



CANDIDATE HANDBOOK

(EHB001)

Revision 2.0, 3rd January 2025

ACCB CERTIFICATION SDN BHD

NO. 77-2, JALAN MH 1, TAMAN MUZAFFAR HEIGHT, AYER KEROH, MUKIM BUKIT KATIL,

75450 MELAKA TENGAH, MELAKA

TEL: +60 12-589 2964

EMAIL: info@accbcert.com

CONTENTS

| NO | ITEM | PAGE |
|-----------|--|-------------|
| 1 | Examination Rules and Regulations | 4 |
| 2 | Use of Certification Certificate | 5 |
| 3 | Penalties and Appeal | 5 |
| 4 | Confidentiality | 5 |
| 5 | Fees and Refund | 5 |
| 6 | Pre-requisite Requirement | 5 |
| | 6.1 Competency Table | 6 |
| | 6.2 Competency Certification Category Table | 9 |
| 7 | Scopes of Examination | 12 |
| 8 | Certification Scheme | 13 |
| | 8.1 Certification Scope for Level 1 | 13 |
| | 8.2 Certification Scope for Level 2 | 13 |
| | 8.3 Certification Scope for Electrical Safety Testing (IEC 60601, IEC 62353 & IEC 61010) | 14 |
| | 8.4 Certification Scope for Safety Healthcare | 14 |
| | 8.5 Certification Scope for Human Anatomy and Physiology | 14 |
| | 8.6 Certification Scope for Healthcare for Biomedical | 15 |
| 9 | Certification | 15 |
| | 9.1 Application Process | 15 |
| | 9.2 Eligibility Appeals | 15 |
| | 9.3 Examination Preparation | 15 |
| | 9.4 Security | 17 |
| | 9.5 Scoring and Results | 17 |
| | 9.6 Change of Contact Information | 18 |
| | 9.7 Use of Designation as Certified Person | 18 |
| | 9.8 Maintaining Your Certification | 18 |
| 10 | Recertification | 19 |
| | 10.1 Recertification Requirements | 19 |
| | 10.2 Recertification Procedures | 20 |
| 11 | Complaint | 20 |
| | 11.1 Complaints Related to Certification Process | 20 |
| | 11.2 Complainant | 21 |
| 12 | Special Arrangement | 21 |
| | 12.1 Request special arrangement | 21 |
| | 12.2 Request on site Examination | 22 |
| 13 | Appeal | 22 |
| | 13.1 Type of Appeal | 22 |
| | 13.2 Scheme Committee Consideration of the Appeal | 22 |
| 14 | Confidentiality | 22 |

| NO | ITEM | PAGE |
|----|------------------------------|------|
| | APPENDICES – Scheme Outlines | |
| | Appendix 1 - BEM-BDIA01 | 24 |
| | Appendix 2 - BEM-BTHE01 | 25 |
| | Appendix 3 - BEM-BLAB01 | 27 |
| | Appendix 4 - BEM-ITHDU02 | 29 |
| | Appendix 5 - BEM-ITVEN02 | 30 |
| | Appendix 6 - BEM-OEST03 | 32 |
| | Appendix 7 - BEM-CCMSHC01 | 33 |
| | Appendix 8 - BEM-CCMHAF01 | 35 |
| | Appendix 9 – BEM-CCMIHC01 | 36 |
| | Appendix 10 – BEM-ITABG02 | 38 |

1) Examination Rules and Regulations

- a) Examination candidates should attend for at least thirty (30) minutes before the designated starting time.
- b) No book, bag/handbag, notes, or other unauthorised material may be brought into the Examination Room without the prior approval of the Invigilator
- c) Candidates must ensure that there is no writing on any rulers, set-squares, calculators and other such instruments (if permitted) brought into the Examination Room
- d) Communication or any behaviour/activity which causes inconvenience/disruption with another candidate is not permitted. If requires assistance; candidate should attract the attention of Invigilator, taking care not to disturb other candidates.
- e) Mobile phones, electronic devices or any mobile communication devices are not permitted in the examination room.
- f) Candidates,
 - i) will not be permitted to enter the Examination Room after thirty (30) minutes of examination time has started;
 - ii) will not be permitted to leave the Examination Room during the last thirty (30) minutes of the Examination and;
 - iii) at the end of examination, must remain seated until examination material has been collected by Invigilator and until permitted to do so.
- g) A candidate must under no circumstances leave his/her seat unless permitted to do so by the Invigilator. Candidate wishing to leave his/her seat should raise hand to attract the Invigilator's attention.
- h) All examination material must be handed up to an Invigilator after the candidate has finished his/her examination.
- i) No candidate shall take out of the Examination Room any answer book(s) or part of an answer book, whether used or unused or other supplied material.
- j) For the purposes of identification and registration during examinations, all candidates are required to present the slip examination and identity card.
- k) Where an open book examination is scheduled, all parties must be informed, prior to the examination, of the material permissible in the Examination Room. Any such material may be examined by the Invigilator or any such other person(s) authorised by ACCB.
- l) Application fee will not be refunded if the candidate fails to attend the examination as per schedule. However, candidate may reschedule the date by notifying ACCB within 5 workings days from the scheduled examination date.
- m) Any complaint concerning the examinations should be brought to the attention of the Invigilator immediately.
- n) Any infringement or violation of these regulations may have serious consequences and may be withdrawn from the examination.
- o) It is in the interests of all examination candidates to co-operate to ensure that the examinations are conducted in a proper and orderly manner.
- p) All candidates are deemed to have read and to have agreed to abide by these and other examination regulations as determined by the ACCB from time to time.

2) Use of Certification Certificate

The Certified Person agrees that:

- a) To comply with the relevant provisions of the certification scheme
- b) To makes claims regarding certification only with respect to the scope or which certification has been granted
- c) Not to use the certification in such a manner as to bring the ACCB into disrepute, and not to make any statement regarding the certification which the ACCB considers misleading or unauthorized.
- d) To discontinues the use of all claims to certification that contain any reference to the ACCB or certification upon suspension or withdrawal of certification and returned any certificates issued by ACCB
- e) Not to use the certificate in a misleading manner

3) Penalties and Appeal

In case of improper use of the Certification mark, the ACCB may forthwith suspend or withdraw the certification and the right to use the Certification Mark in accordance with the sanctions procedures that will be provided by the ACCB upon request. The Certified Person may appeal the ACCB's decision in accordance with the appeal procedure that will be provided by the ACCB upon request.

4) Confidentiality

Certified Person shall keep confidential all documents received from the ACCB with the exception of the Certificate, these Regulations and the Appendices thereof.

5) Fees and Refund

Applicants who are not eligible for the examination will be refunded 70% of the application fees.

Applicants who do not attend the examination without prior notice, are not eligible for any refund of the application fee.

Candidates who failed the examination are not entitled for any refund of the application fees.

6) Pre-requisite Requirement

Pre-requisites are the qualifications or competence required by a certification scheme for persons before can be certified:

- a) Have attended technical training related to the code of certification applied (from any Training Provider).
- b) Fulfil the qualification and experience as stipulated in Competency Table for all certification except Compulsory Competency Module (CCM).

6.1 Competency Table

| BTP Qualification | | BTP Competency Levels | | | | | | | | | |
|-------------------|---|-----------------------|---------------------------|---------|----------------------------------|---------|---------------------------------------|------------------------------|---------------------------------------|------------|------------|
| | | Maintenance | | | | | | | | Management | |
| | | Level 1 | | Level 2 | | Level 3 | | Product Technical Specialist | | Exp | Cert |
| | | Exp ^a | Cert ^b | Exp | Cert | Exp | Cert | Exp | Cert | | |
| 1 | Degree in Biomedical Engineering/Medical Electronics Engineering or equivalent | 6 months | Passed Basic Device + CCM | 1 year | Passed Intermediate Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 5 years | Passed CCM |
| 2 | Degree in Engineering Technology (Biomedical/Medical Electronics) or equivalent | 6 months | Passed Basic Device + CCM | 1 year | Passed Intermediate Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 5 years | Passed CCM |
| 3 | Degree in Electronics Engineering | 9 months | Passed Basic Device + CCM | 2 years | Passed Intermediate Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 5 years | Passed CCM |
| 4 | Diploma in Biomedical Engineering/Medical Electronics/Electronics (Major in Biomedical) | 9 months | Passed Basic Device + CCM | 2 years | Passed Intermediate Device + CCM | 5 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 10 years | Passed CCM |

| BTP Qualification | | BTP Competency Levels | | | | | | | | | |
|-------------------|--|-----------------------|------------------------------------|-------------|---|------------|---|------------------------------|---|-------------|---------------|
| | | Maintenance | | | | | | | | Management | |
| | | Level 1 | | Level 2 | | Level 3 | | Product Technical Specialist | | | |
| | | Exp ^a | Cert ^b | Exp | Cert | Exp | Cert | Exp | Cert | Exp | Cert |
| 5 | Diploma in Biomedical/ Engineering Technology in Medical Electronics | 9 months | Passed Basic Device + CCM | 2 years | Passed Intermediate Device + CCM | 5 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 10 years | Passed CCM |
| 6 | Diploma in Electronics Engineering | 1 years | Passed Basic Device + CCM | 2½ years | Passed Intermediate Device + CCM | 5 years | Passed Intermediate/High Device + CCM | 3 years | Passed Intermediate/High Device + CCM | 10 years | Passed CCM |
| 7 | Certificate in Biomedical Equipment Maintenance | 2 years | Passed Basic Device + CCM | 7 years | Passed Intermediate Device + CCM | | | | | | |
| 8 | Certificate in Electronic | 3 years | Passed Basic Device + CCM | 7 years | Passed Intermediate Device + CCM | | | | | | |

| BTP Qualification | | BTP Competency Levels | | | | | | | | | | | |
|-------------------|---------------------------------------|-----------------------|---------------------------|---------|----------------------------------|---------|------|------------------------------|------|------------|------|--|--|
| | | Maintenance | | | | | | | | Management | | | |
| | | Level 1 | | Level 2 | | Level 3 | | Product Technical Specialist | | | | | |
| | | Exp ^a | Cert ^b | Exp | Cert | Exp | Cert | Exp | Cert | Exp | Cert | | |
| 9 | Certificate in another relevant field | 3 years | Passed Basic Device + CCM | 7 years | Passed Intermediate Device + CCM | | | | | | | | |

NOTES:

- 1 Passed Basic device is optional
- 2 Minimum topic under degree and diploma: (a) Electronics, Digital and Communication; (b) Anatomy and Physiology
- 3 Experiences can be obtained under the supervision and responsibility of a competent BTP in the same/higher competency level
- 4 Any other relevant engineering field will depend on approval of MBCB/ Biomedical Engineering National Committee (BENC)
- 5 This requirement is only applicable for existing BTP. The entry level for new staff intake starting year 2020 shall be from Biomedical Engineering/Medical Electronics or equivalent field only

^a This means "experience". Experience refers to accumulative years of related experiences.

^b This means "certificate A and/or B, C, D".

6.2 Competency Certification Category Table

| Device Complexity | Certification Category | Biomedical Engineering competency certifications description |
|-------------------|---------------------------|---|
| BASIC | Basic Certificate and CCM | Basic Active medical device Maintenance Certification. Provided by competent certifying body recognized by MOH. (Certificate of Competency Biomedical Engineering Maintenance Level 1/2/3 - Radiology and Imaging, Laboratory, Diagnostic and Therapeutic) (optional) |
| | | Compulsory Competency Module (CCM) |

| Device Complexity | Certification Category | Biomedical Engineering competency certifications description |
|---------------------|---------------------------|--|
| INTERMEDIATE | A (Level 1, 2, 3, PTS) | Intermediate Active medical device Maintenance Certification. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 1, 2, 3 - Radiology and Imaging) |
| | B (Level 1, 2, 3, PTS) | Intermediate Active medical device Maintenance Certification. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 1, 2, 3 - Laboratory) |
| | C (Level 1, 2, 3, PTS) | Intermediate Active medical device Maintenance Certification. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 1, 2, 3 - Diagnostics) |
| | D (Level 1, 2, 3, PTS) | Intermediate Active medical device Maintenance Certification. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 1, 2, 3 – Laboratory) |

6.2 Competency Certification Category Table (continued)

| Device Complexity | Certification Category | Biomedical Engineering competency certifications description |
|-------------------|------------------------|--|
| HIGH | A (Level 3) | High Active medical device Specialization Maintenance Certification in Radiology (Ionising & Non-Ionising) and Imaging medical device. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 3 - Radiology and Imaging) |
| | B (Level 3) | High Active medical device Specialization Maintenance Certification in Laboratory equipment and devices. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 3 - Laboratory) |
| | C (Level 3) | High Active medical device Specialization Maintenance Certification in Diagnostic medical devices. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 3 - Diagnostic) |
| | D (Level 3) | High Active medical device Specialization Maintenance Certification in Therapeutic medical devices. Provided by competent certifying body recognized by MOH (Certificate of Competency Biomedical Engineering Maintenance Level 3 - Therapeutic) |
| | A (PTS) | High Active medical device Specialization Maintenance Certification in any specialization of medical devices. Provided by equipment manufacturer and endorsed by competent certifying body recognized by MOH [Certificate of Competency Biomedical Engineering Maintenance for Product Technical Specialist (PTS) - Radiology and Imaging (by Medical Device Model)] |
| | B (PTS) | High Active medical device Specialization Maintenance Certification in any specialization of medical devices. Provided by equipment manufacturer and endorsed by competent certifying body recognized by MOH [Certificate of Competency Biomedical Engineering Maintenance for Product Technical Specialist (PTS) - Laboratory (by Medical Device Model)] |

6.2 Competency Certification Category Table (continued)

| Device Complexity | Certification Category | Biomedical Engineering competency certifications description |
|-------------------|------------------------|--|
| HIGH | C (PTS) | High Active medical device Specialization Maintenance Certification in any specialization of medical devices. Provided by equipment manufacturer and endorsed by competent certifying body recognized by MOH [Certificate of Competency Biomedical Engineering Maintenance for Product Technical Specialist (PTS) - Diagnostics (by Medical Device Model)] |
| | D (PTS) | High Active medical device Specialization Maintenance Certification in any specialization of medical devices. Provided by equipment manufacturer and endorsed by competent certifying body recognized by MOH [Certificate of Competency Biomedical Engineering Maintenance for Product Technical Specialist (PTS) - Therapeutic (by Medical Device Model)] |

| Device Complexity | Certification Category | Biomedical Engineering competency certifications description |
|-------------------|------------------------|---|
| MANAGEMENT | M (LEVEL 1) | Capable of General technical support and facilities, Scheduled maintenance management, Unscheduled maintenance management, Communication skills, Biomedical Engineering Services documentations, Hospital Biomedical Engineering Services administrative functions |
| | M (LEVEL 2) | M (LEVEL 1) and also capable of Education and training for Biomedical Engineering, Staff supervision and monitoring, Relevant contractual management and implementation, Standard, quality and risk management, Advisory services on available Biomedical Engineering technology, Planning, evaluation, procurement and asset management of medical devices |
| | M (LEVEL 3) | M (LEVEL 1 & 2) and also capable of Service management: To provide organization with vision, leadership and resources to achieve planned service goals and objectives, Biomedical Engineering research and development |

CONTROLLED DOCUMENT

7) **Scopes of Examination**

| No | Code of Certification | Scope of Certification |
|----|-----------------------|---|
| 1 | BEM-ITHDU02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Therapeutic-Dialysis) Level 2 |
| 2 | BEM-ITVEN02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Therapeutic-Ventilator) Level 2 |
| 3 | BEM-OEST03 | Competency on Biomedical Engineering Maintenance for Electrical Safety Testing (IEC 60601, IEC 62353 & IEC 61010) |
| 4 | BEM-CCMHAF01 | Compulsory Competency Module for Human Anatomy and Physiology for Biomedical Technical Personnel (BTP) |
| 5 | BEM-CCMIHC01 | Compulsory Competency Module for Introduction of Healthcare for Biomedical Technical Personnel (BTP) |
| 6 | BEM-CCMSHC01 | Compulsory Competency Module for Safety Healthcare for Biomedical Technical Personnel (BTP) |
| 7 | BEM-ITABG02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Blood Gas Analyzer) Level 2 |
| 8 | BEM-BLAB01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Laboratory) Level 1 |
| 9 | BEM-BDIA01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Diagnostic) Level 1 |
| 10 | BEM-BTHE01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Therapeutic) Level 1 |

8) Certification Scheme

Each certification requires a complete application and separate examination. Exams are offered in English only.

8.1 Certification Scope for Level 1

| No | Certification Code | Certification Scope | Details |
|----|--------------------|--|------------|
| 1 | BEM-BLAB01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Laboratory) Level 1 | APPENDIX 1 |
| 2 | BEM-BDIA01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Diagnostic) Level 1 | APPENDIX 2 |
| 3 | BEM-BTHE01 | Competency on Biomedical Engineering Maintenance for Basic Active Medical Device (Therapeutic) Level 1 | APPENDIX 3 |

The assessment strategy for these certifications is through the Written Examination in two (2) hours with 100 multiple choice objective questions to evaluate the knowledge and skill of the candidate. The passing mark is 70%

8.2 Certification Scope for Level 2

| No | Certification Code | Certification Scope | Details |
|----|--------------------|--|-------------|
| 1 | BEM-ITHDU02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Therapeutic-Dialysis) Level 2 | APPENDIX 4 |
| 2 | BEM-ITVEN02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Therapeutic-Ventilator) Level 2 | APPENDIX 5 |
| 3 | BEM-ITABG02 | Competency on Biomedical Engineering Maintenance for Intermediate Active Medical Device (Blood Gas Analyzer) Level 2 | APPENDIX 10 |

This certification is consisting of Written Examination and Oral Assessment to evaluate the knowledge and skill of the candidate. Candidate shall attend both the Written Examination and Oral Assessment with total passing marks is 70%.

a) Written Examination

Examination is two (2) hours and it is a closed book exam consisting of 100 multiple choice questions to evaluate the knowledge and skill of the candidate. Candidates need to answer 35 questions correctly to achieve a passing mark of 70%.

b) Oral Assessment

Candidate will be given 30 minutes to study one scenario related to the certification scope. Based on the scenario, candidate will have to answer 5 questions via interview session in 30 minutes. Candidate need to get passing mark of 70% to pass the examination.

Candidate need to re-seat for failed exam only (e.g., Candidate has failed Written Examination but passed Oral Assessment, candidate only need to re-seat for Written Examination and vice versa).

8.3 Certification Scope for Electrical Safety Testing (IEC 60601, IEC 62353 & IEC 61010)

| No | Certification Code | Certification Scope | Details |
|----|--------------------|---|------------|
| 1 | BEM-OEST03 | Competency on Biomedical Engineering Maintenance for Electrical Safety Testing (IEC 60601, IEC 62353 & IEC 61010) | APPENDIX 6 |

The assessment strategy is through the Written Examination in 1(one) hour, with 50 multiple choice objective questions to evaluate the knowledge and skill of the candidate. Candidates need to answer 35 questions correctly to achieve a passing mark of 70%.

8.4 Certification Scope for Safety Healthcare

| No | Certification Code | Certification Scope | Details |
|----|--------------------|--|------------|
| 1 | BEM-CCMSHC01 | Competency on Biomedical Engineering Maintenance for Safety Healthcare | APPENDIX 7 |

The assessment strategy is through the Written Examination in 1(one) hour, with 50 multiple choice objective questions to evaluate the knowledge and skill of the candidate. Candidates need to answer 35 questions correctly to achieve a passing mark of 70%.

8.5 Certification Scope for Human Anatomy and Physiology

| No | Certification Code | Certification Scope | Details |
|----|--------------------|--|------------|
| 1 | BEM-CCMHAF01 | Competency on Human Anatomy and Physiology | APPENDIX 8 |

The assessment strategy is through the Written Examination in 1(one) hour, with 50 multiple choice objective questions to evaluate the knowledge and skill of the candidate. Candidates need to answer 35 questions correctly to achieve a passing mark of 70%.

8.6 Certification Scope for Healthcare for Biomedical

| No | Certification Code | Certification Scope | Details |
|----|--------------------|--|------------|
| 1 | BEM-CCMIHC01 | Competency on Introduction to Healthcare for Biomedical Engineer | APPENDIX 9 |

The assessment strategy is through the Written Examination in 1(one) hour, with 50 multiple choice objective questions to evaluate the knowledge and skill of the candidate. Candidates need to answer 35 questions correctly to achieve a passing mark of 70%.

9) **Certification**

9.1. **Application Process**

Candidate shall submit complete application form and appropriate fees at least 30 days in advance of the exam date. The application form can be found at www.acbcertification.com website.

Applications are reviewed to verify the information and documentation, to determine eligibility and will be kept confidential. Candidates will not be discriminated against based on race, gender or national origin or ancestry.

Candidates who meet the application requirements will receive examination acceptance confirmation and examination slip. Candidate need to reply within 5 days on the suitability of exam date.

Candidates who do not meet the application requirements will also receive a status via notification letter. The application may be deemed incomplete for reasons such as:

- Application form is not completely filled up, signed
- Appropriate fees are not submitted
- Additional documentation is not submitted

If denied, candidate will receive notification letter ~~via~~ email stating the reason for the denial. Candidates have 7 working days to respond. The application may be denied for reasons such as:

- Failure to demonstrate eligibility in academic, work experience, or specialized training
- Falsification of any information on the exam application

9.2. **Eligibility Appeals**

Candidates will be notified through the notification letter regarding their application status in the certification program. If candidate failed to meet the eligibility requirements for the examination, he/she has 7 working days to appeal the decision. Candidate ~~shall~~ **must** submit the appeal in writing to the ACCB at info@accbcert.com.

9.3. **Examination Preparation**

Candidates should notify ACCB at least 5 working days in advance of the examination date for confirmation of attendance on exam date. All certification programs are self-study.

9.3.1. Examination Content Outlines

Examination content outlines are available for every examination. Candidates may find the outlines at **details 8: Certification Scheme** and **Appendices** at the end of this handbook. The content outline provides information such as the number and type of questions, duration of the exam, percentage of question per category, etc.

9.3.2. Examination Day

All examinations will be carried out at our Authorized Examination Room located at:

1. No. 77-2, Jalan MH1, Taman Muzaffar Height, Ayer Keroh, Mukim Bukit Katil, 75450 Melaka Tengah, Melaka, or
2. No. 11, Jalan Utarid U5/15, Seksyen U5, 40150 Shah Alam, Selangor, or
3. At any examination venue that met the requirement specified under clause 12.2 of this handbook

(a) Candidate Check-in:

Candidates should bring his/her Identification Card and Examination Slip. If candidate loses or does not receive Examination Slip, please contact ACCB at +60 12-5892964.

The candidate shall arrive at the Examination Room at least 15 minutes prior to the exam starting time. Late arrivals will not be admitted to the room and will be considered “no shows” and lose all exam fees paid

(b) Policies During Exam Administration

The following list is the policies that will be maintained during the examination session:

- Candidates are admitted only to their assigned test centre at their assigned time.
- No guests are permitted in the exam room.
- No weapons may be brought into the exam room.
- Candidates will be given the opportunity to write comments about exam items during the exam through the feedback form.
- Candidates are provided a pencil, pen, and eraser during the exam.
- Breaks are not allowed during the exam.
- Food and beverage are not allowed in the exam room.
- Candidates may not copy in writing, transmit or record exam questions and/or answers of any exam material.
- And details in **1: Examination Rules & Regulation**

(c) Policies After Completing the Exam

Candidate who completes the exam may leave the examination room after returning all related exam materials. The **Invigilators** will make sure that the candidate returns all materials

(d) Unexpected Situations

If candidate is unable to arrive at the designated exam site because of inclement weather, terrorist acts, natural disasters, or other unforeseen emergencies beyond the control of the candidate as determined by ACCB, candidate will be allowed to take the next regularly scheduled exam without being charged of the examination fee.

If for any reason the exam is unable to be administered, then the exam will be rescheduled within a reasonable period of time. Candidates may take the exam at the next schedule without any additional cost. Candidates are responsible for their own associated expenses.

9.3.3. Rescheduling an Examination

Candidates are only allowed to reschedule an examination once.

Examination rescheduled within five (5) working days of their scheduled examination date will forfeit all examination fees, provided ACCB is notified in writing by email at info@accbcert.com.

9.3.4. Cancellation/Withdrawing Policy

A cancellation fee will be applied to the candidate who fails to cancel a rescheduled examination within five (5) working business days before the examination date. Cancellations must be made in writing and sent by email to info@accbcert.com

9.3.5. Failure to Appear

If a candidate does not appear to take a scheduled exam, the candidate will forfeit all fees. All fees will need to be paid again if the candidate decides to reschedule at a later date.

9.4. Security

No spouses, children, parents, friends, or other outside parties are permitted near the examination room. Upon completion of the examination, candidates must leave the examination area immediately. Any candidate who gives or receives help during the examination will be asked to leave and their examination will not be assessed. Examination fees will not be refunded and the candidate may be prohibited from taking ACCB examination for a specified period of time.

The performance of all candidates is monitored and may be analysed to detect fraud.

9.5. Scoring and Results

a) Scoring Process

Examination should have scores. ACCB are making every effort to ensure that the score is reported within a reasonable time period and that the score accurately reflects the points received by the candidate. Candidates are encouraged to give feedback on whole examination process which can be related to a specific question; the administration of the examination; or the examination room conditions via ACCB Customer Feedback Form.

b) Notification of Results

Candidates will be notified of their result status within 30 days. Candidate will receive ACCB Certificate of Competency if they passed the examination

Candidates who fail an examination will be notified and they are allow to apply for 2 times re-seat examination. If still failed, the candidates are required to submit a new application. There is no refund for failed exams

9.6. Change of Contact Information

It is the Certified Person’s responsibility to ensure that ACCB has their most current contact information including mailing address, phone number and email address.

9.7. Use of Designation as Certified Person

a) Introduction

After receiving notification of earning a Certified Person, the credential(s) granted may be used only as long as they remain valid and in good standing in the field.

Certified Person may not use the credential(s) until he/she have received specific written notification. Certified Person must comply with re-certification requirements to maintain the use of the credential(s).

Individuals who fail to maintain ACCB certification / recertify or whose Certified Person is suspended or revoked must immediately discontinue use of the designation as Certified Person and are prohibited from stating or implying that they hold the Certified Person from ACCB.

b) Certification of Competency Certificate

Each Certified Person will receive a certificate for each credential granted. Each certificate will include, at a minimum, the following information:

- Name of the certification body
- Name of the Certified Person and Identification Number
- Unique certification number
- Scope of certification
- Effective date of certification and date of expiry
- Endorsement by authorized ACCB Personnel

Certified Person who renews his/her certification (recertify **and passed**) will receive a renewal certification of competency certificate with a new expiration date.

9.8. Maintaining Your Certification

a) Introduction

In a profession that regularly undergoes change; the importance of certification is growing rapidly. The purpose of this program is to ensure that those who are actively certified maintain a level of professional knowledge and skill, that is consistent with the standards according to which certification was initially conferred.

Certification is only as valuable as the standard it represents if the standard is maintained. Recertification programs are extremely important because they require holders of the credential to present evidence that they are maintaining the established standard. This, in turn, enables certification to retain meaning and value for every individual who achieves it, particularly as the years pass after the credential is issued.

b) Rationale

ACCB's goals for recertification are to ensure that ACCB Certified Person remain current with best practices, broaden their understanding of the industry, and continue to be recognized as the competent person of Biomedical Engineering Maintenance (BEM). Given the moderate rate of change for the BEM field, including the standards upon which it relies, ACCB believes a three-year recertification cycle is appropriate

10) Recertification

10.1. Recertification Requirements

10.1.1. These requirements are applied to all certifications except BEM-CCMSHC01, BEM-CCMIHC01 and BEM-CCMHAF01. Certified person shall apply for recertification through the *Application for Certification/Recertification Form* 3 months prior the expiry date as a certified person.

Certified Person is required to submit document (a) and (b) to ACCB as a confirmation of continuing satisfactory work and work experience records:

- a) Record of job/work related to the competency for each year in three (3) years from the date as a certified person.
 - Minimum fifteen (15) records of planned preventive maintenance and fifteen (15) breakdown repair attended.
- b) Professional development records:

Option 1

| No | Details |
|-----|---|
| 1.1 | Copy of training certificate attended from any training provider: <ul style="list-style-type: none"> - Related Soft skill training (8 hours in 36 months) - Regulatory training (8 hours in 36 months) - Safety Training (8 hours in 36 months) - Technical training related to the competency (8 hours in 36 months) |
| 1.2 | Copy of training certificate attended from internal <ul style="list-style-type: none"> - Technical training related to the competency (30 hours in 36 months) |
| 1.3 | Copy of evidence as a trainer related to the competency <ul style="list-style-type: none"> - On job training / internal training / external training (30 hours in 36 months) |

OR

Option 2

| No | Details |
|-----|--|
| 2.1 | Copy of training certificate attended from any training provider: <ul style="list-style-type: none"> - Related Soft skill training (8 hours in 36 months) - Regulatory training (8 hours in 36 months) - Safety Training (8 hours in 36 months) - Technical training related to the competency (60 hours in 36 months) |

10.1.2. These requirements are applied to only BEM-CCMIHC01, BEM-CCMSHC01 and BEM-CCMHAF01. Certified person shall apply for re-certification through the *Application for Certification/Recertification Form* 3 months prior the expiry date as a certified person.

Certified Person is required to submit document (a) and (b) to ACCB as a confirmation of continuing satisfactory work and work experience records:

- a) Record of job/work related to the competency for each year in three (3) years from the date as a certified person
- b) Record of learning activities such as training, seminar, conference, on job training for 10 hours

10.2. Recertification Procedures

All Certified Person are required to submit the application form and all related training certificates for recertification process, three (3) months early from the expiry date. He/she have to ensure application's fee is paid and payment slip is attached together with the submission.

Certified Person must immediately inform ACCB of matters that affect his/her capability to continue to fulfil the certification requirements by email at info@accbcert.com.

If Certified Person apply for recertification after six (6) months of expiry date, he/she are considered not eligible and required to seat for new examination.

11) Complaint

11.1 Complaints Related to Certification Process

ACCB will be responsible for all complaints received among others but are not limited to the following:

- Evidence of falsification of information provided on documents submitted to ACCB.
- Cheating on certification exams.
- Evidence of non-compliance with the Code of Conduct.
- Evidence of improper use of the ACCB certification status and/or logos
- Violation of established ACCB certification policies, rules and requirements.
- Conviction of a felony or other crime of moral turpitude under federal or state law.
- Gross negligence, wilful misconduct, or other unethical conduct in the performance of services for which the individual has achieved certification from ACCB.

ACCB has established procedures to fairly and consistently address alleged violations. Disciplinary procedures are designed to ensure that valid and actionable complaints are investigated and considered, and that all parties involved in the complaint have an opportunity to document circumstances warranting the complaint and to respond to the complaint.

All complaints will first be reviewed by the ACCB personnel. If the complaint can be verified and resolved without further documentation or investigation, ACCB will notify the complainant if necessary and the complaint will be closed.

If the complaint requires additional information or **further investigation**, ACCB will proceed within 14 working days before any actions will be taken.

Following the investigation, ACCB will inform the complainant of the decision in writing. If disciplinary action is imposed, the complainant may submit an appeal of the decision to ACCB. A signed appeal must be submitted in writing within 14 working days from receipt of the written notification that a disciplinary action is imposed and must clearly state the grounds for appeal.

Below are two possible decisions that ACCB may make in regards to a complaint.

a) **Withdrawal/Revocation**

When a complaint is received by ACCB which upon investigation by the policies and processes laid out appears to be due to negligence or intentional malpractice or violation of the code of conduct, the ACCB may withdraw certification. In the event of withdrawal, the Certified Person must refrain from further use of all references to certified status.

b) **Suspension**

When a complaint is received by ACCB which upon investigation by the policies and processes laid out appears to be due to accidental causes, unintentional negligence or oversight, the ACCB may suspend the Certified Person certification for a specific period. ACCB may establish monitoring procedures during the suspension which the Certified Person must conform to. During the suspension time, the Certified Person must refrain from further promotion of his/her certification. If the Certified Person does not remedy the conditions of the suspension, his/her certification may be withdrawn.

11.2 Complainant

Applicant/candidates/Certified Person or other individuals within industry can do a complaint by fill-up **ACCB Complaint Form**.

12) Special Arrangement

12.1 Request special arrangement

Candidates are allowed to request for special arrangement in the **Application for Certification/Recertification Form** by giving a reasonable justification of request and special arrangement include:

- a) Accommodation with additional cost
- b) Wheelchair assistance
- c) Hearing aid assistance

ACCB will give the feedback within 10 working days after received the application form. However, candidate is still allowed to request for special arrangement within 5 days upon receiving the notification letter of examination. ACCB will do a necessary review and arrangement for specific request made.

The request shall be supported with relevant documentation such as letter from a physician or other qualified professional reflecting a diagnosis of the candidate's condition and explanation of exam aids or modifications needed. Kindly take notes all cost incurred shall be borne by candidate.

12.2 Request on site Examination

ACCB also allowed any special request on special Examination Centre arrangement. Your employer shall make a request in writing to ACCB for this request, and we may proceed with this condition:

- a) All cost incurred on ACCB invigilator are bill to client such as travelling expenses, accommodation, logistic, etc.
- b) Clients are required to follow Examination Guideline – seating arrangement, security of Examination Room, etc.
- c) Client shall make a request 2months prior propose examination date.

13) **Appeal**

For appeal process candidate has to provide minimum requirement as follows:

- Appeal letter
- Examination result, applicable for 13.1(a)
- Certification Certificate, applicable for 13.1(b)
- Fee amounting RM1,000.00 per application

13.1 **Type of Appeal**

- a) Appeal for examination result

Candidate may appeal for ACCB to review examination result, within 14 working days from the notification of the examination result.

- b) Appeals for withdrawing and/or reducing the scope of certification result

In addition to appeals of disciplinary action, an individual or Certified Person who was denied certification or had his/her certification revoked may file an appeal within 14 working days of receipt of notice of the action taken that is eligible for appeal.

13.2 **Scheme Committee Consideration of the Appeal**

The Scheme Committee (SC) is the appeals body that hears appeals. The SC reviews all properly filed and documented appeals to determine if significant evidence exists of a substantive error or omission in the certification process or outcome. When the SC reaches a decision, the appellant will be notified in writing within 30 days of such decision being made. There are no further appeals once the SC has acted.

14) **Confidentiality**

ACCB will release the candidate's result ONLY to individual. Any question concerning result, should be referred to ACCB.

ACCB shall kept all information related to candidate as CONFIDENTIAL and it shall not be disclosed to third party without Certified Person consent.

APPENDICES

CONTROLLED DOCUMENT

APPENDIX 1

BEM-BDIA01

SCHEME OUTLINES

- 1.0 Introduction of diagnostics equipment (15%)
 - 1.1 Theory and understanding of diagnostics equipment classification
 - 1.2 Theory and understanding of anatomy and physiologic
 - 1.2.1 Organ function
 - 1.2.2 System body related to the diagnostics equipment
 - 1.2.3 Diseases

- 2.0 Functions & Operations (30%)
 - 2.1 Group C (Diagnostic)

| No | Asset Description | No | Asset Description |
|----|---------------------------|----|----------------------------|
| 1 | Airflow Detectors, Airway | 10 | Ophthalmoscopes / Otoscope |
| 2 | Analysers, Point-of-Care | 11 | Recorders |
| 3 | Balances | 12 | Sphygmomanometers |
| 4 | Calipers | 13 | Thermometers |
| 5 | Dialysis | 14 | Transilluminators |
| 6 | Endoscopy | 15 | Treadmills |
| 7 | Eye Equipment | 16 | Uroflowmeters |
| 8 | Fetal Heart Detectors | 17 | Vacuum Electrode System |
| 9 | Light Sources | | |

- 3.0 Safety (15%)
 - 3.1 Safety features of the diagnostics equipment

- 4.0 Service and Repair (30%)
 - 4.1 Plan Preventive Maintenance
 - 4.2.1 Special Precaution
 - 4.2.2 Test Apparatus
 - 4.2.3 Qualitative & Quantitative Tasks
 - 4.2.4 Preventive Maintenance Tasks
 - 4.2.5 Electrical Safety Test
 - 4.2 Breakdown Repair
 - 4.3.1 Identification of the common problems
 - 4.3.2 Troubleshoot and repair minor defect related to power supply
 - 4.3.3 Spare part identification

- 5.0 Managing (10%)
 - 5.1 Understanding on Biomedical Engineering related documentation
 - 5.1.1 Testing and Commissioning
 - 5.1.2 Management of Warranties
 - 5.1.3 Schedule Maintenance
 - 5.1.4 Unscheduled Maintenance
 - 5.1.5 Risk Management

APPENDIX 2

BEM-BTHE01

SCHEME OUTLINES

- 1.0 Introduction of Therapeutic Equipment (15%)
 - 1.1 Theory and understanding of therapeutic equipment classification
 - 1.2 Theory and understanding of anatomy and physiologic
 - 1.2.1 Organ function
 - 1.2.2 System body related to the therapeutic equipment
 - 1.2.3 Diseases

- 2.0 Functions & Operations (30%)
 - 2.1 Group D (Therapeutic)

| No | Asset Description | No | Asset Description |
|----|---------------------------------------|----|------------------------------------|
| 1 | Aerosol Generators | 26 | Lights, Surgical |
| 2 | Analgesia units | 27 | Lights, Ultraviolet |
| 3 | Analgesia units | 28 | Massage Machines, Physical Therapy |
| 4 | Aspirators | 29 | Mattress Systems |
| 5 | Baths | 30 | Nebulizers |
| 6 | Baths, Paraffin, Physical Therapy | 31 | Photometers |
| 7 | Baths, water | 32 | Phototherapy Units |
| 8 | Battery Chargers | 33 | Pumps, Alternating-Pressure Pad |
| 9 | Bilirubinometers, Cutaneous | 34 | Pumps, Breast |
| 10 | Cast cutters | 35 | Resuscitators |
| 11 | Compression Units | 36 | Resuscitators, Pulmonary |
| 12 | Dental Equipment | 37 | Saws |
| 13 | Dialysis | 38 | Stimulator Analyzers |
| 14 | Dynamometers | 39 | Stimulators, Caloric |
| 15 | ENT Equipment | 40 | Tables/ Beds |
| 16 | Ergometres | 41 | Tourniquets |
| 17 | Exercisers, continuous passive motion | 42 | Traction Units |
| 18 | Eye Equipment | 43 | Training Aids |
| 19 | Flowmeters | 44 | Training Manikins |
| 20 | Heating Units | 45 | Ultrasound Cleaning Systems |
| 21 | Infusion Devices | 46 | Vacuum Extractors |
| 22 | Injectors, Medication/Vaccine | 47 | Vibrators |
| 23 | Lights | 48 | Warming Units |
| 24 | Lights, Dental | 49 | Warming Units, Patient |
| 25 | Lights, Infrared | 50 | Washers |

- 3.0 Safety (15%)
 - 3.1 Safety features for the Therapeutic equipment

SCHEME OUTLINES**4.0 Service and Repair (30%)****4.1 Plan Preventive Maintenance Procedure**

- 4.1.1 Special Precaution
- 4.1.2 Test Apparatus
- 4.1.3 Qualitative and Quantitative Tasks
- 4.1.4 Preventive Maintenance Tasks
- 4.1.5 Electrical Safety Test

4.2 Breakdown Repair

- 4.2.1 Identification of the common problems
- 4.2.2 Troubleshoot and repair minor defect related to power supply
- 4.2.3 Spare part identification

5.0 Managing (10%)**5.1 Understanding on Biomedical Engineering related documentation**

- 5.1.1 Testing and Commissioning
- 5.1.2 Management of Warranties
- 5.1.3 Schedule Maintenance
- 5.1.4 Unscheduled Maintenance
- 5.1.5 Risk Management

CONTROLLED DOCUMENT

BEM-BLAB01

SCHEME OUTLINES

- 1.0 Introduction of Laboratory Equipment (15%)
 - 1.1 Theory and understanding of laboratory equipment classification
 - 1.2 Theory and understanding of anatomy and physiologic
 - 1.2.1 Organ function
 - 1.2.2 System body related to the laboratory equipment
 - 1.2.3 Diseases

- 2.0 Functions & Operations (30%)
 - 2.1 Group B (Laboratory)

| No | Asset Description | No | Asset Description |
|----|-------------------------|----|----------------------------|
| 1 | Air Samplers | 19 | Incubators, Laboratory |
| 2 | Balances | 20 | Mixers |
| 3 | Baths, Water | 21 | Microscope |
| 4 | Bilirubinometers | 22 | Microtomes |
| 5 | Bone Mills | 23 | pH Meters |
| 6 | Bunsen Burners | 24 | pH Monitors |
| 7 | Calibrators | 25 | Pipettors |
| 8 | Centrifuges | 26 | Pumps, Laboratory |
| 9 | Chambers, Anaerobic | 27 | Rotators |
| 10 | Concentrators, Specimen | 28 | Sedimentation Rate Units |
| 11 | Diluters | 29 | Separators |
| 12 | Dispensers | 30 | Shakers |
| 13 | Densitometer | 31 | Slide Stainers |
| 14 | Dryers, Slide | 32 | Stirrers |
| 15 | Evaporators | 33 | Strippers, Donor Tube |
| 16 | Fluorometers | 34 | Timers |
| 17 | Hot Plates | 35 | View Boxes |
| 18 | Hygrometers | 36 | Water Purification Systems |

- 3.0 Safety (15%)
 - 3.1 Safety features for the laboratory equipment

- 4.0 Service and Repair (30%)
 - 4.1 Plan Preventive Maintenance Procedure
 - 4.2.1 Special Precaution
 - 4.2.2 Test Apparatus
 - 4.2.3 Qualitative and Quantitative Tasks
 - 4.2.4 Preventive Maintenance Tasks
 - 4.2.5 Electrical Safety Test
 - 4.2 Breakdown Repair
 - 4.3.1 Identification of the common problems
 - 4.3.2 Troubleshoot and repair minor defect related to power supply
 - 4.3.3 Spare part identification

SCHEME OUTLINES

5.0 Managing (10%)

5.1 Understanding on Biomedical Engineering related documentation

- 5.1.1 Testing and Commissioning
- 5.1.2 Management of Warranties
- 5.1.3 Schedule Maintenance
- 5.1.4 Unscheduled Maintenance
- 5.1.4 Risk Management

CONTROLLED DOCUMENT

BEM-ITHDU02

SCHEME OUTLINES

- 1.0 Introduction of Dialysis (15%)
 - 1.1 Theory and understanding of active medical device classification
 - 1.1.1 Group D (Therapeutic-Dialysis)
 - 1.2 Theory and understanding of anatomy and physiologic
 - 1.2.1 Organ function (kidney)
 - 1.2.2 System body related to the medical device (Urinary)
 - 1.2.3 Diseases

- 2.0 Functions & Operations (25%)
 - 2.1 Group D (Therapeutic-Dialysis)

| No | Asset Description |
|----|--|
| 1 | Dialyzer Reprocessing Units |
| 2 | Haemodialysis Unit Conductivity Monitors |
| 3 | Haemodialysis Units |
| 4 | Hemofiltration Units |
| 5 | Peritoneal Dialysis Units |
| 6 | Water Purification Systems, Reverse Osmosis |
| 7 | Water Purification Systems, Reverse Osmosis, Haemodialysis, Portable |

- 3.0 Safety (15%)
 - 3.1 Safety features for the Dialysis and related equipment

- 4.0 Service and Repair (30%)
 - 4.1 Identify and Understand on Plan Preventive Maintenance Procedure
 - 4.1.1 Special Precaution
 - 4.1.2 Test Apparatus
 - 4.1.3 Qualitative and Quantitative Tasks
 - 4.1.4 Preventive Maintenance Tasks
 - 4.1.5 Electrical Safety Test
 - 4.2 Breakdown Repair
 - 4.2.1 Identification of the common problems
 - 4.2.2 Troubleshoot and repair minor defect related to power supply
 - 4.2.3 Spare part identification
 - 4.2.4 Repair and replacement of equipment modules, assemblies or boards (PCB)
 - 4.2.5 Equipment calibration requirement
 - 4.2.6 Repair and replacement of component or subcomponent of the equipment PCB

- 5.0 Managing (15%)
 - 5.1 Understanding on Biomedical Engineering Maintenance Service Management:
 - 5.1.1 General technical support and facilities
 - 5.1.2 Schedule maintenance management
 - 5.1.3 Unscheduled maintenance management
 - 5.1.4 Communication skill
 - 5.1.5 Biomedical Engineering Services and administrative function

BEM-ITVEN02

SCHEME OUTLINES

- 1.0 Introduction of Ventilators (15%)
 - 1.1 Theory and understanding of active medical device classification
 - 1.1.1 Group D (Therapeutic-Ventilators)
 - 1.2 Theory and understanding of anatomy and physiologic
 - 1.2.1 Organ function (Lung)
 - 1.2.2 System body related to the medical device (Respiratory)
 - 1.2.3 Diseases

- 2.0 Functions & Operations (25%)
 - 2.1 Group D (Therapeutic-Ventilator)

| No | Asset Description |
|----|---|
| 1 | Continuous Positive Airway Pressure Units |
| 2 | Ventilators |
| 3 | Ventilators, Anaesthesia |
| 4 | Ventilators, Intensive Care |
| 5 | Ventilators, Intensive Care, Adult |
| 6 | Ventilators, Intensive Care, Adult, High-Frequency |
| 7 | Ventilators, Intensive Care, Neonatal/ Paediatric |
| 8 | Ventilators, Intensive Care, Neonatal/ Paediatric, High-Frequency |
| 9 | Ventilators, Portable/Home Care |
| 10 | Ventilators, Transport |
| 11 | Humidifiers, Heated |

- 3.0 Safety (15%)
 - 3.1 Safety features for the medical devices

- 4.0 Service and Repair (30%)
 - 4.1 Plan Preventive Maintenance Procedure
 - 4.1.1 Special Precaution
 - 4.1.2 Test Apparatus
 - 4.1.3 Qualitative and Quantitative Tasks
 - 4.1.4 Preventive Maintenance Tasks
 - 4.1.5 Electrical Safety Test
 - 4.2 Breakdown Repair
 - 4.2.1 Identification of the common problems
 - 4.2.2 Troubleshoot and repair minor defect related to power supply
 - 4.2.3 Spare part identification
 - 4.2.4 Repair and replacement of equipment modules, assemblies or boards (PCB)
 - 4.2.5 Equipment calibration requirement
 - 4.2.6 Repair and replacement of component or subcomponent of the equipment PCB

SCHEME OUTLINES

5.0 Managing (15%)

5.1 Understanding on Biomedical Engineering Maintenance Service Management:

5.1.1 General technical support and facilities

5.1.2 Schedule maintenance management

5.1.3 Unscheduled maintenance management

5.1.4 Communication skill

5.1.5 Biomedical Engineering Services documentation and administrative function

CONTROLLED DOCUMENT

BEM-OEST03**SCHEME OUTLINES**

- 1.0 Objective of performing Electrical Safety Testing
 - 1.1 Physiological Effects / Shock Hazards
- 2.0 Standards Requirements
 - 2.1 MS 2058:2018
 - 2.2 IEC 60601
 - 2.3 IEC 62353
 - 2.4 IEC 61010
- 3.0 Classification of Active Medical Equipment
- 4.0 Type of Applied Part in Medical Equipment
- 5.0 Limit and Parameters:
 - 5.1 IEC 60601
 - 5.2 IEC 62353
 - 5.3 IEC 61010
- 6.0 Electrical Safety Testing for:
 - 6.1 Internal Electrical Power Source
 - 6.2 Fix Wired and 3 phase

BEM-CCMSHC01

SCHEME OUTLINES

Electrical Safety Test (IEC 60601-1, 62353 & 61010-1)

- 1.0 Objective of performing Electrical Safety Testing
- 2.0 Physiological Effects / Shock Hazards
- 3.0 Standards Requirements
 - 3.1 MS 2058: 2018
 - 3.2 IEC 60601
 - 3.3 IEC 62353
 - 3.4 IEC 61010
- 4.0 Classification of Active Medical Equipment
- 5.0 Type of Applied Part in Medical Equipment
- 6.0 Limit and Parameters
 - 6.1 IEC 60601
 - 6.2 IEC 62353
 - 6.3 IEC 61010
- 7.0 Electrical Safety Testing for:
 - 7.1 Internal Electrical Power Source
 - 7.2 Fix Wired and 3 phase

Safety in Healthcare

- 1.0 Patient Safety
 - 1.1 Access
 - 1.2 Communication
 - 1.3 Diagnostic errors
 - 1.4 Prescribing errors
 - 1.5 Error in organizational systems
 - 1.6 Technology failures
- 2.0 Staff safety
 - 2.1 Workplace violence
 - 2.2 Dangerous patients
 - 2.3 Work-related injuries
 - 2.4 Infections
 - 2.5 Illnesses
 - 2.6 Natural Disasters
- 3.0 Infection Control
 - 3.1 Basic Measures for Infection Control
 - 3.2 Protection of Healthcare Workers
 - 3.3 Surveillance
 - 3.4 Incident monitoring
 - 3.5 Outbreak investigation
 - 3.6 Research

- 4.0 Healthcare Waste
 - 4.1 H Healthcare Waste Management
 - 4.2 Health Worker Safety
 - 4.3 Segregation of Waste
 - 4.4 Handling Storage and Transport of Healthcare Waste
 - 4.5 Healthcare Waste Treatment and Disposal

- 5.0 Fire Safety
 - 5.1 Fire safety equipment

- 6.0 Medical Gases Safety
 - 6.1 Hazard Identification
 - 6.2 Medical Gas System

Safety for Equipment

- 1.0 Radioactive Materials

- 2.0 Cleaning, Disinfection and Sterilization

- 3.0 Infection Control for Electrical Safety Test

- 4.0 Operation for Radiology and Imaging Equipment
 - 4.1 X-ray
 - 4.2 Magnetic Resonance Imaging (MRI)

Risk Management in Medical Device ISO 14971

- 1.0 Hazard Identification

- 2.0 Risk Assessment

- 3.0 Risk Management

BEM-CCMHAF01

SCHEME OUTLINES

- 1.0 Objective of Compulsory Competency Module
- 2.0 The Body as a Whole
 - 2.1 Organization of the body
 - 2.2 The chemical basis of life
 - 2.3 Cell
 - 2.4 Tissue
- 3.0 Support and Movement
 - 3.1 Skin and its Appendages
 - 3.2 Skeletal tissues
 - 3.3 The skeletal Systems
 - 3.4 Articulations
 - 3.5 Physiological of the Muscular System
 - 3.6 Anatomy of the Muscular System
- 4.0 Communication, Control and Integration
 - 4.1 Nervous Systems Cells
 - 4.2 The Central System
 - 4.3 The Peripheral Nervous System
 - 4.4 Senses Organ
 - 4.5 The Endocrine System
- 5.0 Transportation and Defence
 - 5.1 Blood
 - 5.2 Anatomy of the Cardiovascular System
 - 5.3 Physiology of the Heart
 - 5.4 Lymphatic System
 - 5.5 Immune System
- 6.0 Respiration, Nutrition and Excretion
 - 6.1 Anatomy of the Respiration System
 - 6.2 Physiology of the Respiratory System
 - 6.3 Anatomy of the Digestive System
 - 6.4 Physiology of the Digestive System
 - 6.5 Nutrition and Metabolism
 - 6.6 The urinary system
 - 6.7 Fluid and electrolyte balance
 - 6.8 Acid Base Balance
- 7.0 Reproduction and Development
 - 7.1 Male reproductive system
 - 7.2 Female reproductive system
 - 7.3 Growth and development
 - 7.4 Genetic and heredity

BEM-CCMIHC01

SCHEME OUTLINES

- 1.0 O&G Services
 - 1.1 O&G Services
 - 1.2 Sub specialty
 - 1.3 Specific Procedure
 - 1.4 Ultrasound
 - 1.5 Colposcopy
- 2.0 Surgical & Emergency Services
 - 2.1 Functional Surgery and Emergency Services Unit
 - 2.2 Surgical services and type at MOH Hospital
 - 2.3 Anaesthesiology and Intensive Care Services
 - 2.4 Fire Treatment Unit Facility (Burn Unit)
 - 2.5 Emergency Medicine and Trauma Service (EMTS)
 - 2.6 Organ Transplantation
 - 2.7 Example of equipment based on surgical discipline
- 3.0 Paediatric Services in MOH Hospitals
 - 3.1 Paediatric Services – functional
 - 3.2 Paediatric Services in MOH Facilities
 - 3.3 List of equipment
 - 3.4 Routine maintenance of medical equipment
- 4.0 Clinical Support Division
 - 4.1 What is clinical support
 - 4.2 The branches of Radiology
 - 4.3 Pathology Services and Transfusion Services
 - 4.4 Blood Donation in Malaysia
 - 4.5 CSSU & Forensic
 - 4.6 Medicine Services
 - 4.7 Rehabilitation Medicine Services
 - 4.8 Allied Health
 - 4.9 List of equipment
- 5.0 Introduction to Medical Specialist & Sub-specialties
 - 5.1 Function
 - 5.2 General Medicine
 - 5.3 Dermatology
 - 5.4 Psychiatry
 - 5.5 Cardiology
 - 5.6 Nephrology
 - 5.7 Palliative Medicine
 - 5.8 Rheumatology
 - 5.9 Geriatrics
 - 5.10 Clinical Haematology
 - 5.11 Radiotherapy and Oncology
 - 5.12 Contagious disease
 - 5.13 National Cancer Institute
 - 5.14 Equipment used

- 6.0 Introduction to Hospital Functions
 - 6.1 Hospital function
 - 6.2 Patient care
 - 6.3 Medical staff training
 - 6.4 Hospital Organization Structure
 - 6.5 Hospital units
 - 6.6 Privatized services
 - 6.7 Hospital facilities
 - 6.8 Hospital classification
 - 6.9 Reference between facilities
 - 6.10 Traditional & complementary medicine

- 7.0 Pharmacy Activities in MOH Facilities
 - 7.1 Hospital Pharmacy activities
 - 7.2 Health Clinic Pharmacy activities
 - 7.3 Pharmacy Unit, PKD
 - 7.4 Ambulatory Services
 - 7.5 In Patients Pharmacy Services
 - 7.6 Ward Pharmacy Services
 - 7.7 Nuclear Pharmacy
 - 7.8 Research activities
 - 7.9 Extended Hours Services
 - 7.10 Equipment used

- 8.0 Overview Oral Healthcare in MOH
 - 8.1 Introduction to Oral Health
 - 8.2 Common Oral Health Problem
 - 8.3 Radiograph and treatment
 - 8.4 Orthodontic
 - 8.5 Oral Health Program
 - 8.6 Oral Health Facilities
 - 8.7 Equipment used

CONTROLLED DOCUMENT

BEM-ITABG02

| SCHEME OUTLINES |
|---|
| <p>6.0 Introduction to Blood Gas analyzer (17%)</p> <p>6.1 Theory and understanding of active medical device classification 6.1.1 Group B (Laboratory – Blood Gas Analyzer)</p> <p>6.2 Theory and understanding of anatomy and physiologic 6.2.1 Interaction with bloods and other body fluids 6.2.2 Chemicals and other characteristics in biological samples 6.2.3 Diseases</p> |
| <p>7.0 Functions & Operations (28%)</p> <p>7.1 Group D (Laboratory - Analyzers, Laboratory) 7.1.1 Analyzer, Laboratory, Blood Gas/pH 7.1.2 Analyzer, Laboratory, Blood Gas/Ph/Electrolyte</p> |
| <p>8.0 Safety (15%)</p> <p>8.1 Safety features of the devices 8.2 Electrical Safety Test</p> |
| <p>9.0 Service and Repair (33%)</p> <p>9.1 Plan Preventive Maintenance Procedure 9.1.1 Asset Details 9.1.2 Special Precaution 9.1.3 Test Apparatus 9.1.4 Qualitative Tasks 9.1.5 Preventive Maintenance Tasks 9.1.6 Calibrations 9.1.7 Quantitative Tasks 9.1.8 Electrical Safety Test</p> <p>9.2 Repair 9.2.1 Identification of the common problems 9.2.2 Troubleshoot and repair minor defect related to power supply 9.2.3 Spare part identification 9.2.4 Repair and replacement of equipment modules, assemblies or boards (PCB) 9.2.5 Equipment calibration requirement 9.2.6 Repair and replacement of component or subcomponent of the equipment PCB</p> |

SCHEME OUTLINES**10.0 Managing (7%)**

10.1 Understanding on Biomedical Engineering Maintenance Service

Management:

- 10.1.1 General technical support and facilities
- 10.1.2 Schedule maintenance management
- 10.1.3 Unscheduled maintenance management
- 10.1.4 Communication skill
- 10.1.5 Biomedical Engineering Services documentation
- 10.1.6 Biomedical Engineering Services administrative function

CONTROLLED DOCUMENT