations and Records	8.1 MD Disposal Documentations and Records Handling Requirements/ Procedures, includes: • Environment Quality (Scheduled Waste) Regulations 2005 • MS 2058 • Other Related Regulations 8.2 MD Disposal Documentations and Records Handling/ Maintenance Methods/ Processes. 8.3 MMIS updating procedure	8.1 Determine MD Disposal Documentations and Records Handling Requirements/ Procedures. 8.2 Compile and update MD Disposal Documentations and Records. 8.3 Maintain MD Disposal Documentations and Records.	<u>ATTITUDE</u> • Focus and attentive in Handling MD Disposal Documentations and Records. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Eliminate infection risks. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/	8.1 MD Disposal Documentations and Records Handling Requirements/ Procedures explained based on Environment Quality (Scheduled Waste) Regulations 2005/ Other Related Regulations. 8.2 MD Disposal Documentations and Records Handling/ Maintenance Methods/ Processes explained based on Environment Quality (Scheduled Waste) Regulations 2005/ Other Related Regulations. 8.3 MMIS updating procedure explained based on MS 8.4 MD Disposal Documentations and Records Handling Requirements/ Procedures determined based on MS 2058/ Other Related Reference Documents. 8.5 MD Disposal Documentations and Records compiled and updated based on Related Regulations. 8.6 MD Disposal Documentations and Records

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	maintained and retained based on Related Regulations.

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

1 NIIR Board of Consultants & Engineers. 2018. Handbook on Recycling and Disposal of Hospital Waste, Municipal Solid Waste Biomedical Waste, Plastic Waste. Niir Project Consultancy Services. ISBN 9381039879, 9789381039878.

2 Keith Willson, Keith Ison, Slavik Tabakov. 2013. Medical Equipment Management. CRC Press. ISBN 1420099582, 9781420099584.

3 Singh, Singh Anantpreet, Kaur Sukhjit. 2012. Biomedical Waste Disposal. Jaypee Brothers Publishers. ISBN 9350255545, 9789350255544.

4 Peter A. Reinhardt. 2018. Infectious and Medical Waste Management. CRC Press. ISBN 1351090437, 9781351090438.

5 M.N. Rao, Razia Sultana, Sri Harsha Kota, Anil Shah, Naresh Davergave. 2016. Solid and Hazardous Waste Management: Science and Engineering. Butterworth-Heinemann. ISBN 0128098767, 9780128098769.

6 Yves Chartier. 2014. Safe Management of Wastes from Health-care Activities. World Health Organization. ISBN 9241548568, 9789241548564.

7 Mohd. Faisal Khan. 2004. Hospital Waste Management: Principles and Guidelines. Kanishka Publishers, Distributors. ISBN 8173916322, 9788173916328.

15.6. Medical Devices Maintenance (MDM) Administrative Coordination

SECTION	(C) Manufacturing		
GROUP	(331) Repair and Installation of Machinery and Equipment		
AREA	Medical Devices Engineering Services (MDES)		
NOSS TITLE	Medical Devices Maintenance		
COMPETENCY UNIT TITLE	Medical Devices Maintenance (MDM) Administrative Coordination		
LEARNING OUTCOMES	The outcome of this competency unit is to perform MDM Administrative Coordination according to Manufacturer's Manual, MS 2058 and Related Reference Documents. Upon completion of this competency unit, trainees shall be able to: 1. Maintain MD Parts and Inventory Database and Technical Documentations 2. Coordinate MD Warranty Maintenance Activities 3. Coordinate MD Recalls		
TRAINING PRE-REQUISITE (SPECIFIC)	Completed and Passed C331-006-3:2019-C05 - Medical Devices (MD) Disposal and Waste Administration.		
CU CODE	C331-006-3:2019-C06	NOSS LEVEL	Three (3)

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
1. Maintain MD Parts and Inventory Database and Technical Documentations	1.1 MD Parts and Inventory Database and Technical Documentations Requirements/Procedures, includes: • Manufacturer's Manual • MS 2058 • MD History Records • Related Database 1.2 MD Parts and	1.1 Interpret MD Parts Inventory Database and Technical Documentations Requirements. 1.2 Project MD parts consumption. 1.3 Carry out MD parts and inventory stock taking. 1.4 Audit MD parts and inventory list. 1.5 Check MD Technical	ATTITUDE • Focus and attentive in Maintaining MD Parts and Inventory Database and Technical Documentations. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Determine and observe personal safety.	1.1 MD Parts and Inventory Database and Technical Documentations Requirements/ Procedures explained based on Manufacturer's Manual/ MS 2058/ MD History Record/ Related Database. 1.2 MD Parts and Inventory Database and Technical Documentations explained based on Manufacturer's Manual/ MS 2058/ MD

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	Inventory Database and Technical Documentations, includes: • Parts Consumptions • MD Parts and Inventory Stock Taking • MD Parts and Inventory Records Updating 1.3 MD Parts and Inventory Audit Procedures	Documentations to the latest version. 1.6 Update MD Technical Documentation and Inventory List.	ENVIRONMENT • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	History Record/ Related Database. 1.3 MD Parts and Inventory Audit Procedures based on Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records. 1.4 MD Parts Inventory Database and Technical Documentations Requirements interpreted based on Manufacturer's Manual and Related Reference Documents. 1.5 MD parts consumption projected based on Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records. 1.6 MD parts and inventory stock taking carried out Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records. 1.7 MD parts and inventory list audited to confirm availability based on Manufacturer's

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
				Recommendations and/or Historic Consumption, Manual and History Records. 1.8 MD Technical Documentations checked to the latest version. 1.9 MD Technical Documentation and Inventory List updated based on Manufacturer's Recommendations and/ or Historic Consumption, Manual and History Records.
2. Coordinate MD Warranty Maintenance Activities	2.1 MD Warranty Maintenance Activities Coordination Requirements, includes: • Manufacturer's Manual • Manufacturer's Recommendations • Department's Administrative Procedures • Department's Regulations • Related Reference Documents	2.1 Interpret MD Warranty Maintenance activities and Schedule Requirements. 2.2 Carry out MD registration. 2.3 Coordinate MD Maintenance Schedule. 2.4 Update MD Maintenance Schedule. 2.5 Control MD Warranty.	<u>ATTITUDE</u> • Focus and attentive in Coordinating MD Warranty Maintenance Activities. <u>SAFETY</u> • Establish immediate workplace surrounding safety and hazards-free. • Determine and observe personal safety. <u>ENVIRONMENT</u> • Clean work area. • Reduce waste. • All waste removed and	2.1 MD Warranty Maintenance Activities Coordination Requirements explained based on Manufacturer's Manual and Related Reference Documents. 2.2 MD Maintenance Schedule Requirements explained based on Manufacturer's Manual and Related Reference Documents. 2.3 MD Maintenance Schedule Coordination and Updating explained Manufacturer's Recommendations, Risks, Ages, Usage Frequency and Location.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
	2.2 MD Maintenance Schedule Requirements 2.3 MD Maintenance Schedule Coordination and Updating 2.4 MD Warranty Coordination		disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/Solid Waste and Public Cleansing Management Act 2007.	2.4 MD Warranty Coordination explained based on Manufacturer's Recommendation and Department's Regulations. 2.5 MD Warranty Maintenance activities and Schedule Requirements interpreted based on Manufacturer's Manual and Related Reference Documents. 2.6 MD Registration carried out base on Manufacturer's Manual and Related Reference Documents. 2.7 MD Maintenance Schedule coordinated based on Manufacturer's Recommendations, Risks, Ages, Usage Frequency and Location. 2.8 MD Maintenance Schedule updated according to Department's Administrative Procedures. 2.9 MD Warranty controlled in accordance with the Manufacturer's Recommendation and Department's Regulations.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
3. Coordinate MD Recalls	3.1 Updating Alerts and Device Recalls Coordination Procedures, includes: • Check Alerts and MD Recall Notices • Determine MD • Check and Tag Recalled MD • Record and update MD Inventory List	3.1 Determine and confirm alerts and MD recall notices. 3.2 Dismantle/ collect and segregate MD to quarantine area. 3.3 Isolate, tag and label recalled MD. 3.4 Report/ refer MD recall cases to appropriate personal for further actions. 3.5 Update Related Forms/ Reports/ Inventory List.	ATTITUDE • Focus and attentive in Coordinating MD Recalls. SAFETY • Establish immediate workplace surrounding safety and hazards-free. • Determine and observe personal safety. ENVIRONMENT • Clean work area. • Reduce waste. • All waste removed and disposed-off. • Apply 3R (Reduce, Reuse and Recycle) Concept. • Apply Workplace Housekeeping Procedures in accordance with Workplace Housekeeping Procedures/ OSHA Guidelines/ Environmental Quality (Scheduled Waste) Regulation 2005/ Solid	3.1 Updating Alerts and Device Recalls Coordination Procedures explained based on Related Reference Documents. 3.2 Alerts and MD recall notices determined and confirmed against MD Inventory List. 3.3 MD dismantled/ collected and segregated to quarantine area. 3.4 Recalled MD isolated, tagged and labelled. 3.5 MD recall cases reported/ referred to appropriate personal for further actions. 3.6 Related Forms/ Reports/ Inventory List updated.

WORK ACTIVITIES	RELATED KNOWLEDGE	RELATED SKILLS	ATTITUDE/ SAFETY/ ENVIRONMENT	ASSESSMENT CRITERIA
			Waste and Public Cleansing Management Act 2007.	

Employability Skills:

Core Abilities:

- Please refer NCS- Core Abilities latest edition.

Social Values & Social Skills:

- Please refer Handbook on Social Skills and Social Values in Technical Education and Vocational Training.

References for Learning Material Development:

1 Binseng Wang. 2012. Medical Equipment Maintenance: Management and Oversight. Morgan & Claypool Publishers. ISBN 1627050566, 9781627050562.
2 Keith Willson, Keith Ison, Slavik Tabakov. 2013. Medical Equipment Management. CRC Press. ISBN 1420099590, 9781420099591.
3 Beth Ann Fiedler. 2016. Managing Medical Devices within a Regulatory Framework. Elsevier. ISBN 0128041927, 9780128041925.

16. Delivery Mode

The following are the **recommended** training delivery modes:-

KNOWLEDGE	SKILL
• Lecture • Group discussion • E-learning, self-paced • E-learning, facilitate • Case study or Problem based learning (PBL) • Self-paced learning, non-electronic • One-on-one tutorial • Shop talk • Seminar	• Demonstration • Simulation • Project • Scenario based training (SBT) • Role play • Coaching • Observation • Mentoring

Skills training and skills assessment of trainees should be implemented in accordance with TEM requirements and actual situation.

17. Tools, Equipment and Materials (TEM)

MEDICAL DEVICES MAINTENANCE

LEVEL 3

CU No.	CU CODE	COMPETENCY UNIT TITLE
CU1	C331-006-3:2019-C01	Basic Medical Devices (BMD) Scheduled Maintenance (SM)
CU2	C331-006-3:2019-C02	Basic Medical Devices (BMD) Unscheduled Maintenance (UM)
CU3	C331-006-3:2019-C03	Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)
CU4	C331-006-3:2019-C04	Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)
CU5	C331-006-3:2019-C05	Medical Devices (MD) Disposal and Waste Administration
CU6	C331-006-3:2019-C06	Medical Devices Maintenance (MDM) Administrative Coordination

* Items listed refer to TEM's **minimum requirement** for skills delivery only.

Bil	ITEM*	RATIO (TEM : Trainees or AR = As Required)		
		CU1	CU2	CU3
A. Tools				
1	Hand Tools	1:1	1:1	1:1
B. Equipment				
1	Computer	1:1		
2	Scales	1:10	1:10	
3	Laryngoscopes	1:10	1:10	
4	Eye Charts	1:10	1:10	
5	Ophthalmoscopes	1:10	1:10	
6	Light Sources	1:10	1:10	
7	Meters Aneroid	1:10	1:10	
8	Audiometers	1:10	1:10	
9	Cardiographs	1:10	1:10	
10	Cardiotocographs	1:10	1:10	

11	ECG Monitors	1:10	1:10	
12	Electrocardio-graphs	1:10	1:10	
13	Pulse Oximeters	1:10	1:10	
14	Microscopes	1:10	1:10	
15	Patient Monitors	1:10	1:10	
16	Non-Invasive Blood Pressure, Electronics	1:10	1:10	
17	Fatal Heart Detectors/Doppler	1:10	1:10	
18	Slit Lamp	1:10	1:10	
19	Baths, Paraffin, Physical Therapy, Water	1:10	1:10	
20	Cast Cutters	1:10	1:10	
21	Lights - Headlights, Dental, Infrared, Surgical	1:10	1:10	
22	Mattress Systems	1:10	1:10	
23	Nebulizers	1:10	1:10	
24	Phototherapy Units	1:10	1:10	
25	Pumps - Breast	1:10	1:10	
26	Warming blanket	1:10	1:10	
27	Enteral Pump	1:10	1:10	
28	Nerve Stimulator	1:10	1:10	
29	Analgesia Units	1:10	1:10	
30	Baths	1:10	1:10	
31	Defibrillators	1:10	1:10	
32	Dental Equipment - Endodontic, Chairs, Examination/Treatment, Delivery Units	1:10	1:10	
33	Dynamometer	1:10	1:10	
34	Humidifiers	1:10	1:10	
35	Incubators	1:10	1:10	
36	Infusion Devices	1:10	1:10	
37	Microwave Therapy Systems	1:10	1:10	
38	Diathermy	1:10	1:10	
39	Oxygen Concentrators	1:10	1:10	

40	Stimulators, Electrical Neuromuscular/ Peripheral	1:10	1:10	
41	Warming/Cooling Units	1:10	1:10	
42	Traction Units	1:10	1:10	
43	Electrosurgical Units	1:10	1:10	
44	Aspirator	1:10	1:10	
45	Tourniquets	1:10	1:10	
46	Balances	1:10	1:10	
47	Baths, Water	1:10	1:10	
48	Hot Plates	1:10	1:10	
49	Mixers	1:10	1:10	
50	pH Meters	1:10	1:10	
51	Rotators	1:10	1:10	
52	Separators	1:10	1:10	
53	Shakers	1:10	1:10	
54	Slide Strainers	1:10	1:10	
55	Stirrers	1:10	1:10	
56	Centrifuges	1:10	1:10	
57	Incubators, Laboratory	1:10	1:10	
58	Incubators- Aerobic, Anaerobic, Thermocycling	1:10	1:10	
59	Microscope, Light	1:10	1:10	
60	Cameras - Multi-Image, Video	1:10	1:10	
61	Film Digitisers	1:10	1:10	
62	Film Processor	1:10	1:10	
63	Printers	1:10	1:10	
64	Surgical Masks	1:1	1:1	1:1
65	Gloves	1:1	1:1	1:1
66	Safety Shoes	1:1	1:1	1:1
67	BMD Consumables	1:10	1:10	
68	IMD Consumables	1:10	1:10	
69	Decontamination Kits	1:10	1:10	

70	Spillage Kits	1:10	1:10	
C. Materials				
1	Alcohol	AR	AR	
2	Swab	AR	AR	
3	Manufacturer's Service Documents	1:5	1:5	1:5
4	PPM Forms	1:1	1:1	
5	PPM Checklist	1:1	1:1	

18. Competency Weightage

The following table shows the percentage of training priorities based on consensus made by the Standard Development Committee (SDC).

MEDICAL DEVICES MAINTENANCE

LEVEL 3

CU CODE	COMPETENCY UNIT TITLE	COMPETENCY UNIT WEIGHTAGE	WORK ACTIVITIES	WORK ACTIVITIES WEIGHTAGE
C331-006-3:2019-C01	Basic Medical Devices (BMD) Scheduled Maintenance (SM)	30%	Prepare BMD SM Activities	13%
			Perform BMD Qualitative Tasks	3%
			Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3%
			Perform BMD Quantitative Tasks (Performance Tests)	3%
			Perform BMD Quantitative Tasks (Electrical Safety Test-EST)	3%
			Perform BMD Parameters Setting-up/ Calibration	3%
			Perform BMD Routine Inspection (RI)	2%
C331-006-3:2019-C02	Basic Medical Devices (BMD) Unscheduled Maintenance (UM)	14%	Prepare BMD UM Activities	2%
			Perform BMD Resetting, General Checking and Rectification	3%
			Perform BMD Power Section Troubleshooting and Rectification	3%
			Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification	3%
			Perform BMD Electro-Mechanical Trouble-shooting and Rectification	3%

C331-006-3:2019-C03	Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)	20%	Prepare IMD SM Activities	2%
			Perform IMD Qualitative Tasks	3%
			Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	3%
			Perform IMD Quantitative Tasks (Performance Tests)	3%
			Perform IMD Quantitative Tasks (Electrical Safety Test-EST)	3%
			Perform IMD Parameters Setting-up/ Calibration	3%
			Perform IMD Routine Inspection (RI)	3%
C331-006-3:2019-C04	Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)	14%	Prepare IMD UM Activities	2%
			Perform IMD Resetting, General Checking and Rectification	3%
			Perform IMD Power Section Troubleshooting and Rectification	3%
			Perform IMD Input Signal Status (Applied Part) Troubleshooting and Rectification	3%
			Perform IMD Electro-Mechanical Troubleshooting and Rectification	3%
C331-006-3:2019-C05	Medical Devices (MD) Disposal and Waste Administration	16%	Prepare MD Disposal	2%
			Perform Waste Identification	2%
			Perform MD Collection and Transportation	2%
			Perform MD Storage	2%
			Perform MD Decontamination	2%
			Perform MD Disposal Processes	2%
			Handle Spillage Waste	2%
			Handle MD Disposal Documentations and Records	2%

C331-006-3:2019-C06	Medical Devices Maintenance (MDM) Administrative Coordination	6%	Maintain MD Parts and Inventory Database and Technical Documentations	2%
			Coordinate MD Warranty Maintenance Activities	2%
			Coordinate MD Recalls	2%
TOTAL PERCENTAGE (CORE COMPETENCY)		100%		
CORE ABILITY		160 Hrs		

Sample Calculation for Summary of Training Hours

The following table shows the nominal training hours based on recommendations made by the Standard Development Committee (SDC). For purpose of Malaysian Skills Certification through accredited centre training, the program duration is subject to Malaysian Skills Certification System.

MEDICAL DEVICES MAINTENANCE

LEVEL 3

CU CODE	COMPETENCY UNIT TITLE	WORK ACTIVITY	WORK ACTIVITY TRAINING DURATION (HOURS)		TRAINING DURATION (HOURS)	SKILLS CREDIT
			KNOWLEDGE	SKILLS		
C331-006-3:2019-C01	Basic Medical Devices (BMD) Scheduled Maintenance (SM)	Prepare BMD SM Activities	104	208	720	72
		Perform BMD Qualitative Tasks	24	48		
		Perform BMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	24	48		
		Perform BMD Quantitative Tasks (Performance Tests)	24	48		
		Perform BMD Quantitative Tasks (Electrical Safety Test-EST)	24	48		

		Perform BMD Parameters Setting-up/ Calibration	24	48		
		Perform BMD Routine Inspection (RI)	16	32		
C331-006-3:2019-C02	Basic Medical Devices (BMD) Unscheduled Maintenance (UM)	Prepare BMD UM Activities	16	32	330	33
		Perform BMD Resetting, General Checking and Rectification	24	48		
		Perform BMD Power Section Troubleshooting and Rectification	24	48		
		Perform BMD Input Signal Status (Applied Part) Troubleshooting and Rectification	24	48		
		Perform BMD Electro-Mechanical Trouble-shooting and Rectification	24	48		
C331-006-3:2019-C03	Intermediate Medical Devices (IMD) Scheduled Maintenance (SM)	Prepare IMD SM Activities	16	32	480	48
		Perform IMD Qualitative Tasks	24	48		
		Perform IMD Quantitative Tasks (Preventive Maintenance-PM Tasks)	24	48		

		Perform IMD Quantitative Tasks (Performance Tests)	24	48		
		Perform IMD Quantitative Tasks (Electrical Safety Test-EST)	24	48		
		Perform IMD Parameters Setting-up/ Calibration	24	48		
		Perform IMD Routine Inspection (RI)	24	48		
C331-006-3:2019-C04	Intermediate Medical Devices (IMD) Unscheduled Maintenance (UM)	Prepare IMD UM Activities	16	32	330	33
		Perform IMD Resetting, General Checking and Rectification	24	48		
		Perform IMD Power Section Troubleshooting and Rectification	24	48		
		Perform IMD Input Signal Status (Applied Part) Troubleshooting and Rectification	24	48		
		Perform IMD Electro-Mechanical Troubleshooting and Rectification	24	48		

C331-006-3:2019-C05	Medical Devices (MD) Disposal and Waste Administration	Prepare MD Disposal	16	32	380	38
		Perform Waste Identification	16	32		
		Perform MD Collection and Transportation	16	32		
		Perform MD Storage	16	32		
		Perform MD Decontamination	16	32		
		Perform MD Disposal Processes	16	32		
		Handle Spillage Waste	16	32		
		Handle MD Disposal Documentations and Records	16	32		
C331-006-3:2019-C06	Medical Devices Maintenance (MDM) Administrative Coordination	Maintain MD Parts and Inventory Database and Technical Documentations	16	32	140	14
		Coordinate MD Warranty Maintenance Activities	16	32		
		Coordinate MD Recalls	16	32		
TOTAL HOURS (CORE COMPETENCY)			800	1600	2380	238
TOTAL HOURS OF COMPETENCY UNIT					2380	
CORE ABILITY					160	

The sample calculations performed are based on table in section 18 for delivery of Level 3 training program at 2400 hours excluding delivery of core abilities.

Annex A

List of Active/ Non-Active Medical Devices/ Biomedical Equipment Required Maintenance (Not Limited To)

Diagnostic Medical Devices (Biomedical Equipment)		
Basic Diagnostic Medical Devices (Biomedical Equipment)	**Intermediate Diagnostic Medical Devices (Biomedical Equipment)**	**Advanced Diagnostic Medical Devices (Biomedical Equipment)**
1. Scales. 2. Laryngoscopes. 3. Eye Charts. 4. Ophthalmoscopes. 5. Light Sources. 6. Meters Aneroid.	1. Audiometers. 2. Cardiographs. 3. Cardiotocographs. 4. ECG Monitors. 5. Electrocardiographs. 6. Pulse Oximeters. 7. Microscopes. 8. Patient Monitors. 9. Non-Invasive Blood Pressure, Electronics. 10. Fetal Heart Detectors/Doppler. 11. Slit Lamp.	1. Analysers, Point of Care, Whole Blood, Cardiac. 2. Cardiac Output Units. 3. Endoscopy. 4. Eye Equipment-Scanning Laser, Optical. 5. Stereotactic Systems.

Therapeutic Medical Devices (Biomedical Equipment)		
Basic Therapeutic Medical Devices (Biomedical Equipment)	**Intermediate Therapeutic Medical Devices (Biomedical Equipment)**	**Advanced Therapeutic Medical Devices (Biomedical Equipment)**
1. Baths, Paraffin, Physical Therapy, Water. 2. Cast Cutters. 3. Lights - Headlights, Dental, Infrared, Surgical. 4. Mattress Systems. 5. Nebulizers. 6. Phototherapy Units. 7. Pumps - Breast. 8. Warming blanket 9. Enteral Pump. 10. Nerve Stimulator.	1. Analgesia Units. 2. Baths. 3. Defibrillators. 4. Dental Equipment - Endodontic, Chairs, Examination/Treatment, Delivery Units. 5. Dynamometer. 6. Humidifiers. 7. Incubators. 8. Infusion Devices. 9. Microwave Therapy Systems. Diathermy. 10. Oxygen Concentrators. 1. Stimulators, Electrical Neuromuscular/ Peripheral. 2. Warming/Cooling Units. 3. Traction Units. 4. Electrosurgical Units. 5. Aspirator. 6. Tourniquets.	1. Anaesthesia Units. 2. Apheresis Units. 3. Cryosurgical Units. 4. Defibrillator/Pacemaker. 5. Dialysis. 6. Electrosurgical Units. 7. Endoscopy. 8. ENT Equipment. 9. Vaporisers. 10. Ventilators.

`Laboratory Medical Devices (Biomedical Equipment)		
Basic Laboratory Medical Devices (Biomedical Equipment)	**Intermediate Laboratory Medical Devices (Biomedical Equipment)**	**Advanced Laboratory Medical Devices (Biomedical Equipment)**
1. Balances. 2. Baths, Water. 3. Hot Plates. 4. Mixers. 5. pH Meters. 6. Rotators. 7. Separators. 8. Shakers. 9. Slide Strainers. 10. Stirrers.	1. Centrifuges. 2. Incubators, Laboratory. 3. Incubators- Aerobic, Anaerobic, Thermocycling. 4. Microscope, Light.	1. Concentrators, Specimens 2. Analysers, Laboratory. 3. Calibrators. 4. Cytometers. 5. Densitometers, Laboratory. 6. Homogenisers. 7. Microscopes, Fluorescence. 8. Osmometers. 9. Spectroflurometers. 10. Spectrometers. 11. Chromatography Systems. 12. Tissue Embedding Equipment. 13. Tissue Processor.

Radiology and Imaging Medical Devices (Biomedical Equipment)		
Basic Radiology and Imaging Medical Devices (Biomedical Equipment)	**Intermediate Radiology and Imaging Medical Devices (Biomedical Equipment)**	**Advanced Radiology and Imaging Medical Devices (Biomedical Equipment)**
None	1. Cameras - Multi-Image, Video. 2. Film Digitisers. 3. Film Processor. 4. Printers.	1. Radiographic Systems, Film. 2. Scanning Systems, Ultrasonic. 3. Brachytherapy Systems. 4. Densitometers, Bone. 5. Radiographic Units.