

Indian Bio-Medical Skill Consortium

About Indian Biomedical Skill Consortium (IBSC):

Andhra Pradesh MedTech Zone (AMTZ), Kalam Institute of Health Technology (KIHT), National Accreditation Board for Certification Bodies (NABCB) under the Quality Council of India (QCI) with support of Indian Medical Devices Industry have jointly proposed to evolve a consortium for biomedical engineering skills in India. The proposed “Indian Bio-medical Skill Consortium (IBS)” shall put in place an equivalence system of value-based assessment covering educational training, work experience and competency possessed by practitioners of biomedical engineering skills. To facilitate this a large number of assessment centers are being planned across several states in India where competency test on key bio-medical engineering skills could be undertaken by practitioners of bio-medical engineering from mechanical, electronics, electrical, health IT, clinical and allied engineering subjects. The outcome shall be a Technology Competency Score (TCS) level (1 to 10) which shall be framed on parity with other such professional bodies in many other countries. While the TCS score shall not be a licence to practice the subject, it shall be an internationally harmonised rating for skill recognition.

Several professional bodies, academic institutions of clinical merit and engineering excellence, quality assessment agencies and training partners have consented to become members of the consortium. The consortium partners will not carry any legal or commercial responsibility with regards to their membership of the consortium and the partnership shall be renewal once every year as well as compensated for their contribution as per ISBC program guidelines.

The Consortium nominated three Committees for smooth functioning of IBSC named as

- i) **Assessment Committee:** The Assessment Committee identified and invites the module experts from reputed organizations and shall take responsibility to develop and maintain question bank repository.
- ii) **Certification Committee:** The purpose of this committee is to accredit certification centres.
- iii) **Strategy Committee:** The purpose of this committee is to identify the suitable consortium partners to promote and support the IBSC at National and International level.

Objective:

The proposed objective of this study is to understand and analyse the methodology of existing Certification / Licencing for Clinical Engineers or Biomedical Equipment Technicians by Institute / Association in various countries and prepare a module to benefit Indian Biomedical Engineering professionals. The outcomes of this study include, as follows,

1) Issuing Certification / Licence to practice Biomedical Engineering profession:

Problem: In India approximately 2 lakh BME Professional working in various domains such as Clinical Engineers, Service Engineers, and etc. There is no recognised professional body to certify these professionals.

Possible Solution: To encourage best practices in Biomedical Engineering profession it's necessary to recognise the importance of skilled engineers and issue certification. This

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certification includes different Technology Readiness Levels (TRL) i.e., TRL – 1 to TRL – 10, based on their experience, competency and qualifications.

2) Skill Cell:

Problem: In India certain government and private institutes offers hands on training on Medical Equipments to practice as Biomedical Engineer. However, such programs are only benefiting to students / fresh graduates to understand the basic operation and troubleshooting of medical Equipments. Hence, the engineers supposed to spend almost 2-3 years to establish them self as well-trained engineers. Moreover, few MNC companies have their own training centres for their employees.

Possible Solution: We need Skill Cell which offers programs for both students as well as professional engineers from basic level to advance levels. These programs and modules will be prepared according to the industry needs in the similar lines of National Skill Development Corporation (NSDC). The duration of these Skill programs are prepared according to training modules.

3) Equivalence to Experiences / Skills:

Problem: Many of our engineers might have started their career with minimum education qualifications i.e., ITI / Diploma, those engineers with more than decade experience are earning less salary than who qualified either Bachelors / Masters with just 2-3 years of experience.

Possible Solution: Skill Cell will recognise such minimum qualified engineers and certified them in level according to their experiences.

4) Well Trained Engineers at International level

Problem: i) When Indian manufactures exports their products they need certified experts to install, calibrate and service those equipment's. ii) Indian BME Professionals who wish to practice profession in foreign they need equivalence certification.

Possible Solution: Skill Cell programs are designed at internationals standards, after completing the training each engineer able to practice independently in India or abroad. By signing MOU's with other similar certification agencies / institutes from all over the world, the Certification issued by Skill Cell will be recognised as equivalent certificate in their country. Hence, more job opportunities for our engineers across the globe. Moreover, other national engineers also get trained and certification at Skill Cell.

Societal Benefits of IBMSC

- 1) Health care industry is one of the major source of economy to our nation, this industry needs well trained and skilled engineers particularly in Medical Devices areas. Most of the health care industry is dependent on medical devices and diagnostic equipment's for diagnosis, treatment and etc., However, like doctors, nurses, pharmacists and lab technicians, healthcare industry required well trained and skilled biomedical engineers. This benefits hospitals, patients and stakeholders and etc.,

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- 2) The main outline of IBSC is to develop skill programs in the areas of Medical Devices and related areas that full fill the required manpower to hospitals, medical equipment companies and manufacturing industries and etc.,
- 3) This Cell will certify the trained engineers, this impacts the health care industry at large scale. Only certified engineers will be recruited in Clinics / Hospitals / industries or other related areas where they are already trained and skilled in their domains so from the date of joining job they are able to start working effectively. Hence, employers no need to focus on training to newly recruited employees at any levels, this saves lot of money and time for them.
- 4) Manufactures / industries will be benefited by Skill Cell where they can easily find skilled manpower who trained as per their requirements. This Cell will act as a hub for training and also for placements.

NOTE:

- The proposed Skill Cell will be hub for both national and international BME students and Engineers to learn and gain in depth knowledge on all Medical Devices, medical equipment's, calibration and relevant areas.
- Programs will also be designed according to the industry need, there by manufactures can recruit skilled engineers.

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Summary of BMET Examination (USA, Canada, UK & Ireland)

	USA	USA	Canada	UK	Ireland
Name of the Board / Agency / Sponsored	American College of Clinical Engineering (ACCE)	Board of Examiners for Biomedical Equipment Technicians. Association for the Advancement of Medical Instrumentation (AAMI) (7000 Members certified)	The Canadian Board of Examiners for Biomedical Engineering and Dialysis Technologist and Technicians	The Register of Clinical Technologist (RCT)	Clinical Engineering Voluntary Registration Board
Year of Establishment	1990	1973	1982	2000	2003
Accredited	US Board of Examiners for Certification in Clinical Engineering (USECCE)	AAMI Credentials Institute (ACI) Under US Board of Examiners for Certification in Clinical Engineering (USECCE)	International Certification Commission (ICC) From 1982 till 2014 AAMI Credentials Institute (ACI) as of Jan.1, 2015 ICC is replaced by ACI	Professional Standards Authority (PSA) Since 2015	Biomedical Engineering Association of Ireland and Biomedical Engineering Division
Name of the Exam	Certification in Clinical Engineering (CCE)	Certified Biomedical Equipment Technician (CBET)	Certified Biomedical Engineering Technologist or Technician "CBET(C)"	Certification in Clinical Engineering	Certification of Clinical Engineering
Eligibility	1. Licensure Professional Engineer with 3 Years of Experience	Associate's degree in BME with 2 years of experience Or	1. Associate degree with 3 Years' experience (or) Bachelor Degree with 1-year internship.	1) (Primary route) successfully completing training programme Degree or Diploma	Experience as Clinical Engineering and support of 2 registered Clinical Engineers

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	2. BS Degree with 4 Years of Experience 3. Bachelor of Science in Engineering Technology degree with 8 Years of experience	Associate's degree in Electronics with 3 years of BME experience Or 4 years full time BME work experience	5 Reference Letters	Offered by Institute of Physics and Engineering in Medicine (IPEM) 2) (Equivalence route) Bachelor's Degree with relevant Experience	
Application Procedures	Formal submission of application with 3 references	Formal submission of application before 30 days of exam	Formal submission of application along with details of references	Formal Application with qualifications and experience details	Formal Application with qualifications and experience details
Application Review Process	Board Members will review application and recommend for exam.	Board Members will review application and recommend for exam.	3 Board Members will review application and recommend for exam.	Review by Board and recommend to registration	Board members will review candidate's eligibility and experience
Examination Duration	Written: 4 Hours Oral: 2 hours On three clinical engineering scenarios (5-7 questions in each scenarios)	3 hours	8 Hours (usually 5 hours full time)	No Exam	No Exam
Examination Fee	\$450	\$350 for (AAMI Members) \$ 400 for non-members	\$ 195	£45 (Application fee)	£30
Supplementary Exam Fee	Retest written: \$175 Retest Oral: \$150	\$ 275 for (AAMI Members) \$ 325 for non-members	\$ 90 per each section	£45 (re-application fee) If candidate not meeting eligibility criteria.	-NA-
Examination format	Written exam: 150 (objective questions) Online Oral exam: after qualifying written exam Two examiners in panel	165 objective questions (online)	Part A (objective) 5 Sections (117 Questions) Part B (Essay) 1 Section (2 questions)	No exam	No exam

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Pass Criteria	Pass or Fail	Pass or Fail	Minimum 50 % in each Section; 75% from Part A and 25% from Part-B; with overall score of 60%	Board will evaluate application and declare Eligible or not; Eligible candidates recommend to register	Board will evaluate application and declare Eligible or not; Eligible candidates recommend to register
Re-Exam process (Supplementary)	One retest for written exam after 6 months and should be within 2 years One retest for oral exam after one years and should be within 3 years	After 60 days of announcing results	Unsuccessful section/s can take re-exam and qualify within 2 years.	-NA-	-NA-
Evaluation Procedures	Examiners will evaluate papers and announce results in 8 weeks	Examiners will evaluate papers and announce results within 60 days.	2 Examiners will evaluate papers	Application review, education and experiences review	Board members will review application and consider for certification
Repeal procedures	Should appeal within 90 days after exam results.	Within 30 days after announcing results	Should appeal within 90 days after exam results.	Within 30 days	-NA-
Certification process	Board Recommended qualified candidates to US Board of Examiners for Certification in Clinical Engineering (USECCE)	After announcing results within 30 days ACI will issue Certification	Board Recommended qualified candidates to ICC	RCT Board Issues Registered Certification	Qualified candidates can register in Board
Frequency of Examination	Once in a Year (every November) Two weeks text period	Twice in a year May & November	Twice in a Year	-NA-	-NA-
Validity	3 Years	3 Years	Life long	One year	3 Years
Renewal process	Every three years with self-assessment process	Every three years with self-assessment process \$ 100 (Members) \$ 150 (Non-members)	Annual renewal fee: \$60 By 31 st March	£ 21 (annual) By 31 st January	£30 (Annual)

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Contact Details	Healthcare Technology Certification Commission 5200 Butler Pike Plymouth Meeting, PA 19462-1298 Phone: (610) 567-1240 Fax: 815-642-0658 certification@accenet.org	ACI - 4301 N. Fairfax Drive, Suite 301, Arlington, aci@aami.org	BMET Certification Canada 87 Halley St. Nepean, ON K2J 3R5 Canada bmetcertcanada@ncf.ca	The Registrar The Register of Clinical Technologists Fairmount House 230 Tadcaster Road York YO24 1ES Email: enquiries@therct.org.uk	8 Priory Hall, Stillorgan Co Dublin, Ireland
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Note I: (USA)

1) ACCE written exam modules

1	Technology Management	32.2 %
2	Service Delivery Management	16.8 %
3	Product Development, Testing, Evaluation, & Modification	4.9 %
4	Telecom	8.0 %
5	Education of Others	10.6 %
6	Facilities Management	4.7 %
7	Risk Management / Safety	10.6 %
8	General Management	10.7 %
9	Other	1.5 %
	Total	100%

2) AAMI Exam Modules

CBET Subject Areas	Percentage
Anatomy and Physiology	12%
Public Safety in the Healthcare Facility	15%
Fundamentals of Electricity and Electronics	13%
Healthcare Technology Function and Operation	25%
Healthcare Technology Problem Solving	25%
Healthcare Information Technology	10%
Total	100%

Note I (A): AAMI (USA)

AAMI also offer certification in i) Certified Laboratory Equipment Specialist (CLES) ii) Certified Radiology Equipment Specialist (CRES)

iii) Certified Healthcare Technology Manager (CHTM) iv) Certified Industrial Sterilization Specialist (CISS) v) Certified Quality System Manager (CQSM)

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In USA other board offers certification, Biomedical Electronics Technician Certification (BDM) from the Electronics Technician Association (ETA)

Healthcare Technology Management (HTM) is professional services assist to candidates appearing CBET examination.

Note II: (Canada):

- 1) The prerequisites are registration in provincial association as Certified Engineering Technologies (CET) / Applied Science Technologist (AScT) or Technician (CTech).
- 2) The Secretariat will send the letter of recommendation (LOR) to the references and ask to fill the confidential questionnaires on candidate's competences The Secretariat will send the letter of recommendation (LOR) to the references and ask to fill the confidential questionnaires on candidate's competences.
- 3) Acceptable Items inside exam hall: Scientific Calculator, Formulas on que Card (7.6 cm by 12.7 cm) with 8 pinch fonts
- 4) Part-A sections: 1) Anatomy & Physiology [21 questions] 2) Basic Electronics [22 q] 3) Medical Instrumentation [24 q] 4) Safety and Standards [15 q] 5) Troubleshooting [22 q]
- 5) Website: <http://bmetcertcanada.ncf.ca/index.htm>

Note III: (UK)

Certification in RCT includes, Medical physics, Nuclear medicine, Radiotherapy physics, Radiation physics, Radiation engineering, Rehabilitation engineering, Renal technology.

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BioMedical Engineering in India

Biomedical Engineering profession is part of Healthcare Industry and expecting quality practice from BME Engineers / Technicians. In India more than 2 lakh Biomedical Engineers / Technicians working in Hospital / Clinical Laboratories / Company / Organization and etc., However, there is no such apex body to certify competency skills of these Engineers.

Number of Colleges offering BME course at various levels		
Course	Number of Colleges	Annual Intake
Diploma / ITI (Medical Electronics)	~ 30	~ 1,500
Engineering (B.E / B. Tech)	~ 100	~ 4,500
Masters (M.E / M. Tech)	~ 44	~ 8,50
Total		~ 6,850

Estimated No. of working professionals In Biomedical Engineering Field

Years of experience	Estimated No. of Professionals
0 -1	~ 7000
1-3	~ 15,000
3 or more	~ 1.8 Lakh

Job Domains in Biomedical Engineering:

Below listed shows various job categories in BME field,

Clinical Engineer	Sales Engineer	Healthcare Finance	Product Design Engineer
Service Engineer	Self-Entrepreneur	Healthcare IT	Quality Control Engineer
Application Specialist	Consultation Business	Rehabilitation Engineer	Validation & Verification Engg.
Product Specialist	JCI / NABH / NABL Consultant	Patents Examiner	Medical Device Regulatory Engg.
Procurement Engineer	Scientist	Academic	Market Research Analyst

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Indian Biomedical Skill Consortium (IBSC)

The Indian BioMedical Skill Consortium (IBMSC) Certifies Indian & International Biomedical Engineers based on their **Experience, Competency and Qualification** levels. The Certified BioMedical Engineers will be highly preferred to practice profession in BioMedical field and also gets equivalence certification to work in abroad. Initially more than 2 lakhs Biomedical Engineers from India will be benefited by this proposal and expecting 6,500 or more fresh graduates will use this platform every year. Those who graduated from non-BME background and working in BME field are also eligible for this certification.

Sl. NO	Name of the Exam	Education Qualifications	Experiences
1	Indian Biomedical Skill Certificate	ITI / Diploma / B. Tech / B. E / M. E / M. Tech / Ph. D / Post – Doctoral in Biomedical Engineering / Bioengineering / Medical Engineering / Medical Electronics or equivalent.	Fresh graduates (or) working professionals in Biomedical Field.

Note: Engineers and Technicians has to appear same exam and issued same certification, no separate certification issued for Technicians.

Proposed Modules for Certification of Biomedical Engineers

SI No	Subject
1	Anatomy and Physiology
2	Fundamentals of Electricity and Electronics
3	Healthcare Technology Function and Operation
4	Healthcare Technology Problem Solving and Troubleshooting
5	Healthcare Information Technology
6	Healthcare Technology Management
7	Healthcare Safety & Standards
8	NABH & NABL Accreditation
9	Product Development, Testing, Evaluation, & Modification
10	Medical Terminology for Engineers
11	Risk Management / Safety
12	Radiation Safety
13	Medical Device Regulatory
14	Facilities / General Management
15	Service Delivery Management

NOTE:

- I) Since this is first time certification to BME professionals, experienced candidates can apply to all modules.
- II) Candidates can apply for 15 modules at a time or part (3 each modules).

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Detail Course Content	
1. Anatomy & Physiology	2. Fundamentals of Electricity and Electronics
<p>A. Systems Respiratory, Gastrointestinal, Nervous, Circulatory, Musculoskeletal, Endocrine</p> <p>B. Organs Heart, Lungs, Liver, Kidneys, Brain, Gallbladder, Pancreas & Others</p> <p>C. Blood Components, Metabolism</p>	<p>A. Transducers</p> <p>B. Calculations and Conversions Hex /Decimal/Binary</p> <p>C. Devices Active Devices, Solid State Devices, Analog & Digital, Passive, Active, Digital</p> <p>A. Circuits and Components Operational Amplifier, Power Supplies, Common Base/ Emitter/ Collector Transistor Circuits; E AC Power - Transformer, CRTs, X-Ray tubes, Photomultipliers.</p> <p>E. Test Equipment</p> <p>F. Power Distribution and Storage Systems: Transformers, Distribution, Batteries, UPS / Line Conditioning</p>
3. Healthcare Technology and Function	4. Healthcare Technology Problem Solving & Troubleshooting
<p>A. Understand physiological concepts as applicable to healthcare technology (e.g., PEEP sphygmomanometer, manometer, Korotkoff sounds, Einthoven’s triangle, 10-20-10 EEG pattern).</p> <p>B. Understand normal function, use, and underlying technology of test equipment (electrical safety analyzer, defibrillator analyzer, electro surgical analyzer, physiologic simulators, DVM, meters).</p> <p>Monitoring Equipment</p> <p>C. Understand normal function and underlying technology of monitoring systems (e.g., EtCO₂, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration).</p> <p>Diagnostic Equipment</p> <p>D. Understand normal function and underlying technology of laboratory equipment (e.g., centrifuges, water baths, analyzers, cryostats, microtomes).</p>	<p>A. Identify and resolve fault conditions of modules/subsystems including power supplies.</p> <p>B. Prioritize repairs of medical devices based on level of risk and/or urgency.</p> <p>C. Differentiate between a device error and a use error (User Training, Applications) to determine appropriate action.</p> <p>Monitoring Equipment</p> <p>D. Differentiate between an issue with a localized monitoring device on a network and a system-wide problem.</p> <p>E. Identify the fault conditions and apply appropriate corrective action for monitoring systems (EtCO₂, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration).</p> <p>Diagnostic Equipment</p> <p>F. Identify the fault conditions and apply appropriate corrective action for laboratory equipment (Centrifuges, Water Baths, Analyzers, cryostats, microtomes).</p> <p>G. Identify the fault conditions and apply appropriate corrective action for diagnostic equipment (otoscope, ophthalmoscope, audiometer, uroflow meter).</p>

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<p>E. Understand normal function and underlying technology of imaging devices (e.g., Ultrasound, Radiographic / Fluoroscopy).</p> <p>F. Understand normal function and underlying technology of diagnostic equipment (e.g., otoscope, ophthalmoscope, audiometer, uroflow meter).</p> <p>Therapeutic Equipment</p> <p>G. Understand normal function and underlying technology of infusion equipment (e.g., feeding pumps, infusion devices, syringe pumps, PCA pumps).</p> <p>H. Understand normal function and underlying technology of life support equipment (e.g., defibrillators, anesthesia machines, ventilators, balloon pumps, external pacemakers).</p> <p>I. Understand normal function and underlying technology of therapeutic equipment (e.g., infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light).</p> <p>J. Understand normal function and underlying technology of operating room equipment (e.g., electro surgical generators, video equipment, lasers, tourniquets, sterilizers, warmers).</p>	<p>Therapeutic Equipment</p> <p>H. Identify the fault conditions and apply appropriate corrective action for infusion equipment (feeding pumps, infusion devices, syringe pumps, PCA pumps).</p> <p>I. Identify the fault conditions and apply appropriate corrective action for therapeutic equipment (infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light, defibrillators, external pacemakers).</p> <p>J. Identify the fault conditions and apply appropriate corrective action for operating room equipment (electro surgical generators, video equipment, tourniquets, sterilizers, warmers).</p> <p>Troubleshooting</p> <p>K. Electronic Component Level</p> <p>L. Situational (i.e. User error, user training, applications)</p>
5. Healthcare Information Technology	6. Healthcare Technology Management
<p>A. Foundations</p> <p>1. Hardware</p> <p style="margin-left: 20px;">a. Topology</p> <p style="margin-left: 20px;">b. PCs / Laptops / Servers</p> <p style="margin-left: 20px;">c. Wiring / Structured Cabling / Connectors</p> <p style="margin-left: 20px;">d. Switches / Hubs / Routers</p> <p style="margin-left: 20px;">e. Wireless Communications</p> <p>2. Software / Middleware / Applications</p> <p style="margin-left: 20px;">a. EMR/EHR</p> <p style="margin-left: 20px;">b. Healthcare Information Systems (PACs, LIS, RIS)</p> <p style="margin-left: 20px;">c. Network Protocols (IP, CCP, UDP)</p> <p style="margin-left: 20px;">d. Operating Systems</p> <p>B. Function and Operation</p> <p>1. Hardware</p> <p style="margin-left: 20px;">a. PCs, Switches, Patch Panels</p>	<p>A. Product Selection / Vendor Selection</p> <p>B. Technology Assessment</p> <p>C. Project Management</p> <p>D. Capital Planning</p> <p>E. Interpretation of Codes and Standards</p> <p>F. Usability/Compatibility Assessment</p> <p>G. Healthcare Technology Strategic Planning</p> <p>H. Clinical Device Use and/or Application</p> <p>I. Device/System Upgrade Planning</p> <p>J. Device Integration Planning</p> <p>K. Clinical Systems Networking</p> <p>L. Life Cycle Analysis</p> <p>M. Coordinating Device Interoperability / Interfacing</p> <p>N. Other Technology Management Responsibilities</p> <p>O. Return on Investment (ROI) Analysis</p>

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<ul style="list-style-type: none"> b. Networks, Topology c. Peripherals 2. Integration <ul style="list-style-type: none"> a. Bedside Medical Device Integration (BMDI) b. Medical Device Integration (MDI) (Labs, Printers, etc.) c. Mobile Devices (Handhelds, Smart Phones, Tablets, etc.) 3. Test Equipment <ul style="list-style-type: none"> a. Cable Test Devices (Copper, Fiber) b. Network Test Devices 4. Security C. Problem Solving <ul style="list-style-type: none"> 1. Computer Networks 2. Integration 3. PCs, Switches, Hubs 	<ul style="list-style-type: none"> P. EMI/RFI Management Q. Pre-clinical Procedure Set-up / Testing R. Clinical Trials Management (Non-investigational) S. Water Quality Management T. Participation in Clinical Procedures (e.g., surgery)
7. Healthcare Safety & Standards	8. NABH & NABL Accreditation
<ul style="list-style-type: none"> A. Electrical – Micro / Marco-shock, Electrical Safety Testing B. Chemical - Material Safety Data Sheet C. Biological - Universal Precautions D. Fire <ul style="list-style-type: none"> 1. Class, 2. Fire Extinguishers E. Regulations, Codes and Standards <ul style="list-style-type: none"> 1. CSA Standards 2. Electromedical 3. Laser Safety 4. Low Pressure Connecting Assemblies (Medical Gases) 5. Stability and Transport F. Biomedical Waste Management <ul style="list-style-type: none"> 1. Non-Hazardous 2. Hazardous <ul style="list-style-type: none"> i) Radioactive waste ii) Discarded Glass iii) pressurized Containers 	<p>NABH</p> <ul style="list-style-type: none"> A. Access, Assessment & Continuity of Care (AAC) B. Care of Patients (COP) C. Management of Medication (MOM) D. Patient Rights & Education (PRE) E. Hospital Infection Control (HIC) F. Continual Quality Improvement (CQI) G. Responsibilities of Management (ROM) H. Facility management & Safety (FMS) I. Human Resource Management (HRM) J. Information Management System (IMS) K. Documentation Requirements & Implementation Guidelines L. Accreditation Process M. Final Assessment <p>NABL</p> <ul style="list-style-type: none"> A. Accreditation and International dimensions B. Accreditation criteria & their interpretations C. Laboratory Accreditation

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<ul style="list-style-type: none"> iv) Chemical Waste v) Cytotoxic Waste vi) Plastic Disposables vii) Liquid Wastes 	<ul style="list-style-type: none"> D. Process of Accreditation E. NABL operations F. Accreditation process & Assessment techniques
9. Product Development, Testing, Evaluation, & Regulatory Compliance	10. Medical Terminology for Engineers
<ul style="list-style-type: none"> A. Regulatory Compliance Activities B. New Product Testing & Evaluation C. Documentation Development / Management D. Human Factors Engineering E. Product / Systems Quality Management F. Device Modifications G. Medical Device Design H. Product Research and Development I. Medical Device Concept Development / Invention J. Other Product Development Responsibilities K. Product Sales / Sales Support 	<ul style="list-style-type: none"> A. Disease and Treatment B. Circulation, Blood and Immunity C. Respiration and Digestion D. Urinary and Male Reproductive System E. Female Reproductive System, Pregnancy and Birth F. Endocrine and Nervous Systems, Behavioral Disorders G. The Senses H. The Skeleton and Muscular Systems The Skin
11. Risk Management / Safety	12. Radiation Safety
<ul style="list-style-type: none"> A. Patient Safety B. Product Safety / Hazard Alerts / Recalls C. Incident / Untoward Event Investigation D. Engineering Assessment of Medical Device Failures E. Root Cause Analysis F. Medical Device Incident Reporting G. Infection Control I. Failure Mode and Effect Analysis J. Hazardous Materials K. Other Risk Management / Safety Responsibilities 	<ul style="list-style-type: none"> A. X-Ray Equipment and Production B. Radiation Units for Measurement of Radioisotopes C. Radiation Units for Measurement of Ionizing Radiation D. Personal Maximum Permissible Doses E Proposed I.C.R.P. New Maximum Permissible Doses F. Radiation Detection and Monitoring G. Basic Principles of Radiation Protection H. Leak Test and Storage of Radiographic Exposure Devices I. Biological Effects of Ionizing Radiation J. Nuclear Regulatory Commission Regulations K. Documentation and Record Keeping L. Transportation of Radioactive Material
13. Medical Device Regulatory	14. Facilities / General Management
<ul style="list-style-type: none"> A. Medical Devices, In –vitro devices, Biologics & Combination Products: Introductory Module B. FDA Regulations and Guidelines on Medical Devices 	<p>Facilities</p> <ul style="list-style-type: none"> A. Facility Emergency Preparedness Activates B. Emergency Electrical Power

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<ul style="list-style-type: none"> C. European Union Regulatory Guidelines on Medical Devices D. Medical Device Regulations from Indian perspective E. Management of the risks associated with Medical devices F. Biocompatibility Studies and Medical Devices G. Clinical Trials: Medical Devices H. Overview of In – Vitro Device Regulation I. Overview of Combination Products Regulation J. Dossier preparation in CTD format, eCTD submissions 	<ul style="list-style-type: none"> C. Hospital Building Plan Review D. Hospital Building Design E. Medical Gas System Testing F. Other Facility Management Responsibilities G. Facility / Utility Remediation Planning H. Supervise / Manage / Direct Facilities Management <p>General</p> <ul style="list-style-type: none"> A. Budget Develop / Execution B. Personnel Management / Supervision C. Staffing D. Staff Skills / Competency Assessment E. Policy / Procedure Management / Development F. Performance Improvement G. Business / Operation Plan Development / Management H. Committee Management
15. Service Delivery Management	
<ul style="list-style-type: none"> A. Technician / Service Supervision B. Equipment Repair and Maintenance C. Equipment Acceptance D. Service Contract Management E. Equipment Performance Testing F. Maintenance Software Administration G. Develop Test/Calibration/Maintenance Procedures H. Parts/Supplies Purchase and/or Inventory Management I. Other Service Delivery Responsibilities. J. Technical Library / Service Manuals Management 	

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Examination Procedures

Here the Examination Procedure Details:

- 1) Mode of Application: Online
- 2) Examination Pattern: Objective
- 3) Number of questions in each module: 30
- 4) Time duration for 1 modules: 90 minutes

Evaluation Procedures:

- 1) Minimum 60% in each module is required to qualify exam.
- 2) If any candidate has not qualified any module/s s/he can take re-exam in that module/s.
- 3) Three modules count as 1 unit; total 5 units for 15 modules.
- 4) Every three years candidates need to apply for certification renewal.
- 5) Candidate can gain bonus point by **Continues Professional Development (CPD)** assessments

Experience, Competency & Qualification (E, C, Q) equivalence

Experience	Corresponding points	Competency	Corresponding points	Qualification	Corresponding points
≤ 3 years	1	3 modules	1	Diploma	1
≤ 6 years	2	6 modules	2	B.E / B. Tech	2
≤ 9 years	3	9 modules	3	M.E / M. Tech	3
≤ 12 years	4	12 modules	4	Ph. D	4
≥ 15 years	5	15 modules	5	Post – Doctoral	5

NOTE: In the evaluation process,

- I) **Experience:** For every 3 years of experience is consider as 1 point, maximum 5 points for ≥ 15 years. No more additional points beyond this.
- II) **Competency:** Qualifying in every 3 modules consider as 1 point, maximum 5 points for 15 modules.
- III) **Qualification:** corresponding points for education is followed as; Diploma -1, B.E / B. Tech -2, M.E / M. Tech -3, Ph. D – 4, Post -Doctoral – 5.

Experience Corresponding points	Competency Corresponding points	Qualification Corresponding points	Projected Score
1	1	1	1 (minimum) 125 (maximum)
2	2	2	
3	3	3	
4	4	4	
5	5	5	

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Technology Readiness Level (TRL)

Technology Readiness Level (TRL) Score will be used to estimate the competency levels.

(E X C X Q) Score	TRL Level
1 - 5	TRL - 1
6 - 10	TRL - 2
11 - 20	TRL - 3
21 - 30	TRL - 4
31 - 40	TRL - 5
41 - 50	TRL - 6
51 - 60	TRL - 7
61 - 80	TRL - 8
81 - 100	TRL - 9
101 - 125	TRL - 10

Continuous Professional Development (CDP)

Continuous Professional Development (CDP):

CPD refers to the process of tracking and documenting the skills, knowledge and experience that one can gain both formally and informally. It's a record of what candidate experience, learn and then apply. This process helps candidate record, review and reflect on what s/he learn also grow s/he professional networks and contacts. CPD including following categories; maintain technical competence, retain and enhance effectiveness in the workplace, serve the professional community and etc.,

SI NO	Activity	Bonus Points
1.	Educational Activates	
	Participation in a course less than 1-day duration	1
	Participation in a course less than 5-day duration	1
	Participation as a Lecturer / Recourse person	1
	Pursuing Higher education (part-time)	1
	Relevant Certification courses (Diploma / PG Diploma)	1
2.	Scientific Meetings	
	Participation in professional / Conference / association meetings	1
	Participation in professional / Conference / association meetings as speaker	1
	Organiser / Member of Scientific / Organising Committee at national level	1
	Organiser / Member of Scientific / Organising Committee at international level	1










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	Professional Activates	
3.	Membership in Association / Society	1
	Member in Governing Body	1
	Organised a course / training / workshop / Medical Expos and etc.,	1
	Resource person for course / training / workshop / medical Expos and etc.	1
	Participation in course / training / workshop, Medical Expos and etc.,	1
	Publications (Articles / Scientific)	
4.	Article Published in refereed Journal (National)	1
	Article Published in refereed Journal (International)	1
	Accepted provisional Patent	1
	Book Chapter	1
	Editor of Multi-author Book	1
	Editor of Solo or Joint author	1
	Editor of peer-reviewed Journal	1
	Member of an editorial Board	1
	Technical Articles in Electronic / Print Media	1







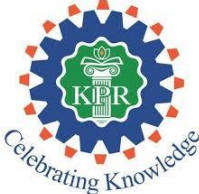


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Knowledge & Technical Partners









Here the list of Knowledge and Technical partners of IBSC

Sl No	Name of Institute / Organization	Logo
1.	Andhra Pradesh MedTech Zone (AMTZ)	
2.	Quality Council of India (QCI)	
3.	Association of Indian Medical Device Industry (AIMED)	
4.	Panjab University, Chandigarh	
5.	IIT Guwahati	
6.	Health Sector Skill Council (HSSC)	
7.	North-East Hill University, Shillong, Meghalaya	
8.	Agni College of Technology	
9.	B V Raju Institute of Technology	









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10.	SIMS Healthcare Pvt. Ltd	
11.	Mahendra Institute of Technology,	
12.	Mahendra College of Engineering	
13.	M/S Tenx Health Technologies Pvt. Ltd.	
14.	M/S PrimedeQ Indian Pvt. Ltd.	
15.	BMS College of Engineering	
16.	KPR Institute of Engineering & Technology	
17.	Annamalai University	
18.	Sahrdaya College of Engineering and Technology, Thrissur, Kerala	

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19.	Rajiv Gandhi Institute of Technology, Bangalore	 RAJIV GANDHI INSTITUTE OF TECHNOLOGY
20.	Indian Institute of Engineering Science and Technology	
21.	KLE Dr. M S Sheshgiri College of Engineering and Technology,	
22.	Prul University, Vadodara	
23.	Mahatma Gandhi Mission's College of Engineering and Technology, Navi Mumbai, Maharashtra	 MGM's College of Engineering and Technology Kamothe, Navi Mumbai <small>Approved by AICTE, Recognized by Govt. of Maharashtra & Affiliated to University of Mumbai</small>
24.	Dr. N.G.P. Institute of Technology, Coimbatore	
25.	SSN College of Engineering	
26.	Sri Siddhartha Institute of Technology,	

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27.	MS Ramaiah Institute of Technology	
28.	Vignan University,	
29.	Karpaga Vinayaga College of Engineering & Technology	
30.	Thadomal Shahani Engineering College, Mumbai, Maharashtra	
31.	JIS College of Engineering, Kalyani, West Bengal	
32.	Sri Ramakrishan Engineering College,	
33.	FBA India,	
34.	IFMBE	
35.	AAMI	