

ELECTRICAL & ELECTRONIC MEDICAL DEVICES TESTING LABORATORY

World Health Organization
COUNTRY OFFICE FOR India

NHSRC

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सत्यमेव जयते

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Ministry of Commerce & Industry
Department of Commerce
Udyog Bhawan, New Delhi-110011
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MESSAGE

Medical Devices form an important component of patient care. From tongue depressor to dialysis machine, medical devices encompass a very broad and complex variety of technologies. The complexities are coupled with presence of power factors in most medical devices. Thus, apart from performance the crucial aspect of devices safety, patient safety and health provider's safety gets incorporated. In order to comply with all safety requirements, sets of universal standards and norms have been prescribed, compliance to which ensures delivery of right technology in the right way. A means to verify the devices against this desired compliance is testing. Thus, product testing brings into existence the first level of assessment of appropriateness and safety of a devices.

Since devices have a very broad range, so are tests and testing requirements for safety. However, all electrical and electronic devices that deal with electrical power and electromagnetic interference have a common set of prescribed tests and standards. This report highlights the basic requirements, work flow, infrastructure and human resources required for establishing medical device testing laboratory/ facility for testing of electrical and electronic medical devices.

With Government encouraging medical devices sector in the country, and 'Make in India' drive pushing industrial growth, this technical concept note is both timely and encouraging. I congratulate National Health Systems Resource Centre, a technical support institution under Ministry of Health & Family Welfare, Government of India in formulating this report. This would serve the needs of government agencies, laboratories and research institutions, as well as medical devices manufactrers in a highly complex technical area of work. Department of Commerce shall ensure its support in this endeavour.

Ravi Cappor

Foreword

Electrical and Electronic equipment constitutes over 60% of all general medical equipment used in Health facilities. This puts an obligation of part of manufacturers, purchasers and users to have the equipment tested for safety and efficiency. While there remains inadequacy of infrastructure to provide the bulk of testing services, modest beginning has been made and several departments within the Government both at the Centre and in the States are working cohesively to enable this essential requirement of medical devices Eco-system. The team from Healthcare Technology Division of NHSRC visited 23 laboratories across the length and breadth of country that deal with testing of general electric & electronic products as well as some that test medical devices. I sincerely thank the staff of all those laboratories for having shared their wisdom with NHSRC team. The support provided by Society for Microwave Electronics, Engineering and Research (SAMEER) from both Chennai & Mumbai has been commendable. I also appreciate the team from Underwriter Laboratories (UL) India Pvt. Ltd. for providing valuable edits and feedback to the document. I thank World Health Organization Country Office for India for providing several insights and technical support. The team from Healthcare Technology Division of NHSRC that worked on this report including Swati Barwala, Jitendar Sharma, Mohammad Ameel and Prabhat Arora deserve special mention. This report would serve as an extremely useful technical resource in establishment and operationalising electrical and electronic medical devices testing laboratory, taking us one step closer to the goal “Make in India”

Dr. Sanjiv Kumar
Executive Director

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CHAPTER 01

Safety of Medical Electrical Equipment

Standards form the fundamental building blocks for product development. Standards also make it easier to understand and compare competing products. As standards are globally adopted and applied in many markets, they also fuel international trade. It is only through the application of standards that the credibility of new products and new markets can be verified. In summary standards fuel the development and implementation of technologies that influence and transform the way we live, work and communicate.

Standards are published documents that establish specifications and procedures designed to ensure the reliability of the materials, products, methods, and/or services people use every day. Standards address a range of issues, including but not limited to various protocols that help ensure product functionality and compatibility, facilitate interoperability and support consumer safety and public health.

These become more so important in the domain of Medical & Healthcare since we would be dealing with a person who is already incapacitated in some or other way due to his medical condition. Hence use of standards that ensure the safety of the equipment & in turn ensure safety to the user and patient become indispensable. Standards & regulations are primarily concerned with enabling patient access to high quality, safe and effective medical devices, and restricting access to those products that are unsafe or have limited clinical use. When appropriately implemented, they ensure public health benefit and the safety of patients, health care workers and the community.

IEC 60601 SERIES OF STANDARDS

The most commonly used standard to establish safety for medical electrical equipment is the IEC 60601 series of standards, published by International Electrotechnical Commission, which is a non-profit organization that writes & publishes standards for variety of electrical & electronic equipment. It is a series of a number of standards that deals with the safety of Medical Equipment from different dimensions, as listed below, in Table 1.

Table 1: Tests for IEC 60601 Series of Standards

Electrical Tests	Mechanical Tests	Thermal Tests	Noise/Vibration/Ingress Pressure
Power Input	Trapping Zones	Temperature Tests	Acoustic Energy
Humidity Preconditioning	Tensile Safety Factor, Suspension Systems	Single Fault Condition (Ventilation Block, Transformer Abnormal)	Hydrostatic Pressure Test
Voltage Mismatch	Stability, Instability & Transportability	Temperature & Overload control devices	Hand transmitted vibration
Voltage or Charge Limitation	Mobile Equipment Force for Propulsion	Overload, Heating elements & Motor	Harmful Ingress (Water & Particles)
Working Voltage Measurements	Mobile Equipment over threshold	Failure of thermostats	
Defib-Proof Applied Parts	Cord-connected foot operated control devices	Thermal Cycling for spaces filled with Insulating Compounds	
Leakage Current Tests	Enclosure Impact		
Dielectric Tests	Drop Impact		
Ball Pressure	Rough Handling		
Electrical single fault conditions	Mold Stress Relief		
Shorting One MOP	Enclosure Force		

In addition to the above mentioned tests, there are certain tests that are applicable for equipment which is intended to be used with flammable anesthetics or intended to be used in Oxygen-Rich atmosphere.

IEC 60601 series of standards also contain requirements for labelling, documentation (User Manual, Service Manual, Training) that ensures higher level of safety while the equipment is in use. Also, IEC 60601-1 urges the manufacturer to determine all the risks associated with the equipment & mitigate the same using risk control measures by applying ISO 14971.

The IEC 60601-1 is the General standard, which is applicable for all types of Medical Electrical Equipment, irrespective of its application. There are wide ranges of different types of equipment in Medical & Healthcare domain ranging from a simple Digital BP Monitor to a very complicated Catlab used for Interventional procedures. There are simple radiography machines that are used for diagnosis might not have any applied parts. Also, there are life supporting machines like ventilators, constantly monitoring ECG machines to therapy machines for infants in the form of Phototherapy Units. However, to cover all the different safety aspects of all the above mentioned types of equipment, a single standard is not sufficient. Hence we have, in the IEC 60601 series of standards, Collateral Standards & Particular Standards.

THE COLLATERAL AND PARTICULAR STANDARDS

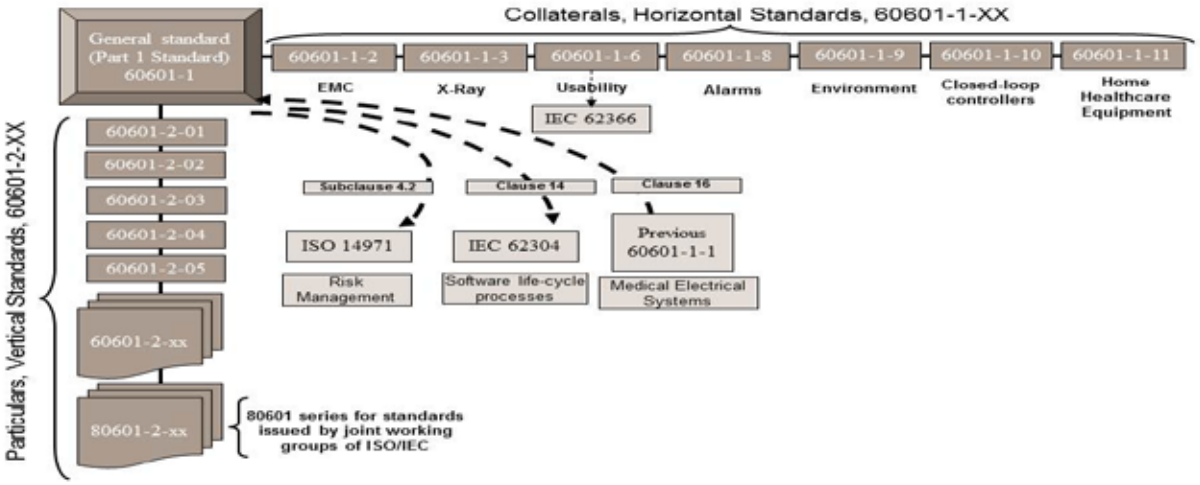

Figure 1: Hierarchy of IEC 60601 Series of Standards

The general requirements of 60601-1 apply to all medical electrical equipment and part 2 standards apply to specific categories of medical electrical equipment. However, there is another level in this hierarchy of standards: the collateral standards. These are applied more selectively than the general requirements, either in terms of the topic they cover or the type of equipment, but they are not as specific as the part 2 standards.

The collateral standards deal with a specific group of equipment. For example, all equipment those produce X-rays, irrespective of their specific application, come under the purview of IEC 60601-1-3, which covers Radiation Protection. Similarly, any medical equipment with Alarm features has to comply with IEC 60601-1-8. IEC 60601-1-6 is applied to ensure safety with respect to Usability (User Errors).

However, to deal with safety concerns specific to equipment application, we have vertical standards as Particular Standards. These standards contain requirements specific to the application of equipment. For example, though equipment produces diagnostic

X-rays, the application might be different in terms of Interventional, Mammography, Dental, Radiography, etc. These applications require different design & documentation requirements which are taken care in the particular standards. These particular standards have requirements on similar lines of the General Standard & all the applicable collateral standards. The requirements in particular standard override the requirements in the General/Collateral standards.

There are numerous particular standards depending on the applications of Medical Equipment. All the particular standards are as listed below, in Table 3.

For example, suppose the medical electrical equipment was to be a Diagnostic Radiography Machine, we would require applying the following standards:

1. IEC 60601-1: The General Standard – Basic Safety & Essential Performance of Medical Electrical Equipment.
2. IEC 60601-1-3: Collateral Standard – Radiation Protection in Diagnostic X-ray Equipment
3. IEC 60601-1-6: Usability (Documentation Review)
4. IEC 60601-2-54: X-ray Equipment for Radiography & Radioscopy

Therefore, in addition to the tests mentioned in Table 1 above, the following tests are commonly conducted as applicable to ensure compliance, depending on the design/features available.

Table 2: Additional Tests from Collateral & Particular Standards for Diagnostic X-ray Equipment

IEC 60601-1-3	IEC 60601-2-54
Test for Half-Value Layer	High-Voltage Dielectric
Leakage Radiation in loading states	Speed of Movements
Leakage Radiation when not in Loading states	Nominal Shortest Irradiation Time
Additional requirements for Labelling & Accompanying documents	Linearity & Constancy in Radiography
	Reproducibility of Radiation Output
	Accuracy of loading factors
	Correspondence between X-ray field and Image Reception Area
	Attenuation Equivalent of items in the X-ray beam
	Light Field Indicator Test

TABLE 3: List of Particular Standards in IEC 60601 Series

Title	Particular Number	Particular Standard Safety and Essential Performance of:
General Medical Equipment (Default Category if there are no applicable Particular Standards)	IEC 60601-1	General Standard
	IEC 60601-2-18	Endoscopic Equipment
	IEC 60601-2-19	Infant Incubators
	IEC 60601-2-20	Infant Transport Incubators
	IEC 60601-2-21	Infant Radiant Warmers
	IEC 60601-2-32	Associated Equipment of X-Ray Equipment
	IEC 60601-2-35	Blankets, Pads and Mattresses, Intended for Heating in Medical Use
	IEC 60601-2-38	Electrically Operated Hospital Beds
	IEC 60601-2-41	Surgical Luminaires and Luminaires for Diagnosis
	IEC 60601-2-46	Operating Tables
	IEC 60601-2-52	Medical Beds
	IEC 80601-2-35	Heating Devices Using Blankets, Pads or Mattresses and intended for Heating in Medical Use
	IEC 80601-2-58	Lens Removal Devices and Vitrectomy Devices for Ophthalmic Surgery
Cardio, Vascular, Pulmonary (Air/ Fluid Pump) Equipment	IEC 60601-2-12	Lung Ventilators
	IEC 60601-2-13	Anaesthetic Systems
	IEC 60601-2-16	Haemodialysis, Haemodiafiltration and Haemofiltration Equipment
	IEC 60601-2-24	Infusion Pumps and Controllers
	IEC 60601-2-39	Peritoneal Dialysis Equipment
Ultrasound Equipment	IEC 60601-2-5	Ultrasonic Physiotherapy Equipment
	IEC 60601-2-36	Equipment for Extracorporeally Induced Lithotripsy
	IEC 60601-2-37	Ultrasonic Medical Diagnostic and Monitoring Equipment
Laser Equipment	IEC 60601-2-22	Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
Patient Monitoring Equipment	IEC 60601-2-23	Transcutaneous Partial Pressure Monitoring Equipment
	IEC 60601-2-25	Electrocardiographs
	IEC 60601-2-26	Electroencephalographs
	IEC 60601-2-27	Electrocardiographic Monitoring Equipment
	IEC 60601-2-30	Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment
	IEC 60601-2-34	Invasive Blood Pressure Monitoring Equipment
	IEC 60601-2-47	Ambulatory Electrocardiographic Systems
	IEC 60601-2-49	Multifunction Patient Monitoring Equipment
	IEC 60601-2-51	Recording and Analysing Single Channel and Multichannel Electrocardiographs
	IEC 60601-2-55	Respiratory Gas Monitors (when issued)
	IEC 80601-2-30	Automated Non-Invasive Sphygmomanometers
	IEC 80601-2-50	Screening Thermographs for Human Febrile Temperature Screening
	IEC 80601-2-61	Pulse Oximiter Equipment (in FDIS stage of development)

Title	Particular Number	Particular Standard Safety and Essential Performance of:
Applied Current/ Energy Equipment	IEC 60601-2-2	High Frequency Surgical Equipment and High Frequency Surgical Accessories
	IEC 60601-2-4	Cardiac Defibrillators
	IEC 60601-2-10	Nerve and Muscle Stimulators
	IEC 60601-2-14	Electroconvulsive Therapy Equipment
	IEC 60601-2-31	External Cardiac Pacemakers with Internal Power Source
	IEC 60601-2-40	Electromyographs and Evoked Response Equipment
	IEC 60601-2-50	Infant Phototherapy Equipment
Applied EM Radiation Equipment	IEC 60601-2-1	Electron Accelerators in the Range 1 MeV to 50 MeV
	IEC 60601-2-3	Short-Wave Therapy Equipment
	IEC 60601-2-6	Microwave Therapy Equipment
	IEC 60601-2-7	High-Voltage Generators of Diagnostic X-Ray Generators
	IEC 60601-2-8	Therapeutic X-Ray Equipment Operating in the Range 10 kV to 1 MV
	IEC 60601-2-9	Patient Contact Dosemeters Used in Radiotherapy with Electrically Connected Radiation Detectors
	IEC 60601-2-11	Gamma Beam Therapy Equipment
	IEC 60601-2-15	Capacitor Discharge X-Ray Generators
	IEC 60601-2-17	Automatically-Controlled Brachytherapy Afterloading Equipment
	IEC 60601-2-28	X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis
	IEC 60601-2-29	Radiotherapy Simulators
	IEC 60601-2-33	Magnetic Resonance Equipment for Medical Diagnosis
	IEC 60601-2-43	X-Ray Equipment for Interventional Procedures
	IEC 60601-2-44	X-Ray Equipment for Computed Tomography
	IEC 60601-2-45	Mammographic X-Ray Equipment and Mammographic Stereotactic Devices
	IEC 60601-2-54	X-ray Equipment for Radiography and Radioscopy
	IEC 60601-2-63	Dental extra-oral X-ray Equipment
	IEC 60601-2-65	Dental intra-oral X-ray Equipment

CHAPTER 02

Introduction To Electromagnetic Interference And Electromagnetic Compatibility

A Medical device may be defined as any appliance, instrument, material, apparatus or other article, either used in a singular form in combination with other equipment/devices, including the software essential for it's intended purpose by the manufacturer to be used for human beings for the following purpose:

1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. diagnosis, monitoring, treatment, alleviation of or compensation for any injury or handicap;
3. investigation, replacement or modification of the anatomy or of a physiological process;
4. control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means[3].

It is highly important that the operation of Medical Devices must not degrade their own performance or the output of other systems. EMI/EMC test labs, therefore, ensure that the medical devices are protected against external effects (lightning, electromagnetic pulse, electrostatic discharge and man-made Radio frequency transmissions) and internal effects (electronic noise emissions, self-generated RF transmissions from antennas and cross-coupling of electrical currents). This would guarantee self-compatibility within the system (internal environment), with other systems as well as the external environment to provide required performance.

Report is to develop a roadmap to facilitate the setting-up of "EMI/EMC Test Laboratory

An Electromagnetic Interference (EMI) may be defined as any degradation in the performance of an equipment (device/system/sub-system) resulting in malfunctioning of the equipment due to quality parameters of incoming energy.

Interference occurs if the received energy causes malfunctioning of the receptor. The Coupling path, the source and the victim determine whether the receiver is functioning in a wanted or unwanted fashion[4].

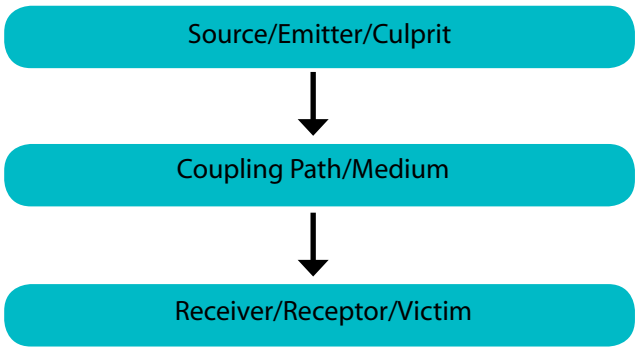

Figure 2: Basic Elements of EMI Situations

Electromagnetic Interference can exist in either of the in two broad divisions:

a) Sources
- Air Conditioners
- Computers and their power cords
- Integrated Circuits (ICs)
- Uninterruptible Power Supply (UPS)
- Fast switching Digital Devices
- Other Medical Electrical and Electronic Equipment

b) Victims
- Medical Devices
- Living beings
- Microprocessors
- Computers
- Device Components
- Communication receivers

Although existence of and interference can be

confirmed only through specialized procedures and test its existence may some times be seen as following examples:

a) Burning of sensitive components of a device.
b) Momentary disturbance in the functioning monitors and radio reception.
c) Reset of computers and data loss.
d) Alteration in the setting of control equipment.
e) Failure to boot into fuction or abrupt dysfunctionality
f) Biological Hazards.

EMI control :

There are serval interfence control techniques that could be applied to reduced or eliminate interfence at source, some of them are :

a) Shielding: In order to reduce the coupling of radiated Electromagnetic energy into the equipment, Metal barriers are used.
b) Proper grounding: Depending upon the frequency of operation, single point, multi point or Hybrid grounding should be done.
c) PCB layout: The early stage design must be modified to a proper PCB design.
d) EMI filtering: The interference on the power, signal and control lines would suppress via EMI filtering.

Overview - Electromagnetic Compatibility (EMC)

Electromagnetic Compatibility (EMC) is a near perfect state in which a receptor (system/device/subsystem) functions satisfactorily in common electromagnetic environment, without introducing intolerable electromagnetic disturbance to any other devices/ equipment/system in that environment. The goal of Electromagnetic compatibility is correct operation, in electromagnetic environment of different equipment which uses electromagnetic phenomena, and the avoidance of any interference effects during the course of the co-existence.-

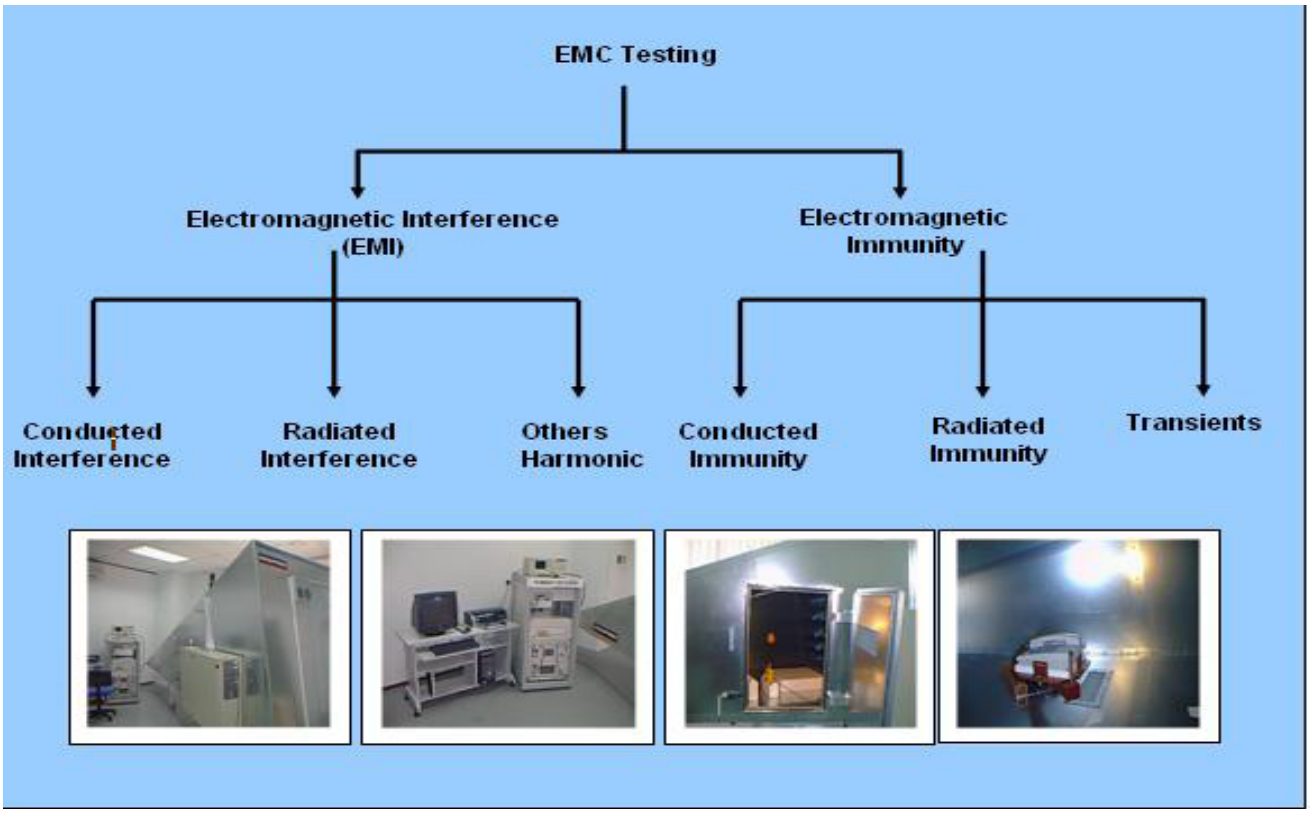

Figure 3: Electromagnetic Compatibility Solution

Electromagnetic compatibility consists of two aspects :

a) **Emission** issues are related to the unwanted generation of electromagnetic energy by some source, and to the measures which should be taken in order to reduce such generation and to avoid the escape of any remaining energies into the external environment.

b) **Susceptibility** or **Immunity issues,** refer to the ability of an electrical equipment to withstand eletromagnetic disturbaces that may co-exist in the environment.

Electromagnetic compatibility is achieved by addressing both emission and susceptibility issues, i.e., quieting the sources of interference and hardening the potential victims. The coupling path between source and victim may also be separately addressed to increase its attenuation.

There are several reputed institutions that set the standards for Electromagnetic compatibility:

a) DOD - Department of Defense (USA)- Immunity and Emission MIL standards

b) IEC - International Electrotechnical Commission (EU) Immunity standards

c) CISPR - International Special Committee on Radio Interference Operating under IEC.-- Emission Standards.

d) FCC - Federal Communication Commission (EU)---Emission standards.

e) BSI - British Standard Institution (UK)-- Emission standards.

f) VDE -Verband Deutscher Electrotechniker (Germany) -Emission standards.

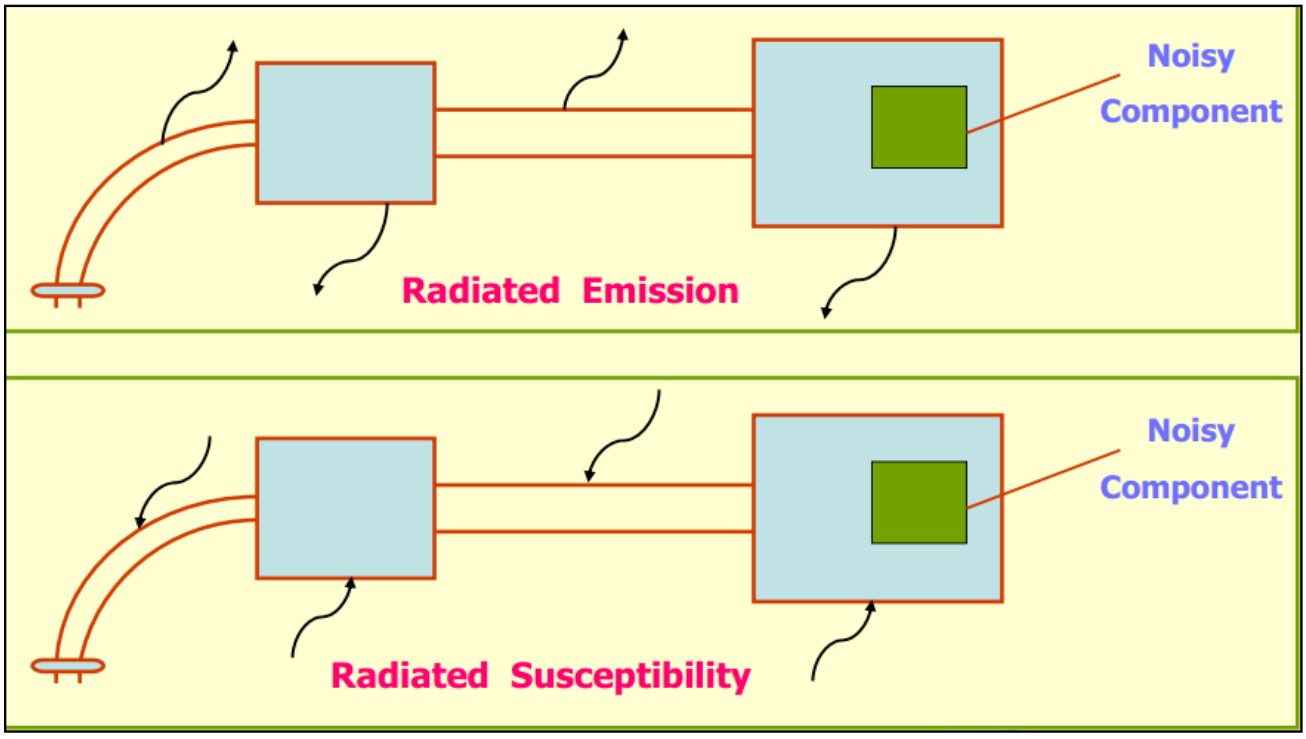

Figure 4: Radiated Emission and Susceptibility

CHAPTER 03

Setting up an EMI/EMC testing laboratory

The Electromagnetic Interference/Electromagnetic Compatibility (EMI/EMC) Test Laboratory forms the backbone for engineering development and product testing. These Laboratory also provide EMI/EMC evaluation and certification testing of various military, industrial, commercial equipments, Biomedical, Guidance and Navigation, Computation, and Robotics equipment/devices.

The purpose of testing electrical products in Medical setups in Developing countries is to protect consumers by ensuring that the products are safe.

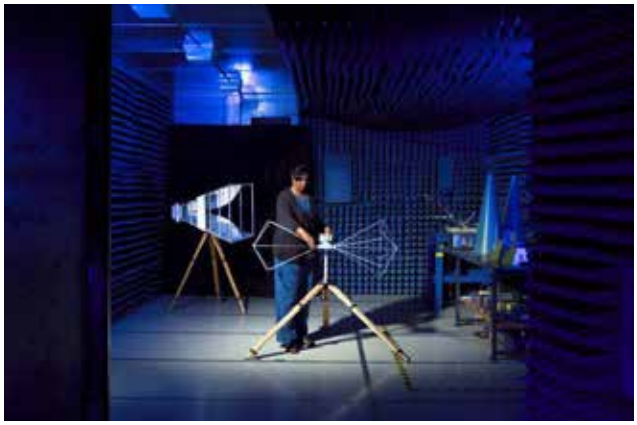

Figure 5 EMI/EMC Lab Set-up

The basic rules to follow in setting up an electrical testing laboratory are:

1. Determine what kind of products, or product categories, are to be tested.
2. Find out the standards that deal with these products.
3. Check the equipment list that is relevant for the type of products that are to be tested.
4. Organize the training of staff including safety protocols.
5. Establish processes form " product receipt for testing to product dispatch after testing.
6. Seek appropiate accreditation for the laboratory for quaility control

There exists three broad categories of testing, out of which testing laboratory's usually perform the first series of test out of the following three :

1. Safety tests are performed by an accredited testing laboratory on representative samples of the product and are usually destructive. They are comprehensive and comply with relevant standards.
2. Routine tests are performed by the manufacturer on each appliance and are non-destructive. They are limited and intended to reveal "unacceptable variations in material of manufacture".
3. Field tests (market surveillance) are performed by inspectors on random samples taken from the market and are limited and non-destructive.

All Medical Devices consist of either one or a combination of the following components:

a) Mechanical

b) Biological

c) Electrical and Electronics

d) Radiation

Therefore, comprehensive testing of Medical Devices is possible when a laboratory has clearly defined the scope of tests that it would support. Each of mechanical, biological, electrical, eletronic and radiation characteristics may invole several complex processes, instruments and supporting infrastructure. In order to achieve efficiency it is desirable that a testing laboratory is :

a) Located in region(s) where a cluster of manufacturing segment exists, so as to facilitate testing volumes of scale.

b) Have a combination of "Self-generating income by providing testing services, have

Decision autonomy, Partnership with a reputed academic Institutions, research and development laboratries and regular training.

c) Has processes that are monitored under sound technical framework.

d) Has technical and scientific work force from multiple technical background.

Need for a Comprehensive EMI/EMC Testing Laboratory

Test facility for EMI/EMC is essential to the needs of medical device manufacturing sector. A Well-equipped laboratory with the state-of-the-art instrumentation, complying with the requirements of National / International standards, is the need of the hour as :-

Almost all Medical Devices contain electronic components which require Electromagnetic Interference (EMI)/ Electromagnetic Compatibility (EMC) testing to ensure they can be used in the intended environment without failing or causing other equipment to fail. There is no single laboratory in India dedicated for testing of medical devices evenn of those that have medical devices as one of the products that are tested, the band-width of standards for which testing is perform is narrow. In the current scenario of import dependency, and the push for" Make in India" adequate systems such as testing infrastructure is requried by the industry

The setting up of a new testing laboratory involves:

1. Selection or construction of a building and facilities required for various analyses.
2. The analytical process and an organizational structure to facilitate this.
3. Selection of analyses to be performed.
4. Selection and purchase of equipment to carry out various tests
5. Maintaining qualified staff.
6. Establishing standard operational procedures (SOPs), i.e. formally written controlled documents outlining all the steps for each of the methods the laboratory decides to undertake.

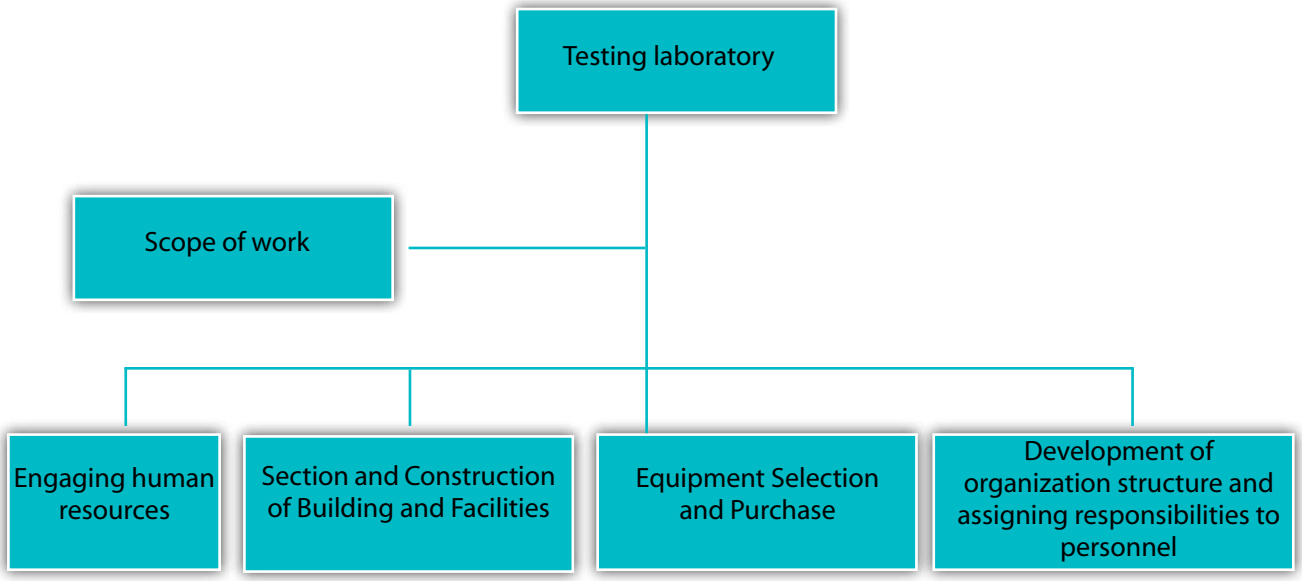

Figure 6: Components of operationalising a laboratory

In most cases a Project Steering Group (PSG) is constituted to bring the above six stages to a satisfactory completion within a fixed time period. This group should contain technical experts with experience in the field of analytical laboratory, laboratory management, finance, procurement and quality assurance. Throughout the process of setting up the laboratory, good communication among the members of the Project Steering Group is vital to ensure success.

Table - 4 Typical tests in an EMI/EMC Test laboratory and their Technical Parameters

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
1.	Any Electrical / Electronic Product	Conducted Emission Test	CISPR 11,2010 CISPR 14-1,2009 CISPR 22,2008 CISPR 25,2008 CISPR 15 FCC Part 15 B & 18 EN 55011,2007 EN 55022:2006+A1:2007 EN 55025:2003 EN 55015:2006+A2:2009 EN 61000-6-3,2007 EN 61000-6-4,2007 IEC 61000-6-3,2011 IEC 61000-6-4,2011 BS EN 55014-1,2006 IEC 60601-1-2,2007 IEC 62040-2,2005 EN/ETSI 300 386 IEC 61326,2006 EN 50091-2,1996 GR 1089,2011 SAE J1113-41	(CISPR 14-1) upto 108MHz Current limitation: 16 A for 1f phase 32 A for 3f Phase	3.75 dB

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
2.	Any Electrical / Electronic Product	Radiated Emission Test	CISPR 11,2010 CISPR 25,2008 CISPR 22,2008 FCC part 15 B & 18 EN 55022:2006+A1:2007 EN 55025:2003 EN55011:2007 EN 61000-6-3:2007 EN 61000-6-4:2007 IEC 61000-6-3:2011 IEC 61000-6-4:2011 IEC 60601-1-2,2007 IEC 62040-2,2005 IEC 62052-11 EN 50121-4 AIS 004 EN/ETSI 300 386 EN 50091-2,1996 95/54/EC 97/24/EC 2004/104/EC FORD-ES XW7T-1A278-AC IEC 61326 GR 1089 SAE J1113-41	upto 7GHz 1m distance 3m and 10m distances	1.55dB 3.62 dB and 3.78 dB
3.	Any Electrical/ Electronic Product	Harmonic Current Emission test	IEC 61000-3-2,2005 BS EN 61000-3-2,2006 IEC 60601-1-2,2007 IEC 62040-2 IEC 61000-6-3,2011 BS EN 61000-6-3,2007	16.7 A / phase	0.0036 (Deviation @ 3rd Harmonics)
4.	Any Electrical/ Electronic Product	Voltage Fluctuation & Flicker test	IEC 61000-3-3,2008 BS EN 61000-3-3,1995 IEC 60601-1-2,2007 IEC 62040-2 IEC 61000-6-3 BS EN 61000-6-3	16.7 A / phase	0.076 (Deviation @ 1.0 Hz)

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
5.	Any Electrical / Electronic Product	RF Radiated Susceptibility Test	EN 61000-4-3 IEC 61000-4-3 CISPR 24 EN 55024 EN 50091-2 EN 55014-2 IEC 60601-1-2 EN 61000-6-1 EN 61000-6-2 IEC 61000-6-1 IEC61000-6-2 IEC 62040-2 IEC 61326 IEC 62052-11 IEEE C37.90.2 95/54/EC 97/24/EC 2004/104/EC AIS 004 ISO 11452-2 FORD-ES-XW7T-1A278-AC EN ETSI 300 386 GR 1089 SAE J1113-21	1V/m-15V/m(3m) upto 75V/m(1m)	1.039 dB
6.	Any Electrical/ Electronic Product	Electrostatic Discharge immunity test	EN 61000-4-2 IEC 61000-4-2 EN 55014-2 EN 55024 EN 50091-2 EN 61000-6-1 EN 61000-6-2 IEC 61000-6-1 IEC 61000-6-2 CISPR 24 IEC 60601-1-2 IEC 62040-2 IEC 62052-11 IEC 61326 ISO 10605 SAE J1113-13 FORD-ES XW7T-1A278-AC EN/ETSI 300 386	upto 30KV	± 0.34% (First Peak Current) ± 0.10% (Rise time)

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
7.	Any Electrical/ Electronic Product	Electrical Fast Transient (EFT)/ Burst Immunity test	EN 61000-4-4 IEC 61000-4-4 IEC 60601-1-2 EN 55014-2 EN 50091-2 EN 55024 CISPR 24 EN 61000-6-1 EN 61000-6-2 IEC 61000-6-1 IEC61000-6-2 IEC 62040-2 IEC 62052-11 IEC 61326 IEC 255-22-4 EN/ETSI 300 386	16 A for 1f Phase 32 A for 3f Phase	0.015% (Amplitude) 0.106% (Rise time) 0.217% (Pulse width)
8.	Any Electrical/ Electronic Product	High Energy/ Telecom Surge Immunity test	BS EN 61000-4-5 IEC 61000-4-5 IEC 60601-1-2 BS EN 55014-2 BS EN 50091-2 BS EN 55024 CISPR 24 BS EN 61000-6-1 BS EN 61000-6-2 IEC 61000-6-1 IEC61000-6-2 IEC 62040-2 IEC 62052-11 IEC 61326 EN/ETSI 300 386	28 A for 1f Phase 26 A for 3f Phase	Telecom Surge: 0.02% (Amplitude) 0.07% (Rise time) 2.77% (Pulse width)

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
9.	Any Electrical / Electronic Product	Conducted RF Susceptibility Test	BS EN 61000-4-6 IEC 61000-4-6 CISPR 24 BS EN 55024 IEC 62040-2 IEC 62052-11 BS EN 50091-2 BS EN 61000-6-1 BS EN 61000-6-2 IEC 61000-6-1 IEC61000-6-2 IEC 60601-1-2 EN 55014-2 ISO 11452-4 SAE J1113-4 IEC 61326 EN/ETSI 300 386 GR 1089	1f phase 16A & 3f phase 32A 150KHz-80MHz,10Vrms 1-400MHz,100mA	2.39 dB
10.	Any Electrical / Electronic Product	Power Frequency Magnetic Field Immunity Test	BS EN 61000-4-8 IEC 61000-4-8 BS EN 55014-2 BS EN 55024 CISPR 24 BS EN 61000-6-1 BS EN 61000-6-2 IEC 60601-1-2 IEC 61000-6-1 IEC61000-6-2 IEC 61326 IEC 62040-2 BS EN 50091-2	EUT size 1 x 1 x 2.6 mts	2.337 dB
11.	Any Electrical/ Electronic Product	Pulse Magnetic field immunity test	BS EN 61000-4-9 IEC 61000-4-9 IEC 62052-11	--	--

Sl. No.	Product / Material of test	Specific tests performed	Standards for which tests are performed	Limitation in the test	Uncertainty of Measurement (±)
12.	Any Electrical/ Electronic Product	Voltage dips, Short Interruption & Voltage Variations Immunity test	BS EN 61000-4-11 IEC 61000-4-11 BS EN 55014-2 BS EN 55024 CISPR 24 BS EN 61000-6-1 BS EN 61000-6-2 IEC 61000-6-1 IEC 61000-6-2 BSEN 50091-2 IEC 60601-1-2 IEC 62040-2 IEC 61326 EN/ETSI 300386	16.7 A / phase	Dip voltage: 1.05% (0%), 1.02% (40%) 1.01% (70 %) Time: 0.03% (0%) 0.63% (40%) 8.7% (70%)
13.	Any Electrical/ Electronic Product	Ring Wave/ Damped Oscillatory Wave Immunity test	BS EN 61000-4-12 IEC 61000-4-12 IEC 60255 – 22 - 1 IEC 62052-11 IEC 255-4 IEC 255-22-1 IEEE C.37.90.1 IEC 61000-4-18	For Ring wave 26 A for 1f Phase 28 A for 3f Phase For Damped 16 A per phase	Ring wave: 0.021% (Amplitude) 0.006% (Rise time) 0.010% (Osc. period) Damped: 0.015% (Amplitude) 0.592% (Rise time) 0.082% (Osc. period)
14.	Any Electrical/ Electronic Product	DC Voltage dips, Short Interruption & Voltage Variations Immunity test	IEC 61000-4-29 BS EN 61000-4-29	16.7 A / phase	Dip voltage: 1.0% (40%) 1.0% (70 %) Time: ± 0.23% (40%) ± 0.13% (70%)

Building and Facilities

An important step in the process is the choice of location, and construction of the laboratory, if there is a choice as to where the laboratory could be located, the presence of good infrastructure i.e. road connectivity, assured uninterrupted power and water supply should be considered as crucial elements. The location should also be chosen with a possibility expansion plans in the future.

Facility Layout

The facility should have shielded enclosures/ chambers, as shown in the figure below. The chamber is designed to accommodate smaller as well as larger pieces of equipment. The wall, ceiling, and floor are constructed with panels of 24-gauge galvanized steel sheets laminated on both sides of a ¾-inch structural core. The floors are covered with tile and are designed to handle a loading capacity of 1,000 lb. per square foot. Each chamber is equipped with a ground plane bench covered with a copper sheet that is electrically bonded to the adjacent wall. The facility consists of a testing room of approximately 20 meters wide with highly insulated wall panels. These walls are made of compressed wood with metal lining on both sides and a specifically designed door which seals completely without a gap .The test benches are mounted 30 inches above the floor. A layer of ferrite tiles are lined on one side wall of the room. In front of the ferrite tile lined walls are stationed two mobile antennas for measuring the sound produced by the equipment/ machine. The other sides of the room are lined with spikes of carbon impregnated foam. The test bench/ round table enclosed among the carbon impregnated spikes has the property to rotate on its own axis.

The equipment or machine to be tested is kept on the test bench against the antennas. The mobile antennas are set at the desired distance and the equipment is powered to start. The sound from the source is that received by the antennas, recorded and analsysed.

A model layout of an EMI/EMC facilites is given below and includs the following:-

D1- Door 1 (Test Room)D2- Door 2 (Control Room)

D3- Door 3 (Equipment/Machine Receiving Room)

D4- Door 4 (Equipment/Machine Dispatch Room)

D5- Door 5 (Equipment/Machine Store Room)

D6- Door 6 (Support Room)

D7- Door 7

A- Test Bench

B- Absorber Material

C- EMI Receiver

D- PC & Printer

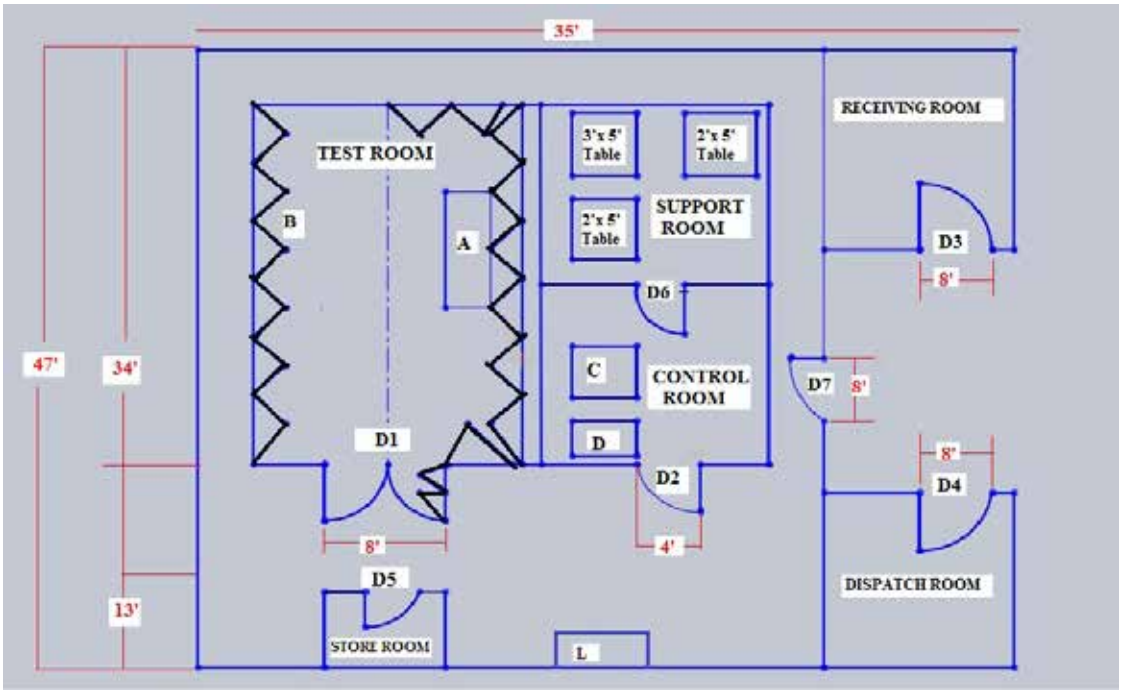

Figure 7: EMI/EMC Facility Layout

The facilities Should also have a safety kit which includes :-

- Laboratory Coat
- Gloves
- Safety Glasses
- Eye Wash station
- Fire Extinguisher
- First Aid Kit

Major divisions or sections of an EMI/EMC laboratory are as follows:

A) Radiated Emission Laboratory

The Radiated Emission measurement facility is used for radiated emission measurements. The laboratory shall be equipped with ferrite lines Shielded Semi Anechoic Chamber to conduct both 10 meter and 3 meter radiated emission measurements according to the most commonly used international standards (such as IEC 60601-1-2, EN 55011, CISPR 11, CISPR 22, EN 55022, EN 50147-2, ANSI C63.4) at the facility.

It should have the provision to test large units such as X-ray machine, C-ARM, Heart Lung Machine and other similar machines inside the chamber. The facility must typically consist of an automated turntable (360 degree) and automated antenna masts facilitating height variation from 1 meter to 4 meter. Capability of conducting radiated emission measurements up to 18 GHz and attaining shielding effectiveness of up to 120dB inside the chamber is usually considered appropiate. Additionally, a Shielded Anechoic Chamber for conducting 3 meter Radiated Emission measurements should also be available at the center of the chamber.

The laboratory must maintain an Open Area Test Site (OATS) for conducting radiated emission measurement up to 10 meter, which would requrie that minimum inner dimension of the chamber should be 10 meter x 10 meter.

The facility should also have the capability to conduct magnetic field measurements for the lighting equipments. Thus measurement can be facilitated using 3-axis loop antenna.

The laboratory must be equipped with the test and measuring equipment comprising of different Electromagnetic Interference (EMI) Receivers covering the frequency range of 20 Hz to 26GHz, EMC Analyzers for the frequency ranges of 9 kHz to 2.5 GHz and 100 Hz to 3GHz, and appropriate preamplifiers.

Radiated Emission laboratory should support:

i. Electric Field:

Frequency Range : 20MHz - 18GHz

Common Standards followed : CISPR 11, CISPR 25, CISPR 22 , FCC part 15 B &18 , BS EN

55022, BS EN55011, BS EN 61000-6-3, BS EN 61000-6-4, IEC 61000-6-3, IEC 61000-6-4, IEC

60601-1-2, IEC 62040-2, IEC 62052-11, BS EN 50021-4 , AIS 004, EN/ETSI 300 386, BS EN

50091-2, 95/54/EC, 97/24/EC, 2004/104/EC, FORD-ES XW7T-1A278-AC, IEC 61326

ii. Magnetic Field : Frequency Range : 9kHz - 30MHz

Common Standards followed: G/EMI-01-01, S/EMI-01-01

B) Radiated Susceptibility Laboratory

The laboratory should have a test and measurement facility equipped with a Shielded Semi Anechoic Chamber for conducting Radiated Susceptibility tests. The facility would be expected to support Radiated Susceptibility tests from 10kHz to 18 GHz.

The laboratory should be equipped with apparatus including Signal Generators for the frequency ranges of 10 MHz - 21.6 GHz and 9 kHz - 2.2 GHz. Also it should have

Radio frequency Power Amplifiers preferably of frequency ranges (80 MHz - 1 GHz, 500W), (10 kHz-30 MHz), (1.5 - 400 MHz), (800 MHz - 4.2 GHz) and (4.2 - 18 GHz).

The facility must house different types of antennae such as Passive Loop Antenna (1 kHz - 30 MHz), Biconilog antenna (26 MHz - 2 GHz and), Double Ridged Waveguide Horn Antenna (1 GHz - 18 GHz). Field Strength upto 100 V/m for the frequency range of 200 MHz - 1 GHz, 50 V/m for the frequency range of 80 MHz - 1 GHz, 30 V/m for the frequency range of 1 GHz - 13 GHz, 10 V/m for the frequency range of 10 kHz - 80 MHz would be requried to be generated. Field Uniformity for the test facility must be better than 6dB for 75% or more points as per the requirement of the IEC 61000-4-3 standard.

The laboratory should have Transverse Electromagnetic (TEM) Cell to carry Radiated Susceptibility test for the frequency ranges of DC - 200 MHz and DC - 800 MHz. Field Strength upto 200 V/m would be requrie to be generated using the TEM cell which is required Electronic Sub Assemblies (ESA).

The radiated emission test is done using automation software. The software allows for precise control of the test parameters through out the testing.

Radiated Susceptibility laboratory should support *:*

i. Radiated Susceptibility (Electric Field)

Frequency Range : 10 MHz to 18 GHz

Common Standards followed : IEC 61000-4-3, BSEN 55014-2, BSEN 50082-1, BSEN 50082-2, BSEN 61000-4-

3, ENV 50140, 1993, 1998-1 G/WLL-01/02, 1997, IS 13779, 1993/1999

ii. Radiated Susceptibility (Magnetic Field)

Frequency Range : Power Frequency

Common Standards followed : IEC 1000-4-8, BSEN 61000-4-8

C) Conducted Emission Laboratory

The conducted emission test facility shall be housed inside a shielded room provided with the required vertical ground and horizontal ground reference planes, complying to the international standards such as EN55011, EN55022, CISPR 11, CISPR 22 and FCC Part 15. The facility must be equipped with the test and measuring equipment comprising of different EMI receivers and Line impedance stabilization network (LISN). The conducted emission measurements carried out using the automated processes ensuring low uncertainty and better repeatability. EMI receivers must preferably cover frequency range 20 Hz - 26.5 GHz. For higher current ratings, voltage probes must be used for conducted noise measurements. The conduct emission, as per the international standards IEC 61000-3-2, capable to measure the current harmonics up to 40th harmonic. For measuring voltage fluctuations and flicker at the supply terminal of the equipment, flickering measurement instrument such as flickering analyzer as per International standard IEC 61000-3-3 should be used.

The laboratory should include LISN for different purpose such as:

- 50uH/50ohm LISN for standards such as CISPR 11, CISPR 22, FCC Part 15 and CISPR 14-1. (Max current : 16A (Single Phase), 32A (per phase for three phase)
- 57uH/50ohm LISN supporting current upto 100A used in DC Application.
- 50uH/50ohm for current rating upto 200A.
- Voltage probe for conducted emission measurements for equipments with higher current ratings.

Conducted Emission laboratory should support *:*

i. Conducted Emission

Common Standards followed : CISPR-11, CISPR-22, FCC PART 15 B, FCC PART 18, BSEN 50081-1, BSEN 50081-2, BSEN 55022, BSEN 55011, BSEN 55011, CISPR -11, G / WLL -01/

02, Oct '97 ETS 300329, Nov' 94

ii. Harmonic Emission

Common Standards followed : IEC 61000-3-2, EN 61000-3-2

iii. Flicker Emission

Common Standards followed : IEC 61000-3-3, EN 61000-3-3

iv. Click Measurement

Common Standards followed : CISPR 14-1

D) Conducted Susceptibility Laboratory

The facility for conducted immunity tests for electrical and electronic equipments as per IEC, BS, EN and ISO standards usually has the following in its scope :-

i) Electrostatic discharge (ESD) immunity test

For simulating the static electric discharges, from operators directly, and to adjacent objects. ESD test facility is equipped with static electric charge generator with different types of energy storage capacitor and discharge resistance as per standard IEC requirements.

ii) Electrical fast transient (EFT) immunity test

For simulating the electrical fast transients originating from switching transients (interruption of inductive loads, relay contact bounce, etc.), EFT test facility is equipped with EFT generator, coupling and decoupling networks for coupling the transients on DC, single phase and three phase supply lines and capacitive coupling clamp for coupling the transients on signal and control lines as per IEC standard requirements.

iii) High Energy Surge immunity test

For simulating the surges caused by over voltages from switching and lightning transients, Surge test facility is equipped with 1.2/50µs and 10/700µs combination wave generator with different type of coupling and decoupling networks for DC, single phase and three phase supply lines and unshielded unsymmetrical & symmetrical interconnection lines as per IEC standard requirements.

iv) Damped Oscillatory waves immunity test

For simulating the non-repetitive damped oscillatory transients (ring wave) occurring in low-voltage power, control and signal lines supplied by public and non public networks and repetitive damped oscillatory waves occurring mainly in power, control and signal cables installed in high voltage and medium voltage stations, this test facility is equipped with test generator, coupling and decoupling networks for DC, single phase and three phase supply lines and signal lines as per IEC standard requirements.

v) Pulse magnetic field immunity test

For simulating the pulse magnetic fields generated by lightning strokes on buildings and other metal structures including aerialmasts, earth conductors and earth networks, this test facility is equipped with test generator, induction coil as per IEC standard requirements.

vi) Voltage dips, short interruptions and voltage variations immunity test

For simulating the dips and short interruptions caused by faults in the network, primary short circuits and sudden large changes of load and for simulating the voltage variations caused by continuously varying loads connected to the network, Voltage dips, short interruptions and voltage variations test facility is equipped with test simulator, coupling and decoupling networks for DC, single phase and three phase supply lines as per IEC standard requirements.

vii) The following table provides for standards applicable for tests described above :-

Table -5 Standards applicable for Conducted Susceptibility Laboratory tests

	Tests	Standards Followed
1	Electro Static Discharge	IEC 61000-4-2
2	Electrical Fast Transient/Burst	IEC 61000-4-4
3	High Energy Surge	IEC 61000-4-5
4	Pulse magnetic field	IEC 61000-4-9
5	Voltage dips,short interruptions & variations	IEC 61000-4-11
6	Damped Oscillatory waves, Ring waves	IEC 61000-4-12
7	Ripple on DC input power port	IEC 61000-4-17
8	Variation of power frequency	IEC 61000-4-28
9	DC dips,Variations and short interruptions	IEC 61000-4-29

Table - 6 List of Equipment/instruments Required For EMI/EMC Testing

Facility / Equipment / Tools	Make and Model (Suggested; but not limited)
EMC Analyzer (9 KHz-6.5 GHz)	HP, 8595 EM
EMI Receiver	Rohde & Schwartz, ESIB7
EMI Receiver	Rohde & Schwartz, ESCS30
Receiver	Rohde & Schwartz, ESIB26
Receiver	Rohde &Schwartz, ESVP & ESH3
Receiver	PMM Italy, PMM9000 Plus
TEM CELL	IFI, CC-102
Cables	HP & Pasternak Enterprises
LISN	R&S, ESH2-Z5
Transient Limiter	HP, Agilent, 11947A
ISN	FCC-TLISN-T2-O2
CDN	Schaffner (M216, M316, M563)
CDN	Schaffner (S200, S360, S501, S900)
CDN	Schaffner, A401
CDN	Schaffner, T004
EM Clamp	Schaffner, KEMZ801
LISN	R&S, ESH3-Z6
LISN	Solar, 9247-50-TS-50-N
Antenna Mast	ETS Lindgren &EMCO
Turn Table	ETS Lindgren& EMCO
Dual Channel Controller	ETS Lindgren
Signal Generator	R&S, SMR20
CDN	EM Test, M2/M3
Harmonics EXT-1000	HAR-EXT-1000
Digital Phosphor Oscilloscope	TDS 3054C
Combined Power Line CDN	CDN2000-06-25
3m&10 m Open Area Test site	--
Shielded Anechoic Chamber	SIEPEL, F276
Directional Coupler	Connecticut Microwave Corporation
CC TV Camera	ETS Lindgren
Preamplifier	1806670 Sonoma Instrument Co. 11909A
Preamplifier	Mini Circuits, ZVA-213 X-S+608300740
RF Current Probe	Solar, 9207-A
Absorbing Clamp	Rohde & Schwartz, MDS-21
RF Attenuator (40 dB)	Broad Wave Tech, 352-023-040
RF Attenuator (6 dB, 75W)	EM Test, ATT6/75
T-Network	Rohde & Schwartz
Biconical Antenna (20-300MHz)	R&S, HK116
Long Periodic Antenna (200MHz-1GHz)	Electrometrics, LPA25
Antennae – Loop , Rod, Horn ,Adj. Dipole Antenna	EMCO
Antenna -Loop	R&S
Antenna – Large Loop antenna (2m Dia)	ERTL
Harmonic & Flicker Test system	Pacific
Immunity Test Facilities	:
Ultra Compact (Combined Immunity) Test Simulator	EM test
ESD Simulator	EM Test
Automatic Dimmer State	EM Test
Capacitor Clamp	EM Test
Signal Interface Coupler Network	EM Test
Single & Three Phase Coupler	EM Test
Loop Antenna (1m x 1m)	--
Surge Generator	Haefley, PIM100
Telecom Surge Generator	Haefley, PIM120
Ring Wave Generator	Keytek
EFT Test Generator	Schaffner, NSG2025-4
EFT Test Generator	Haefley, PEFT 4010
ESD Generator	EMC Partner, ESD 3000
HF Simulator	Schaffner
V Network	ESH-Z6
Interference Simulator	Schaffner
Burst Simulator	Schaffner
Voltage Dip & Interruption Simulator	Keytek, CE Master/CM-3PQF

Facility / Equipment / Tools	Make and Model (Suggested; but not limited)
DC Power Interruption Simulator	Schaffner
Audio Power Generator	Solar
Coupling-Decoupling Network	EM test, (M3 M5)
EM Clamp	EM Test
3 meter Anechoic Chamber	ETS Lindgren
G-TEM Cell Based Radiated. Immunity	EMCO/TDK
RF Amplifier (80-1000MHz, 500W)	AR, 500W 1000AM4
Biconilog Antenna	EMCO, 3142B
Ultra log Antenna	R&S, HL562
Double Ridged Wave guide horn	R&S HF 906
RF Field Probe	Amplifier Research
RF Field Probe	Holladay
E & H meter	Holladay
Over Voltage Simulator	Schaffner
Line Voltage Simulator	Schaffner
G-strip Based Radiated Immunity Test System	--
Current injection Probe	Schaffner, CIP9136
Reference Radiator	ETS Lindgren
1 GHz CRO	Tektronix
3 Phase Digital Power Meter	HSIANG
EMI Receiver (For Emission Measurements) and LISN	SCR3501, Schaffner
Triple Loop Antenna (H-field as per CISPR15)	Rohde & Schwarz, HM 020
Harmonics & Flicker Test System	Schaffner, Profline2100
Electrostatic Discharge Simulator	PESD 1610, Haefely
Pulse Magnetic Field Test System	Haefley, PIM 100/M Surge
Conducted Immunity (EFT, Surge and Dips)	E-Compact, Haefely
Damped oscillatory Wave Generator	Haefley, PIM150
Ring Wave Generator	Haefley, PIM110
Surge Generator	Keytek, CE Master
Surge Generator	Schaffner, NSG2050
Digital Oscillator	Yokogawa, 701311-F-HE
Automotive Test Generator	EM Test
Radiated Immunity	GTEM Cell, EMCO-ETS Lindgren
Conducted RF Immunity	PMM/3000, PMM
Power Frequency Magnetic Fields	PMM/ 1008, PMM, Italy

Table - 7 List of Equipment/instruments Required For Electrical and Electronics Safety Testing

Facility / Equipment / Tools	Make and Model (Suggested; but not limited)
Tracking index analyzer	PTL M3106
Flexing Apparatus for cable	Friborg 7100
Abrasion Test Apparatus	Friborg 7250
Bending Test Apparatus	Friborg 7250
Torque Meter	Tohnichi 2-OT
Spring operated impact Test Apparatus	PTL F22.50
Profile Projector	Dynascan PT-20
Earth bond tester	Friborg
Glow Wire Tester	Friborg GW1000/4
Hot wire ignition Tester	Friborg
Digital Force Gauge	Chattilon DRC 200 N
Exposure Rate Measuring System	Victoreen 440RF/D
Ultrasonic thickness gauge	Imeco UTG-5201
Leakage current tester	Elabo 2G2790-21
High Precision Touch Current Tester	EXTECH 7630
Mobile Carder	Yokogawa MV230
Bump test apparatus	Friborg 5200
Double freq./Double voltage tester	Friborg 2500
Creepage & Clearance gauge Set	Idemi
Vicat tester	Wallace P7E & WEST 2075
Cord anchorage strain device	PTL F47.35
Cord anchorage torque device	PTL F20.12
Digital Multi meter	Rishabh Rish multi 18S
Insulation tester	Elabo 2GA27 90-4K
HF Spark Tester	Edward HV, ST4M
International Safety Analyzer	Bio Tek ISA 470B
Defibrillator Analyzer	Bio-Tek QED 5
Pulse Oximeter Simulator	Fluke Biomedical 2XLFE
Ventilator Tester	Metron QAVTM 16200
X,Y Capacitor tester	EMC Partner MIG1212CAP
Flammability tester	EMC Partner MIG1803CAP
HIPOT Analyser	Chroma 19055
Micro Ohm Meter	CROPICO DS5001

Phases of Testing

The process of testing starts with the receipt of samples and a request from the clients for the analyses to be performed, on receipt of the samples and appropriate storage followed by sample preparation analyses may begin. The results of these tests are collated and checked, and once approved by an authorized person, a final report, including an invoice, is sent to the customer. It is important to make sure that all requests from clients have been noted as well as the most suitable method chosen. Responsibility for checking these details should be clearly defined. Sample materials are stored in the laboratory for a fixed time, after completion of analyses, and thereafter either returned (on request), discarded or destroyed. The detailed test plan and test schedule are finalized during the test preparation phase. The Test Requester provides detailed test requirements and test related documentation to the Test Director.

A complete understanding of test requirements and facility capabilities is essential for a successful test. Test requirements must be carefully defined and reviewed so that the test team understands the effect of the requirements on test facility preparation and test performance, this includes but is not limited to, the following :

1. Applicable EMI/EMC requirements/limits/ specifications
2. Desired test conditions (frequency)and modes of operation
3. Proposed test approach
4. Test data requirements
5. Test article interface
6. Orientation, load points, method of suspension or test article support
7. Electrical, mechanical, fluids, gases, pressure, temperature, etc
8. Data/instrumentation requirements (provided by Test Requester and facility)
9. Any other special requriement.

Diagram below explains the Organizational structure and responsibilities of Personnel in testing process.

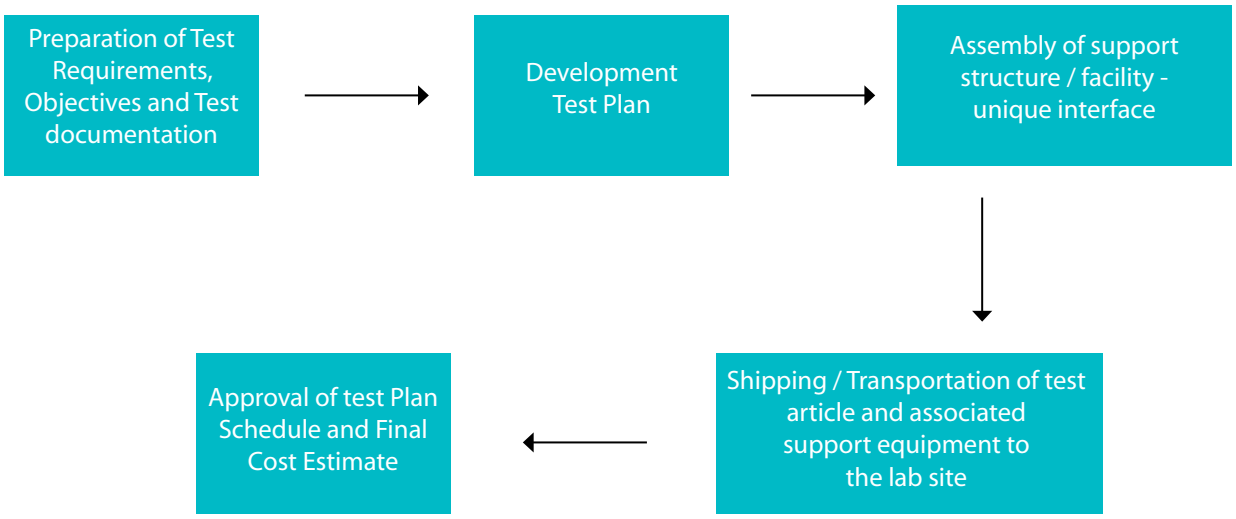

Figure 8: Test Preparation Phase

Human Resources Planning

For the laboratory, the number of personnel and their educational and experience levels depends on the type of tests to be offered, the methods chosen and the expected sample output. The first step is to create an organized structure for the test laboratory and to define the activities that would take place in the laboratory, as illustrated in figure 9.

The laboratory's human resource pool are grouped into different sections depending on the type of EMI/ EMC tests it intends to perform. Similar types of tests are usually grouped into one section. Ideally, a senior scientist is responsible for each area, with 2 or 3 technicians to rotate around the various tests within their 'section'. This enables an overall knowledge to be gained of the working requirements for each area of the laboratory. It is important to keep the job interesting and challenging for staff and to avoid monotonous, repetitive work where ever possible. The vertical division of the laboratory reflects the different positions and responsibilities within the organization. As a guide, some typical positions can be identified as follows:

i. The Laboratory Manager is responsible for the whole laboratory and the development of its strategic plan. A key work of this position is the external communication with clients and potential clients, as well as full responsibility for results reported to clients. Management systems must be put in place to ensure reliable data are produced and that the reporting of this data is thoroughly checked prior to releasing reports.

ii. The Quality Assurance (QA) Manager is responsible for quality assurance within the laboratory, and should have an independent position. The QA Manager may also have responsibility for Health and Safety Management, Environmental Management within the laboratory.

iii. The Section Head or Senior Technician is responsible for the daily organization of the analytical process, ensuring that daily and weekly deadlines within their section are met; quality control for each batch of testing meets requirements and is recorded; staff training is up-to-date; and that there are sufficient staff to meet the workload requirements. Maintaining stocks of the necessary chemicals and consumables are also the responsibility of the senior technician, who should inform the Laboratory Manager in sufficient time to enable ordering and delivery prior to stocks running low. The Section Head or Senior Technician is also responsible for specific equipment and methods, especially trouble-shooting and maintenance as well as continuing training of junior staff.

iv. Junior technician(s) are responsible for performing analytical work following Standard Operating Procedures (SOPs), under the direction of the Section Head or Senior Technician.

This organization reflects an 'ideal' situation in a matured laboratory. In a new laboratory, however, the structure may initially be quite different. From the outset, the laboratory should have all expertise needed to perform all the methods it offers. In practice this means recruiting senior technicians with the background needed for the methods. This group should be regarded as the backbone of the laboratory that trains additional personnel in case of an increasing volume of work and as a back-up for each assay. If the laboratory is part of a larger organization, such as a research organization, its position and relationship with the other units should also be clearly described within its structure. The laboratory has a responsibility to ensure that the quality and credibility of its results are of the utmost quality.

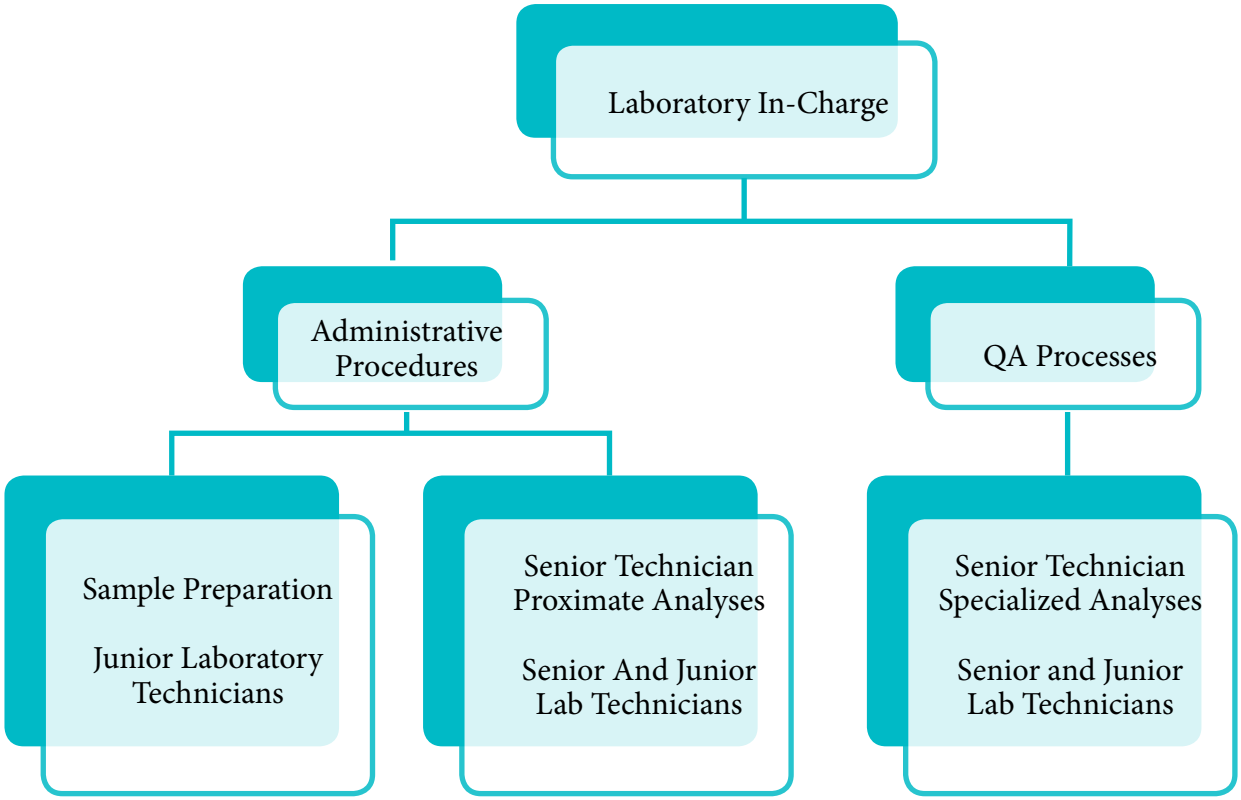

Figure 9: An example of an EMI/EMC Laboratory Organizational Structure

Besides the physical completion of the laboratory, procedures such as SOPs, quality control program, participation in proficiency (both internal and external) programs and use of reference materials are needed to be put in place to ensure that laboratory consistently produces results of a high accuracy. These procedures should guarantee that all aspects of the analytical process are performed efficiently and are traceable. This should be documented in a set of SOPs that form the basis of the Quality Management System (QMS).

Procedures should ensure that the laboratory can prioritize and organize its workload and guarantee the quality of results produced. In the initial phase, however, the focus should be on aspects that directly influence the quality of the results. These includes:

- Acceptance criteria for samples.
- Sample preparation.
- Description of methods, including validation of results.
- Quality control (first line of control).
- Maintenance and calibration records of equipment.
- Job descriptions, including responsibilities and continuing competence of individual technical staff.
- Training records of technical staff, covering which methods they can perform, level of training, whether they can perform a method independently or under supervision, and their ability to train others, etc.
- Traceability and storage of raw data.
- Cleaning procedures for the laboratory.

The presence and implementation of these procedures from the initiation of the laboratory will positively affect the quality of the results, and can be used as a starting point for the implementation of a comprehensive quality system.

EMI/EMC Laboratory Accreditations

i. CISPR

a) CISPR 11: CISPR 11 is analog standard to European standard EN 55011. This is the standard that is very often referenced in all European EMC standards, defining

measurement methods, measurement equipment, limit lines and interpretation of applicability of limit lines, starting from household appliances to medical devices.

b) CISPR 14: The intention of this standard is to establish uniform requirements for the radio disturbance level of the equipment in the scope, to fix limits of disturbance, to describe methods of measurement and to standardize operating conditions and interpretation of results.

c) CISPR 15: Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment.

d) CISPR 22: CISPR 22 is analog standard to European standard EN 55022. This is the standard that is very often referenced in all European EMC standards, defining measurement methods, measurement equipment, limit lines and interpretation of applicability of limit lines, starting from household appliances to medical devices.

e) CISPR 25: Limits and methods of measurement of radio disturbance characteristics for the protection of receivers used on board vehicles.

ii. NABL

NABL accreditation/recognition of the technical competence of a testing, calibration or medical laboratory for a specific task following ISO/IEC 17025:2005, ISO 15189:2007 Standards.

The concept of Laboratory Accreditation was developed to provide a means for third-party certification of the competence of laboratories to perform specific type(s) of testing and calibration.

Laboratory Accreditation provides formal recognition of competent laboratories, thus providing a ready means for customers to find reliable testing and calibration services in order to meet their demands.

Laboratory Accreditation enhances customer confidence in accepting testing / calibration reports issued by accredited laboratories. The globalization of Indian economy and the liberalization policies initiated by the Government in reducing trade barriers and providing greater thrust to exports makes it imperative for Accredited Laboratories to be at international level of competence.

For Accreditation, the laboratories should be legally identifiable & appropriately registered. They can be a part of a big organization or an independent entity. NABL can provide accreditation to:

- Laboratories undertaking any sort of testing or calibration in the specified fields.
- Private or government laboratories.
- Small operations to large multi-field laboratories.
- Site facilities, temporary field operations and mobile laboratories.

iii. ISO 17025

ISO 17025 General requirements for the competence of testing and calibration laboratories is the

main ISO standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25, ISO 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO 17025 is more specific in requirements for competence. And it applies directly to those organizations that produce testing and calibration results.

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard.

Conclusion

Success of the new laboratory depends strongly on its ability to respond to new opportunities and challenges in the commercial market and within the research field. For this purpose, the laboratory should focus on efficiency, expertise and innovation. Efficiency is related to the volume of analytical work performed within a specific time interval. Increased efficiency leads to a lower testing costs making the laboratory more attractive for customers.

The second important factor for success is to provide a consistent high standard of service. This will give customers confidence and ensure repeat business. Laboratory expertise is strongly related to the specific knowledge, skill and experience of the technicians, which is often described as human capital, and this is directly linked to the quality of the laboratory. The laboratory should develop a policy to develop for continuity of this knowledge by utilizing training programs.

The third important issue is innovation, research and development (R&D) to improve the quality and to broaden the scope of analytical possibilities. The first two issues mentioned, i.e. efficiency and expertise, are the basic conditions needed to build a successful R&D policy, which will enable the laboratory to respond successfully to new opportunities in the market. To reduce risk, the laboratory manager should keep themselves up-to-date with current market trends. Being a market leader for new analyses will give the laboratory a clear advantage over competitors.

APPENDIX A- TEST REQUEST WORKSHEET

Test Requester Information

Test Article Expert	Contact Information (Phone, E-mail Address)

Test Objectives

Purpose of Test	
Proposed Test Start Date:	Critical Test Start Date:

Test Article

Test Article Description:	
Physical Dimensions (L/W/H):	
Weight:	Test Article Set-up Time:
Support equipment provided by Test Requester:	

Test Article Handling Requirements

Input Voltage Type (AC, DC, Both):	Input Voltage Requirement (Volts):	
Input Power (Watts or Amps):	Number of Power Connections:	Power phase:

Test Requirements

Ground Plane Requirements (Conductive/Non-Conductive Table, Requester-Provided):
Test Article Interface (eg., Support Structure, Connectors):
EMI Specification (s) to be met:

Instrumentation

List the primary measurements to be made (eg., frequency, voltage, amplitude):

Additional Information

List any other information pertinent to the test:

APPENDIX B- TEST ARTICLE HAZARD CHECKLIST

Hazard	Y	N	Comments
Mechanica			
Handling (> 40 lb or > 4 ft in any dimension)			
Instability			
Sharp Edges			
Pinch Points			
Exposed Mechanisms (e.g., rotating, recipro-cating)			
Pressure Systems			
Stored Energy (e.g., springs, weights, flywheels)			
Ejected Parts, Projectiles			
Electrical			
Voltage (> 50 volts)			
Batteries (type and number)			
Generation/Storage (e.g., coils, magnets, ca-pacitors)			
Electrostatic Sensitive Devices			
Thermal			
Hot Surfaces (> 113 °F, 45 °C)			
Heaters			
Cold Surfaces (< 39 °F, 4 °C)			
Cooling Devices			
Radiation			
Ionizing			
Non-Ionizing			
Laser			
Microwave			
Infrared (IR)			
Ultraviolet (UV)			
Radio Frequency (RF)			
Visible Light, High Intensity			
Material			
Uncontained Brittle Materials			
Contained Fluids			
Toxic, Corrosive, Flammable Fluids			
Biohazards			
Miscellaneous			
Noise Level (> 85 dBA)			
Ultrasonic			
Pyrotechnics/Explosives			

APPENDIX C- EMI/EMC STANDARDS AND THEIR DEFINITIONS

STANDARDS	DEFINITION
CISPR 11,2010	CISPR 11 is analog standard to European standard EN 55011. This is the standard that is very often referenced in all European EMC standards, defining measurement methods, measurement equipment, limit lines and interpretation of applicability of limit lines, starting from household appliances to medical devices.
CISPR 14-1,2009	The intention of this standard is to establish uniform requirements for the radio disturbance level of the equipment in the scope, to fix limits of disturbance, to describe methods of measurement and to standardize operating conditions and interpretation of results.
CISPR 22,2008	CISPR 22 is analog standard to European standard EN 55022. This is the standard that is very often referenced in all European EMC standards, defining measurement methods, measurement equipment, limit lines and interpretation of applicability of limit lines, starting from household appliances to medical devices.
CISPR 25,2008	Limits and methods of measurement of radio disturbance characteristics for the protection of receivers used on board vehicles.
CISPR 15	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment.
FCC Part 15 B	The Federal Code Of Regulation (CFR) FCC Part 15 is a common testing standard for most electronic equipment. FCC Part 15 covers the regulations under which an intentional, unintentional, or incidental radiator that can be operated without an individual license. FCC Part 15 covers as well the technical specifications, administrative requirements and other conditions relating to the marketing of FCC Part 15 devices.
BS EN 55011, 2007	This standard specifies radio disturbance limits for potentially interfering spurious emissions generated by industrial, scientific and medical apparatus.
BS EN 55025:2003	BS EN 55025 contains limits and procedures for the measurement of radio disturbances in the frequency range of 150 kHz to 2 500 MHz. BS EN 55025 applies to any electronic/electrical component intended for use in vehicles, trailers and devices.
BS EN 55015:2006+A2:2009	BS EN 55015 sets out limits and ways to measure radio frequency disturbance from electric lights and similar equipment.
BS EN 61000-6-3,2007	This part of IEC 61000 for EMC emission requirements applies to electrical and electronic apparatus intended for use in residential, commercial and light-industrial environments.
BS EN 61000-6-4,2007	This standard applies to a apparatus intended to be connected to a power network supplied from a high or medium voltage transformer dedicated to the supply of an installation feeding manufacturing or similar plant, and intended to operate in or in proximity to industrial locations, as described below. This standard applies also to apparatus, which is battery operated and intended to be used in industrial locations.
BS EN 55014-1,2006	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission.
IEC 60601-1-2,2007	IEC 60601-1-2:2014 applies to the basic safety and essential performance of Medical Equipment (ME) equipment and ME systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by me equipment and me systems.

STANDARDS	DEFINITION
IEC 62040-2,2005	This standard is intended as a product standard allowing the EMC conformity assessment of products of categories C1, C2 and C3 as defined in this part of IEC 62040, before placing them on the market. The requirements have been selected so as to ensure an adequate level of electromagnetic compatibility (EMC) for UPS at public and industrial locations.
EN/ETSI 300 386	This document covers the EMC requirements for non-radio equipment intended to be used within a public telecommunications network, which provides telecommunications between Network Termination Points (NTPs) (i.e. excluding terminal equipment beyond the NTPs).
IEC 61326,2006	IEC 61326-1:2012 specifies requirements for immunity and emissions regarding electromagnetic compatibility (EMC) for electrical equipment, operating from a supply or battery of less than 1 000 V a.c. or 1 500 V d.c. or from the circuit being measured.
EN 50091-2,1996	Applicable to UPS units or UPS systems which include a number of interconnected UPS and associated control/switchgear to form a single power system, for installation in any operator accessible area or in separated electrical locations which are connected to either industrial or public low voltage supply networks. Takes precedence over all aspects of the generic standards and requires no additional testing.
GR 1089,2011	This all new issue of GR-1089 has NEBS criteria that cover equipment in Central Offices (COs); equipment in the Outside Plant (OSP) at locations such as Controlled Environmental Vaults (CEVs), Electronic Equipment Enclosures (EEEs), and huts; equipment in uncontrolled structures such as cabinets; and network equipment at the customer premises.
SAE J1113-41	This SAE Standard contains limits and procedures for the measurement of radio disturbances in the frequency range of 150 kHz to 1000 MHz. The standard applies to any electronic/electrical component intended for use in vehicles and large devices.
IEC 62052-11	IEC 62052 covers type tests for electricity metering equipment for indoor and outdoor application and applies to newly manufactured equipment designed to measure the electrical energy on 50 Hz or 60 Hz networks, with a voltage up to 600 V.
BS EN 50121-4	This European Standard applies to signalling and telecommunication apparatus which is installed in the railway environment.
AIS 004	This standard applies to the electromagnetic radiated immunity of automotive vehicles and to components or separate electrical/electronic technical units intended for fitment in vehicles.
95/54/EC	This directive requires manufacturers to gain type approval for all vehicles, electronic sub assemblies, components and separate technical units. Products that have direct control of the vehicles must not emit EMC emissions above the limits and must be immune to interference levels stated in the directive.
IEC 61000-3-2,2005	International standard EN 61000 – 3-2:2006 +A1+A2 is applicable for electrical equipment that is supplied from mains network with voltage not less than 220V and current up to 16A (including) to limit the harmonic component emission.
BS EN 61000-3-2,2006	BS EN 61000-3-2 deals with the limitation of harmonic currents injected into the public supply system. It specifies limits of harmonic components of the input current which may be produced by equipment tested under specified conditions.

STANDARDS	DEFINITION
BS EN 61000-3-3,1995	BS EN 61000-3-3 is concerned with the limitation of voltage fluctuations and flicker impressed on the public low-voltage system.
BS EN 61000-4-3	BS EN 61000-4-3:2006+A2:2010 looks at the testing and electrical measurement techniques to ensure protection against radio frequency electromagnetic fields from any source.
IEC 61000-4-3	This part of IEC 61000 is applicable to the immunity requirements of electrical and electronic equipment to radiated electromagnetic energy. It establishes test levels and the required test procedures.
BS EN 55024	BS EN 55024 specifies the requirements for the electromagnetic immunity of information technology equipment, including telecommunication systems, printing and photocopying machines, and facsimile technology.
IEC 62052-11	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard
ISO 11452-2	ISO 11452-2:2004 specifies an absorber-lined shielded enclosure method for testing the immunity (off-vehicle radiation source) of electronic components for passenger cars and commercial vehicles regardless of the propulsion system (e.g spark-ignition engine, diesel engine, electric motor).
BS EN 61000-4-2	BS EN 61000-4-2:2009 looks at the immunity requirements and test methods for electrical and electronic equipment subject to static electric discharges. The standard also defines the ranges of test levels relating to different environmental and installation conditions, and establishes test procedures.
BS EN 61000-6-1	BS EN 61000-6-1 is intended for use by all manufacturers, designers and test houses associated with electrical and electronic equipment for use in residential, commercial and light-industrial environments.
BS EN 61000-6-2	Immunity requirements for electrical and electronic apparatus used in industrial environments.
IEC 61000-6-1	Applies to electrical and electronic apparatus intended for use in residential, commercial and light-industrial environments. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.
IEC 61000-6-2	This part of IEC 61000 for EMC immunity requirements applies to electrical and electronic apparatus intended for use in industrial environments, as described below. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.
ISO 10605	ISO 10605:2008 specifies the electrostatic discharge (ESD) test methods necessary to evaluate electronic modules intended for vehicle use.
BS EN 61000-4-4	BS EN 61000-4-4 is a standard which relates to the immunity of electrical and electronic equipment to repetitive electrical fast transients.
BS EN 55014-2	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard.
IEC 62052-11	Covers type tests for electricity metering equipment for indoor and outdoor application and to newly manufactured equipment designed to measure the electric energy on 50 Hz or 60 Hz networks, with a voltage up to 600 V.

STANDARDS	DEFINITION
EN/ETSI 300 386	This document defines the product-specific performance criteria and operating conditions for equipment intended to be used within a telecommunications network.
BS EN 61000-4-5	This part of BS EN 61000 looks at the immunity requirements, test methods and test levels for electrical equipment and unidirectional surges caused by over-voltages from switching and lightning transients.
IEC 61000-4-9	Testing and Measurement Techniques - Pulse Magnetic Field Immunity Test
BS EN 61000-4-11	This part of EN 61000 defines the immunity test methods and range of preferred test levels for electrical and electronic equipment connected to low-voltage power supply networks for voltage dips, short interruptions, and voltage variations.
IEC 60255 – 22 - 1	IEC 60255-22-5:2008 specifies the general requirements for surge immunity tests for measuring relays and protection equipment for power system protection, including the control, monitoring and process interface equipment used with those systems. Is based on IEC 61000-4-5.
IEC 255-4	Electrical Relays - Single Input Energizing Quantity Measuring Relays With Dependent Specified Time
BS EN 61000-4-29	Electromagnetic compatibility (EMC). Testing and measurement techniques. Testing and measurement techniques. Voltage dips, short interruptions and voltage variations on d.c. input power port immunity tests.

Appendix D- EMI/EMC STANDARDS AND THEIR SCOPE

Standard	Scope
ISO 11137-I	Sterilization of Healthcare Product Radiation – Part-I requirement for development validation and routine control of Sterilization process for Medical Devices
ISO 11137-2	Sterilization of Health Care Products – Radiation – Establishing the Sterilization dose
ISO 11135 – 1	Sterilization of Healthcare product – Ethylene Oxide. Requirements for development validation and routine control of a Sterilization process for Medical devices
ISO 11135-1: ISO / TS 11135 – 2	Sterilization of Healthcare Product – Ethylene Oxide
ISO 14971	Medical devices – Application of Risk Management to Medical Devices
ISO 11607-1	Packing for terminally Sterilized Medical Devices- Requirements for materials, Sterile barrier systems and packaging systems
ISO 11607-2	Packing for terminally Sterilized Medical Devices- Validation requirements for forming sealing and assembly process
ISO 14644 – (Part 1 to Part 7)	Clean Rooms and associated controlled environments

Standard	Scope
IEC 556-2:2003	Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' —Part 2: Requirements for aseptically processed medical devices
ISO 15223-1	Symbols for use in the labeling of medical devices
ISO 10993	Biological evaluation of medical devices —ISO 10993 (Part 1 to Part 18)
ISO 11138-2:2009	Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11138-3:2009	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes
ISO 11140-1:2009	Sterilization of health care products — Chemical indicators — Part 1: General requirements
ISO 11140-3:2009	2009 Sterilization of health care products — Chemical indicators — Part 3:Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
ISO 11737-1:2006	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products

Standard	Scope
ISO 11737-2:2009	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 13408-1:2011	2011Aseptic processing of health care products — Part1: General requirements
ISO 13408-2:2011	2011Aseptic processing of health care products — Part2: Filtration)
ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 14937:2009	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
15986:2011	Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates.
ISO 17664:2004	Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
IEC 60601-1:2006	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

Standard	Scope
IEC 60601-1-2:2007	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
IEC 60601-1-3:2008	Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-8:2007	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems inmedical electrical equipment and medical electrical systems
IEC 60601-1-10:2008	Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers
IEC 60601-2-1:1998	Medical electrical equipment — Part 2-1: Particular requirements for the safety of elec-tron accelerators in the range of 1 MeV to 50 MeV
IEC 60601-2-2:2009	Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Standard	Scope
IEC 60601-2-3:1993	Medical electrical equipment — Part 2: Particular requirements for the safety of short-wave therapy equipment
IEC 60601-2-4:2003	Medical electrical equipment — Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 60601-2-5:2000	Medical electrical equipment — Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-8:1997	Medical electrical equipment — Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-10:2000	Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
IEC 60601-2-11:1997	Medical electrical equipment — Part 2-11:Particular requirements for the safety of gamma beam therapy equipment
IEC 60601-2-12:2006	Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators

Standard	Scope
IEC 60601-2-13:2006	Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems
IEC 60601-2-16:1998	Medical electrical equipment — Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-17:2004	Medical electrical equipment — Part 2-17: Particular requirements for the safety of automatically- controlled brachytherapy afterloading equipment
IEC 60601-2-18:1996	Medical electrical equipment — Part 2: Particular requirements for the safety of Endoscopic equipment
IEC 60601-2-19:2009	Medical electrical equipment — Part 2-19:Particular requirements for the basic safety and essential performance of infant incubators
IEC 60601-2-20:2009	Medical electrical equipment — Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21:2009	Medical electrical equipment — Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

Standard	Scope
IEC 60601-2-22:1996	Medical electrical equipment — Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC 60601-2-23:2000	Medical electrical equipment — Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24:1998	Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers
IEC 60601-2-25:1995	Medical electrical equipment — Part 2-25:Particular requirements for the safety of electrocardiographs
IEC 60601-2-26:2003	Medical electrical equipment — Part 2-26:Particular requirements for the safety of electroencephalographs
IEC 60601-2-27:2006	Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 60601-2-28:2010	Medical electrical equipment — Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

Standard	Scope
IEC 60601-2-29:2008	Medical electrical equipment — Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
IEC 60601-2-34:2000	Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-36:1997	Medical electrical equipment — Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
IEC 60601-2-37:2008	Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-39:2008	Medical electrical equipment — Part 2-39:Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
IEC 60601-2-40:1998	Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
IEC 60601-2-41:2009	Medical electrical equipment — Part 2-41:Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis

Standard	Scope
IEC 60601-2-43:2010	Medical electrical equipment — Part 2-43:Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-45:2001	Medical electrical equipment — Part 2-45:Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-46:1998	Medical electrical equipment — Part 2-46:Particular requirements for the safety of operating tables
IEC 60601-2-47:2001	Medical electrical equipment — Part 2-47:Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC 60601-2-49:2001	Medical electrical equipment — Part 2-49: Particular requirements for the safety of multi function patient monitoring equipment
IEC 60601-2-51:2003	Medical electrical equipment — Part 2-51:Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs

Standard	Scope
IEC 60601-2-52:2010	Medical electrical equipment — Part 2-52:Particular requirements for basic safety and essential performance of medical beds
IEC 62366:2008	Medical devices — Application of usability engineering to medical devices

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NHSRC