Definition of Biomedical, Clinical & Hospital Engineering

Biomedical Engineering is a discipline that advances knowledge in engineering, biology and medicine, and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice. It includes:

1. The acquisition of new knowledge and understanding of living systems through the innovative and substantive application of experimental and analytical techniques based on the engineering sciences.

2. The development of new devices, algorithms, processes and systems that advance biology and medicine and improve medical practice and health care delivery.

The term "biomedical engineering research" is thus defined in a broad sense: It includes not only the relevant applications of engineering to medicine but also to the basic life sciences.

What are the Specialty Areas?
Some of the well established specialty areas within the field of biomedical engineering are bioinstrumentation, biomechanics, biomaterials, systems physiology, clinical engineering, and rehabilitation engineering.

Biomechanics is mechanics applied to biological or medical problems. It includes the study of motion, of material deformation, of flow within the body and in devices, and transport of chemical constituents across biological and synthetic media and membranes. Efforts in biomechanics have developed the artificial heart and replacement heart valves, the artificial kidney, the artificial hip, as well as built a better understanding of the function of organs and musculoskeletal systems.

Biomaterials describe both living tissue and materials used for implantation. Understanding the properties of the living material is vital in the design of implant materials. The selection of an appropriate material to place in the human body may be one of the most difficult tasks faced by the biomedical engineer. Certain metal alloys, ceramics, polymers, and composites have been used as implantable materials. Biomaterials must be nontoxic, noncarcinogenic, chemically inert, stable, and mechanically strong enough to withstand the repeated forces of a lifetime.

Systems physiology is the term used to describe that aspect of biomedical engineering in which engineering strategies, techniques and tools are used to gain a comprehensive and integrated understanding of the function of living organisms ranging from bacteria to humans. Modeling is used in the analysis of experimental data and in formulating mathematical descriptions of physiological events. In research, models are used in designing new experiments to refine our knowledge. Living systems have highly regulated feedback control systems which can be examined in this way. Examples are the biochemistry of metabolism and the control of limb movements.

Clinical engineering is the application of technology for health care in hospitals. A Clinical engineer is defined by ACCE as "a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology." This definition was first adopted by the ACCE Board of Directors on May 13, 1991. Clinical Engineering is also recognized by the Biomedical Engineering Society (BMES), the major professional organization for biomedical engineering, as being a branch within Biomedical Engineering. The clinical engineer is a member of the health care team along with physicians, nurses and other hospital staff. Clinical engineers are responsible for developing and maintaining computer databases of medical instrumentation and equipment records and for the purchase and use of sophisticated medical instruments. They may also work with physicians on projects to adapt instrumentation to the specific needs of the physician and the hospital. This often involves the interface of instruments with computer systems and customized software for instrument control and data analysis. Clinical engineers feel the excitement of applying the latest technology to health care.

Bioinstrumentation is the application of electronics and measurement principles and techniques to develop devices used in diagnosis and treatment of disease. Computers are becoming increasingly important in bioinstrumentation, from the microprocessor used to do a variety of small tasks in a single purpose instrument to the extensive computing power needed to process the large amount of information in a medical imaging system.

Rehabilitation engineering is a new and growing specialty area of biomedical engineering. Rehabilitation engineers expand capabilities and improve the quality of life for individuals with physical impairments. Because the products of their labor are so personal, often developed for particular individuals or small groups, the rehabilitation engineer often works directly with the disabled individual.

These specialty areas frequently depend on each other. Often the biomedical engineer who works in an applied field will use knowledge gathered by biomedical engineers working in more basic areas. For example, the design of an artificial hip is greatly aided by a biomechanical study of the hip. The forces which are applied to the hip can be considered in the design and material selection for the prosthesis. Similarly, the design of systems to electrically stimulate paralyzed muscle to move in a controlled way uses knowledge of the behavior of the human musculoskeletal system. The selection of appropriate materials used in these devices falls within the realm of the biomaterials engineer. These are examples of the interactions among the specialty areas of biomedical engineering.

Where do they Work?

Biomedical engineers are employed in industry, in hospitals, in research facilities of educational and medical institutions, in teaching, and in government regulatory agencies. They often serve a coordinating or interfacing function, using their background in both the engineering and medical fields. In industry, they may create designs where an in-depth understanding of living systems and of technology is essential. They may be involved in performance testing of new or proposed products. Government positions

often involve product testing and safety, as well as establishing safety standards for devices. In the hospital, the biomedical engineer may provide advice on the selection and use of medical equipment, as well as supervising its performance testing and maintenance. They may also build customized devices for special health care or research needs. In research institutions, biomedical engineers supervise laboratories and equipment, and participate in or direct research activities in collaboration with other researchers with such backgrounds as medicine, physiology, and nursing.
Some biomedical engineers are technical advisors for marketing departments of companies and some are in management positions. Some biomedical engineers also have advanced training in other fields. For example, many biomedical engineers also have an M.D. degree, thereby combining an understanding of advanced technology with direct patient care or clinical research.

Hospital engineering is a branch of engineering whose primary function is the upkeep and supervision of the buildings and grounds and the maintenance of hospital physical plant and equipment which requires engineering expertise.

Importance of BME Department

Health Technology Management
Technology assessment, evaluation, strategic planning, acquisition, life cycle cost analysis, upgrades & replacement planning, utilization analysis, resources optimization, regional & national health technology policy, program & personnel administration.

Safety
Systems analysis, hospital safety programs, incident investigation, root cause analysis, user error, risk analysis & management, hazard & recall reporting systems, post-market device surveillance, device-device interactions, electromagnetic compatibility, disaster preparedness.

Medical Device Service
Equipment control, computerized assets & maintenance management systems, inspection, Maintenance, repair, in-house and outsourced programs, independent service organizations, vendor and service management, spare parts management

Technology Application
Engineering at the bedside, specialization in clinical areas, quality assurance & improvement, clinical applications support, home care support, help desk, installation & integration

Information Technology
Information systems integration and management, patient data management, artificial Intelligence, telemedicine, picture archiving and communication systems, wireless networks (telemetry), Health Insurance Portability and Accountability Act

Education & Training
Credentialing, health care provider technology training, distance education, in-service education, training schools, academic programs, international training, professional development, volunteer work

Research & Development
Medical device design & manufacturing, evaluations, modeling & simulation, human factors, failure mode and effect analysis, clinical trials & institutional review board support

Clinical Facilities
Clinical space design, electrical power, medical gases, water, HVAC (heating, ventilation, and air conditioning), sanitation, construction, renovation, communications infrastructure

Standards & Regulations
Compliance assurance, medical device and facilities standards, quality standards, regulations, consensus standards and guidelines, accreditation, expert witness, certification

Servicing & Maintenance

Regulation
Before maintenance and repair work is carried out, it is important to establish the regulatory framework under which such work is to be undertaken, to ensure compliance with local requirements. Requirements vary according to location, the type of equipment being managed, the nature of the health care organization's operation, and possibly among different manufacturers. In some countries there is little regulation, and work might be carried out by any capable person, regardless of qualifications, experience, or training. To some extent this situation exists almost everywhere, as some organizations employ (or contract out to) repair personnel who have had limited training, opting instead To provide skilled supervision so that people who have minimal qualifications can do the Job. Some countries regulate the registration of technical personnel, including supervising personnel, and might further regulate repair and maintenance to the extent that these activities can be audited to ensure that quality control is maintained. In addition, there are various standards that govern medical device management, and most countries adopt at least one such standard, either as part of the overall quality process or more rigorously as a legislative requirement. Typically, such standards define the nature and frequency of safety and performance testing but do not define maintenance requirements other than in the most general terms. These standards seldom if ever define repair quality issues.

Risk Management
The reality of many medical device management programs is that they are relatively Under-resourced, particularly with the adoption of more, and more complex, technology. This presents a difficult situation. If scarce resources are allocated to yearly safety and

performance testing, perhaps for mandatory or accreditation reasons, then the repair backlog may increase to a level where clinical service delivery becomes affected. Also, if the repair backlog increases, then maintenance activity will reduce, thus compounding the problem.

Maintenance Strategy

Regardless of the technique adopted to balance available resources against "risk," fundamental maintenance and calibration strategies will help to improve device management efficiency over time. Further innovative strategies should always be sought out and considered, particularly if they bring increases in efficiency, as any increase in efficiency can reduce the overall risk

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One fundamental step is to move toward "standardization" of the devices being managed and to reduce the different types of devices found across a health care organization.

This may be done without compromising service delivery, while still allowing a degree of clinical choice. If implemented carefully, it will benefit an organization because there will be less variation in maintenance and repair requirements, thus allowing limited resources to be more effectively applied. Staff training (both technical and clinical) can become more focused. Such a strategy seldom needs justification. For the maintenance and repair service provider or medical device manager to have the most valuable insight into this process, they need clinical knowledge as well as technical familiarity with the devices being used.

Pre-purchase estimation of projected maintenance costs needs to be considered, particularly as these costs often can exceed the capital cost of the equipment over its lifetime. Although often overlooked by clinical staff and management, it should be an essential consideration in any procurement process. If the maintenance requirements can be paralleled with existing equipment (e.g., by using the same type of batteries or other components), then such factors should be investigated because it might be possible to reduce overall long-term labor and parts costs.

Maintenance Planning

Forward planning of maintenance procedures is important. This process requires detailed knowledge of maintenance requirements and the resources that are required in order to perform maintenance. The resources required include labor, parts, materials, and tool costs. If maintenance is contracted, then all of these costs are often rolled into one by the contractor, although with some contracts parts costs might be kept separate.

Maintenance planning should be realistic and achievable. Planning initially should focus on major generic maintenance requirements, such as battery replacement, and also on the most critical items, such as ventilators. By tackling the major maintenance requirements first, any increases in efficiency will result in improved availability of resources, allowing smaller (and perhaps more difficult) issues to be tackled. It also will have the added intangible benefit of increasing confidence. With time and confidence, maintenance and repair providers or managers will move from prescriptive and reactive strategies to more

creative and proactive management techniques. In doing so, capacity and capability will increase, and the ability to adapt to changing conditions will improve.

Repair Strategy

Fault Diagnosis

Accurate fault diagnosis is critical and may be simple or extremely complicated. Damage to a device or lack of functionality may be apparent. However, the root cause of many faults is not readily apparent, leaving repair personnel reliant on their skills and experience to accurately identify the cause. As the actual fault might have been caused by disconnected factors, it is important to keep a broad view when trying to identify causes. For example, a blown fuse could be the result of an internal component failure but also could be the result of a transient spike on the power supply, beyond control. Furthermore, with experience, the cause of certain faults becomes more apparent, or certain strategies become more effective. The old adage "If no fault is found in the power supply, then check the power supply" sums up the value of experience when trying to diagnose faults correctly. Should the cause of a fault not be readily apparent, then a strategy needs to be followed. The purpose of such a strategy is to identify accurately the cause of the fault in the least possible time so that the appropriate repair can be made.

If possible, information from a user about the fault should be obtained. This information may be communicated directly by the user or it may be written on some sort of fault tag. One should carefully evaluate the information provided by the user because it may be invaluable in accurately identifying the cause of the fault, or it could be confusing and incorrect and could lead repair staff in the wrong direction.

One should try to replicate the fault if it is safe to do so. The fault might be simple to replicate (e.g., "the device won't turn on") or more complicated (e.g., "the external pacer injector does not appear to be in synch with this patient's ECG"). Complicated faults might be difficult to identify, as the fault may only present under certain clinical conditions or with particular types of patients. Nevertheless, if the fault is linked to a clinical procedure (for example, "this thermometer reads high"), then one should be wary, because the device actually might be functioning correctly and clinical staff are relying on preconceived perceptions of the patient's condition rather than the device. A real fault must never be discounted.

Most modern microprocessor-controlled equipment may contain service menus, error logs, or diagnostic modes of operation. These may be accessed either directly through the device or by some link to a diagnostic program contained in a remote computer. Repair staff should be familiar with, and should have access to, all possible methods of fault identification. Often the only way to identify intermittent faults is by these means, particularly if there is a device history that might contain an error log.

Fault Rectification: Repair

The level to which any repair is undertaken is a combination of technical skill, parts availability, clinical need, and cost. Repairs should be performed only when personnel

have sufficient training, technical information, tools, test equipment, and parts. Should any of these factors be lacking, then the repair should be performed elsewhere or delayed until these factors become available. It is important to establish boundaries as to what type of repairs will be attempted. Should an overly ambitious repair be attempted, then time and spare parts could be wasted if the repair is unsuccessful, or the safety of the device could be compromised. With modern, multilayer circuit boards and programmable surface mount components, often the only option is to swap the board and to have the faulty one repaired by the original equipment manufacturer.

Technical skill is a combination of training and experience. All training will improve technical skill, and both general and specialized training should be made available.

Experience comes with time, but the experience of others may be used. Establishing good relationships with suppliers and other repair organizations can be invaluable. Attempts at either formal or informal "networking" will allow exchange of ideas, experience, and information. Staff members should be encouraged to "network" because it will increase their knowledge and improve their skill.

Obtaining the required technical information can be difficult. Should diagrams, schematics and component information be unavailable, it may be impossible to affect a repair, regardless of technical skill. Nevertheless, all devices will have comprehensive service information somewhere. Unfortunately, this is not always readily available; and even if service information is required to be supplied as part of the procurement process, it might lack sufficient detail to perform a repair in the future. Some manufacturers provide technical information on CD or make it available over the Internet. These sources may be used to good effect.

Testing

After any maintenance procedure or repair, testing is required in order to ensure that the device is safe and performing up to specifications. Whether a full safety and performance test should be run is a matter for professional judgment, dependent on the level of repair. Furthermore, consideration should be given to "soak" testing repaired devices by leaving them functioning for a considerable time, particularly if the original fault was intermittent.

Acceptance Testing Protocols of Medical Equipment

The BME/medical equipment department should ensure processes are in place for acceptance testing. These processes will check that equipment meets safety standards, meets clinical requirements, and the procurement requirements of the Hospital from the day it arrives.

1. **Records**
   The first task is to ensure records are taken that can be entered into the equipment database once the testing is completed.

These details should include:

- The generic equipment type, for example 'defibrillator'
- The Equipment number from (or to be entered into) the equipment database
- The model of the device (as shown on the manufacturers label)
- The job number allocated from the database to this acceptance test
- Any accessories that were delivered with the device must be listed and checked
- The order number for cross reference with the supplier
- The serial number
- The cost of the device with accessories
- The name of the manufacturer, and supplier (if different)
- The telephone contact details for the supplier
- The date of acceptance into the hospital
- The date of warranty expiry
- The signature of the technician who carried out the acceptance testing
- Location of the technical documents
- Location of the equipment (Ward or Dept)
- Person within the ward or department responsible for that device (Departmental equipment controller)

2. Acceptance Checks

When carrying out acceptance testing, not all tests are valid for all devices but the form must be an assessment tool for all. With every device the individual checks should be recorded as a 'Pass', 'Fail', or not applicable 'N/A'. If a device has any minor failures that can be easily rectified, any remarks and faults corrected must be recorded on the acceptance form and database.

2.1 General considerations when carrying out an acceptance check include inspection of the packaging, whether the equipment arrived intact (as specified in the order) with the correct accessories and documentation.

2.2 Technical inspections should firstly ensure that the equipment is complete and undamaged. All the control knobs and fuses etc are intact. If the device contains chemicals or liquids, these should be inspected to ensure that they are correct. If the device has Wheels, or castors ensure they roll freely and the brakes work. All labeling should be inspected to ensure it is in the correct language, and meets expectations.

2.3 Electrical Safety Markings should be indicated on the device labels. I.e. Class I or II, Type B, BF, CF or Type AP, APG. Record Class and type on the acceptance form and on the database.

2.4 It is important to check the mains connection, paying attention to the condition and type of cable, whether the plug is intact, the plug terminal connections are terminated properly with correct cable colour code, cord grip is attached, fuses are correct and in accordance with the rating stated on the device, or in the

technical documentation. The equipment Protection is in accordance with current requirement, for example, some laser equipment will be terminated with a special interlocking electrical supply socket. Voltages are set to the correct value for the mains supply. Earth terminal symbol is correct (if applicable to the device).

2.5 Once the equipment classification and type have been determined, you then need to ensure the device meets the safety requirements by carrying out the electrical measurements that will determine a pass or fail for earthing of the equipment, earthing of accessories, insulation resistance, earth leakage current, enclosure leakage current, and patient leakage current where applicable to the device. (This will usually be carried out using an automated safety analyser.)

2.6 Installation and Operational tests must ensure the equipment functions correctly. This should be done through the user carrying out tests, or the supplier carrying out tests. The clinician should decide whether or not the device is operating correctly in the clinical environment and inform the technician once they are happy that everything operates as expected.

2.7 Any connections, whether plug / socket or permanently installed should be inspected. Other services such as gas, water, vacuum etc should also be inspected to ensure compatibility. Some devices will need a controlled environment to operate correctly (This will be indicated in the user manual). The actual device controls, indicators, alarms, and emergency stop will all have to be verified before formal acceptance. (Where applicable)

3.FormalAcceptance

Once all the criteria for acceptance have been satisfied, the device can be labeled with an asset number, and tested label then formally handed over to the user. After the equipment has been accepted the supplier should be informed, the internal supplies dept should be informed, and the equipment given to the user.

4.FurtherAction

Where modifications are necessary to ensure the device will pass acceptance, the supplier (as agreed by the hospital) should make these modifications. The modification should then be checked for compliance.

If any serious shortcomings remain, the device should be rejected.

Computerized preventive maintenance Planning System

The core of an equipment management system comprises equipment inventory, repair and maintenance history, and work order control. The equipment inventory is an automated file of all of the equipment that has been included in the CPMPS. The repair and maintenance history is a record of each repair and maintenance event, independent of who initiated the event and who provided the service. Work order control is used to dispatch and to prioritize requested work, to schedule periodic inspections and preventive

maintenance (PM), and to track the status of pending scheduled and unscheduled workorders.

Equipment Inventory
In the typical CPMPS, when new equipment is received, a biomedical equipment technician (BMET) ensures that the order is complete; inspects and tests the device in accordance with the service manual that is provided as part of the order; and, based on the type of device, the organization's inclusion criteria, and the policies of the clinical engineering organization, determines whether the device needs to be included in the equipment management program. If it does, the BMET then enters the new item onto the database (or completes a form so that a data entry clerk can enter it) as well as completing an incoming inspection work order. For those new devices whose model and/or type description are not yet in the CPMPS, the equipment type record must be built first, and then the model record, before the new Equipment record can be generated.

The Integrated History Record
The second part of the core of the CPMPS is the integrated history record. Whereas equipment records are fairly standardized across most CPMPSs, the maintenance and repair records are not standardized, nor is there a consensus on the data that are necessary to collect. There is a large variation among CMMS regarding the particular data that are collected, how they are collected, and how they are used.
The integrated history record concept provides a service provider with independent date-and-time-tagged repair and maintenance history associated with each service event.

The typical history record contains the following information:

- Original problem or request: Text of original problem request
- Work order type: Category of work (e.g., scheduled maintenance, repair, incoming inspection, project, and recall/alert)
- Open date and time: Origination date and time
- One or more tasks where each contains the following information:
- Start and end dates, and times for each task
- Status of the work order at the end of the task (e.g., complete or awaiting parts) and referred to a vendor
- Service provider, technician, engineer identification: Who performed the task (e.g., vendor, CE, or BMET)
- Labor hours for the task, including travel and overtime
- Parts and materials cost
- Reference to a parts purchase order, vendor repair order, or stock parts sales order
- Down time: Especially important for high-cost medical equipment (e.g., imaging
- equipment) where down time significantly adversely affects patient throughput and thus revenue

Work Order Subsystem
The work order subsystem of the typical CPMPS consists of the following modules: An unscheduled (requested) work order manager and technician dispatcher and an inspection

and PM scheduler. Some systems also include an inspection preventive maintenance procedure library.

The unscheduled work order manager documents incoming requests for repair services and keeps track of the work order until completion. Typical tracked information includes request for name and phone number, equipment identification, equipment problem and/or service requested, equipment location, type of work order (i.e., repair, new inspection, or product recall/alert), and priority of the work order (i.e., how soon the customer needs the work completed). PM are actions that are necessary or desirable in order to extend the operational intervals between failure, to extend the life of the equipment, or to detect and correct problems that are not apparent to the user. PM could include scheduled parts replacement and inspection activities, but PM is generally more invasive, typically requiring the equipment to be brought to a shop location and requiring access to the internal portions of the equipment. For example, lubricating the moving parts of an electric bed would be preventive maintenance.

Parts and Service Provider Management

One of the underlying philosophies of a quality CPMPS is that all services be tracked and costs recorded regardless of the service provider. One of the ways to categorize repair parts is by the way that they are obtained. Repair parts typically are obtained from one of the following types of sources: Stock parts, parts purchased directly from a vendor and shipped to the hospital for specific use on a specific repair, or parts supplied by the vendor as part of vendor service that includes installation labor.

CPMPS-based parts management software usually requires that all parts entered have a previously issued and unique clinical engineering part number. Alternatively, some systems do not require a unique clinical engineering-generated part number and instead use the manufacturer's part number as the index to the parts management system. Other fields that typically are collected include a part description, price(s), manufacturer, manufacturer part number, vendor, and vendor part number.

Data Accuracy and Integrity

New equipment entries and equipment service history entries comprise the majority of data collected in a CPMPS. Service history data are typically collected by biomedical equipment technicians and then either directly keyboarded into the CPMPS or a paper form filled out and data entry clerk keyboards the data into the CPMPS. Equipment data can be entered by clerks or technicians from purchase orders or new equipment forms filled out by technicians for later entry by clerks. Service reports from other service providers are entered into the CMMS by technicians or clerks, or they are scanned. Data entry requirements are intended to optimize data accuracy while minimizing data entry times. Data entry times can be minimized by using defaults and not requiring any redundant entries or keystrokes. Data accuracy and data integrity can be optimized by making the CPMPS easy to use correctly, enforcing data integrity rules when appropriate, and establishing operational policies and practices that require every employee to enter accurate and complete data.

Reports

The reporting capabilities of a CPMPS are the heart and soul of a vendor's product from a management perspective. The ability of the CMMS to produce relevant, informative, concise reports transforms the software into a management tool. When justifying the purchase of a CPMPS, a demonstration of reporting capabilities to senior administration is one key to whether or not the deal is consummated (with considerations for price). All successful technology management processes are dependent on the ability to gather data, to aggregate the data to convert it to useful management information, and then to produce reliable decisions based on the information. Reporting is the fundamental communication and decision support tool for the CPMPS.

Training of men for Maintenance & Servicing

The maintenance of medical equipment requires a wide range of technical abilities, and the costs and time required to train a man increase markedly with the level of skill that has to be attained. Experience in many developing countries has revealed that training a person to a high level of skills is very expensive. Furthermore, upon completion of their training, staffs are often lured away by companies paying higher salaries.

Therefore, the approach recommended for the training of men to do front-line maintenance for medical equipment in district health facilities. This strategy requires less time, costs less, and delivers benefits to a larger population by supporting primary health care. Because of less stringent prerequisites for selection, a large number of candidates can be recruited for training, enabling a relatively rapid multiplication of technical human resources to serve the large volume of essential medical equipment in widely distributed district health facilities in the country.

The selection of candidates should emphasize technical aptitude and motivation rather than academic qualifications. Practising electricians and plumbers already working in the health facilities are good candidates. If possible, candidates should pay at least a portion of their training fees to show motivation. To utilize the scarce technical human resources in the districts optimally, multi-skills training should be encouraged. For example, frontline medical equipment maintenance can be combined with electrician training.

The content of training should emphasize more on practice (70%) and less on theory (30%). A simple course, which can be offered at local technical colleges, should be worked out. A sample curriculum for such a course is given below. Teachers should periodically visit practising maintenance workers at their jobs, so that teachers are updated with current maintenance problems.

Some opportunities for further training

During the purchase of new equipment, suppliers can be requested to train in-house technicians in maintenance, often at no cost. This condition should be included in the call for tender or purchase order. Because equipment suppliers are obliged to provide comprehensive warranty and maintenance services, it may be quite expensive for them to establish a local service staff. They may be quite willing to train in-house technicians.

Major health development projects frequently include large volumes of equipment procurement. This provides excellent opportunities for maintenance training and for obtaining current equipment for training.

Planning officials should be approached to include such requirements in the procurement agreements:
(1) comprehensive operation and maintenance training to in-house staff or local trainers;
(2) an extra set of major equipment should be purchased for the training workshops. This way, the most relevant training can be given.

In bilateral aid programmes, donor countries often provide modern health facilities and sophisticated equipment to developing countries. This is an excellent opportunity to request advanced technical and medical equipment management training for in-house staff.

District workshops can request teaching from technicians in national hospitals that frequently have higher skill levels. However, training must focus on existing equipment in the districts.

In-house technicians can also learn from external companies while monitoring their services.

Importance of ISO 9000 Certificates

Quality and customer satisfaction are key priorities for today's most successful organizations. Where the market place is competitive, there are significant efficiency pressures, and consumer's demands are increasing, success does not just happen. Attaining it requires commitment, buy-in, and the appropriate management system. While commitment starts with management, and depends upon the organization, several frameworks exist to assist in developing the management system. One such framework is the globally recognized ISO 9001:2000. ISO 9001:2000 is a standard, which provides organizations with a guide to achieving the goals of quality, and customer satisfaction. It has been successfully implemented by hundreds of thousands of organizations, in a wide variety of industries, with healthcare being no exception.

ISO 9001:2000, derives a number of benefits for healthcare organizations, including:

• **Potential for efficiency gains and cost reduction:** ISO 9001:2000 can create significant efficiency gains because of its process orientation. The standard focuses organizations upon areas where costs can be reduced, both internally, and in relation to its customers.

• **Potential for quality and reliability improvements:** The process orientation, and the need to be customer focused and continually improve, provides significant opportunities to increase the reliability, and quality of healthcare. ISO 9001:2000 provides opportunities to standardize the service throughout organizations, and the healthcare industry as a whole.

• **Potential for regulatory support and funding:** Increasingly, regulators and legislators are regarding quality as vital to improving healthcare. Bodies such as the JCAHO, Health Canada, and Institute of Medicine have emphasized this. Registration may therefore lead to greater funding and support.

• **Potential to simplify the implementation of other quality systems:** ISO 9001:2000 has the potential to make accreditation and conformity to other requirements much simpler. It has been regarded as a building block to JCAHO accreditation, and the Baldrige awards.

• **Potential for an improved care process:** ISO 9001:2000 focuses organizations on the processes involved. In healthcare it can improve the organization's understanding of the complexities of the industry, including the relationships between organizations such as hospitals and medical practices.

• **Potential for Differentiation:** Registration differentiates an organization from its competition. It shows customers that the organization is committed both to their needs, and improving the quality of the service they provide.

• **Potential for continuous improvement:** ISO 9001 stipulates the importance of review, and continual improvement. In healthcare, where these are paramount, registration can be beneficial.

Obtaining ISO Certificates in Hospitals

There are nine steps to implementing ISO 9001:2000 in the healthcare sector:

✓ **PURCHASE THE STANDARD**
Before you can begin preparing for your application, you will require a copy of the standard. You should read this and make yourself familiar with it. Copies can be purchased from **www.bsiamericas.com**

✓ **REVIEW SUPPORT LITERATURE & SOFTWARE**
There are a large number of tools that can be very helpful at every stage of the process of implementing any ISO 9001:2000 based QMS. We recommend "The Route to Registration" published by BSI, and available at **www.bsiamericas.com**

✓ **ASSEMBLE A TEAM**
You should begin the entire implementation process by preparing your implementation team. Responsibility for a QMS lies with Senior Management; therefore it is vital that Senior Management is involved from the beginning of the process.

✓ **CONSIDER TRAINING**
There are a wide range of training courses available to assist, at every level of understanding, see **www.bsiamericas.com/training**.

✓ **REVIEW CONSULTANCY OPTIONS**
Using a consultant to help you through the process can be very helpful, but consider the cost/benefits. Download BSI's 10 Tips for the Selection and Use of a Quality Management Systems consultant from **www.bsiamericas.com** for further help.

✓ **IMPLEMENT YOUR QMS**
You don't just write the documents or develop processes; you've got to get staff to use them through training and awareness.

✓ **CHOOSE A REGISTRAR**

The registrar is a third-party, like BSI Management Systems, who assesses the effectiveness of your quality management system, and issue a certificate if it meets the requirements of the standard. Factors to consider when choosing a registrar include industry experience, geographic coverage, price and service level offered.

✓ **GAIN REGISTRATION**

The key step in the process is a registration assessment, at which your quality management system will be assessed.

FDA

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

The FDA also enforces other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs. These include sanitation requirements on interstate travel and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.

The FDA is led by the Commissioner of Food and Drugs, appointed by the President with the advice and consent of the Senate. The Commissioner reports to the Secretary of Health and Human Services. The 21st and current Commissioner is Dr. Margaret A. Hamburg. She has served as Commissioner since February 2009.

The FDA has its headquarters at White Oak, Maryland. The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008, the FDA started opening offices in foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

In recent years, the agency began undertaking a large-scale effort to consolidate its operations in the Washington Metropolitan Area from its main headquarters in Rockville and several fragmented office buildings in the vicinity to the former site of the Naval Ordnance Laboratory in the White Oak area of Silver Spring, Maryland.[2][4] When the FDA arrived, the site was renamed from the White Oak Naval Surface Warfare Center to the Federal Research Center at White Oak. The first building, the Life Sciences Laboratory, was dedicated and opened with 104 employees on the campus in December 2003. The project is slated to be completed by 2013.

While most of the Centers are located around the Washington, D.C., area as part of the Headquarters divisions, two offices - the Office of Regulatory Affairs (ORA) and the

Office of Criminal Investigations (OCI) - are primarily field offices with a workforce spread across the country.

The Office of Regulatory Affairs is considered the "eyes and ears" of the agency, conducting the vast majority of the FDA's work in the field. Consumer Safety Officers, more commonly called Investigators, are the individuals who inspect production and warehousing facilities, investigate complaints, illnesses, or outbreaks, and review documentation in the case of medical devices, drugs, biological products, and other items where it may be difficult to conduct a physical examination or take a physical sample of the product. The Office of Regulatory Affairs is divided into five regions, which are further divided into 13 districts. Districts are based roughly on the geographic divisions of the federal court system. Each district comprises a main district office, and a number of Resident Posts, which are FDA offices located away from the district office to serve a particular geographic area. ORA also includes the Agency's network of laboratories, which analyze any physical samples taken. Though samples are usually food-related, some laboratories are equipped to analyze drugs, cosmetics, and radiation-emitting devices.

Regulatory programs

The programs for safety regulation vary widely by the type of product, its potential risks, and the regulatory powers granted to the agency. For example, the FDA regulates almost every facet of prescription drugs, including testing, manufacturing, labeling, advertising, marketing, efficacy and safety, yet FDA regulation of cosmetics is focused primarily on labeling and safety. The FDA regulates most products with a set of published standards.

Recent and ongoing reforms

- **Critical Path Initiative**

The Critical Path Initiative is FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured. The Initiative was launched in March 2004, with the release of a report entitled Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.

- **Patients' rights to access unapproved drugs**

A 2006 court case, Abigail Alliance v. von Eschenbach, would have forced radical changes in FDA regulation of unapproved drugs. The Abigail Alliance argued that the FDA must license drugs for use by terminally ill patients with "desperate diagnoses," after they have completed Phase I testing. The case won an initial appeal in May 2006, but that decision was reversed by a March 2007 rehearing. The US Supreme Court declined to hear the case, and the final decision denied the existence of a right to unapproved medications.

Critics of the FDA's regulatory power argue that the FDA takes too long to approve drugs that might ease pain and human suffering faster if brought to market sooner. The AIDS crisis created some political efforts to streamline the approval process. However, these

limited reforms were targeted for AIDS drugs, not for the broader market. This has led to the call for more robust and enduring reforms that would allow patients, under the care of their doctors, access to drugs that have passed the first round of clinical trials.

- **Post-marketing drug safety monitoring**

The widely publicized recall of Vioxx, a non-steroidal anti-inflammatory drug now estimated to have contributed to fatal heart attacks in thousands of Americans, played a strong role in driving a new wave of safety reforms at both the FDA rulemaking and statutory levels. Vioxx was approved by the FDA in 1999, and was initially hoped to be safer than previous NSAIDs, due to its reduced risk of intestinal tract bleeding. However, a number of pre- and post-marketing studies suggested that Vioxx might increase the risk of myocardial infarction, and this was conclusively demonstrated by results from the APPROVe trial in 2004.[46] Faced with numerous lawsuits, the manufacturer voluntarily withdrew it from the market. The example of Vioxx has been prominent in an ongoing debate over whether new drugs should be evaluated on the basis of their absolute safety, or their safety relative to existing treatments for a given condition. In the wake of the Vioxx recall, there were widespread calls by major newspapers, medical journals, consumer advocacy organizations, lawmakers, and FDA officials for reforms in the FDA's procedures for pre- and post- market drug safety regulation.

In 2006, a congressionally requested committee was appointed by the Institute of Medicine to review pharmaceutical safety regulation in the U.S. and to issue recommendations for improvements. The committee was composed of 16 experts, including leaders in clinical medicine medical research, economics, biostatistics, law, public policy, public health, and the allied health professions, as well as current and former executives from the pharmaceutical, hospital, and health insurance industries. The authors found major deficiencies in the current FDA system for ensuring the safety of drugs on the American market. Overall, the authors called for an increase in the regulatory powers, funding, and independence of the FDA. Some of the committee’s recommendations have been incorporated into drafts of the PDUFA IV bill which was signed into law in 2007.

- **Pediatric drug testing**

Prior to the 1990s, only 20% of all drugs prescribed for children in the United States were tested for safety or efficacy in a pediatric population. This became a major concern of pediatricians as evidence accumulated that the physiological response of children to many drugs differed significantly from those drugs' effects on adults. There were several reasons that not many medical trials were done with children. For many drugs, children represented such a small proportion of the potential market, that drug manufacturers did not see such testing as cost-effective. Also, because children were thought to be ethically restricted in their ability to give informed consent, there were increased governmental and institutional hurdles to approval of these clinical trials, as well as greater concerns about legal liability. Thus, for decades, most medicines prescribed to children in the U.S. were done so in a non-FDA-approved, "off-label" manner, with dosages "extrapolated" from adult data through body weight and body-surface-area calculations.

An initial attempt by the FDA to address this issue was the 1994 FDA Final Rule on Pediatric Labeling and Extrapolation, which allowed manufacturers to add pediatric labeling information, but required drugs which had not been tested for pediatric safety and efficacy to bear a disclaimer to that effect. However, this rule failed to motivate many drug companies to conduct additional pediatric drug trials. In 1997, the FDA proposed a rule to require pediatric drug trials from the sponsors of New Drug Applications. However, this new rule was successfully preempted in federal court as exceeding the FDA's statutory authority. While this debate was unfolding, Congress used the 1997 Food and Drug Administration Modernization Act to pass incentives which gave pharmaceutical manufacturers a six-month patent term extension on new drugs submitted with pediatric trial data. The act reauthorizing these provisions, the 2002 Best Pharmaceuticals for Children Act, allowed the FDA to request NIH-sponsored testing for pediatric drug testing, although these requests are subject to NIH funding constraints. Most recently, in the Pediatric Research Equity Act of 2003, Congress codified the FDA's authority to mandate manufacturer-sponsored pediatric drug trials for certain drugs as a "last resort" if incentives and publicly funded mechanisms proved inadequate.

ICRP

The work of the International Commission on Radiological Protection (ICRP) helps to prevent cancer and other diseases and effects associated with exposure to ionizing radiation, and to protect the environment.

Since 1928, ICRP has developed, maintained, and elaborated the International System of Radiological Protection used world-wide as the common basis for radiological protection standards, legislation, guidelines, programmes, and practice.

ICRP has published more than one hundred reports on all aspects of radiological protection. Most address a particular area within radiological protection, but a handful of publications, the so-called fundamental recommendations, each describe the overall system of radiological protection. The International System of Radiological Protection has been developed by ICRP based on

(i) the current understanding of the science of radiation exposures and effects and
(ii) Value judgments. These value judgments take into account societal expectations, ethics, and experience gained in application of the system.

ICRP is an independent, international organization with more than two hundred volunteer members from approximately thirty countries across six continents. These members represent the leading scientists and policy makers in the field of radiological protection.

ICRP is funded through a number of ongoing contributions from organizations with an interest in radiological protection.

ICRP Activities

The work of ICRP helps to prevent cancer and other diseases and effects associated with exposure to ionising radiation, and to protect the environment.

ICRP is a Registered Charity (a not-for-profit organisation) in the United Kingdom, and has a Scientific Secretariat in Ottawa, Canada.

Structure

ICRP is comprised of a Main Commission, a Scientific Secretariat, five standing Committees (on Effects, Doses, Medicine, Application, and the Environment), and a series of Task Groups and Working Parties.

The Main Commission and the Scientific Secretariat work together to direct, organize, and oversee the work of ICRP. All ICRP reports are approved by the Main Commission prior to publication.

The Committees advise the Main Commission in their area of expertise. They direct the work of Task Groups, and play an important role in ensuring the quality of ICRP reports.

Task Groups are established to undertake a specific task, normally the production of a single ICRP publication, and are generally comprised of a mixture of Committee members and other experts in the field invited to contribute to the work.

Working Parties are normally formed of Committee members to explore particular issues, and are sometimes transformed into Task Groups if their work is to result in an ICRP publication.

Members

ICRP consists of eminent scientists and policy makers in the field of radiological protection. All members of the Main Commission, Committees, and Task Groups are volunteers, most whose employers pay for their time and travel expenses to work with ICRP. Some volunteer their time outside of regular work or after retirement. Members are invited to serve with ICRP based on the skills and knowledge they bring to the work, and as such do not represent their countries or employers when working with ICRP.

The Work of ICRP

In preparing its recommendations, ICRP considers the fundamental principles and quantitative bases upon which appropriate radiation protection measures can be established, while leaving to the various national protection bodies the responsibility of formulating the specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries.

ICRP has published well over one hundred publications on all aspects of radiological protection. Most address a particular area within radiological protection, but a handful of

publications, the so-called fundamental recommendations, each describe the overall system of radiological protection. The system of radiological protection is based on the current understanding of the science of radiation exposures and effects, and value judgments. These value judgments take into account societal expectations, ethics, and experience gained in application of the system. As the understanding of the science and societal expectations have evolved over time, so too has the system of radiological protection. As well, the recommendations continue to take into account novel uses of radiation in medicine and other fields to help ensure an adequate level of safety under all circumstances.

ICRP offers its recommendations to regulatory and advisory agencies and provides advice the intended to be of help to management and professional staff with responsibilities for radiological protection. Legislation in most countries adheres closely to ICRP recommendations. The International Atomic Energy Agency (IAEA) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources is based heavily on ICRP recommendations, and the International Labor Organization (ILO) Convention 115, Radiation Protection Convention, General Observation 1992, refers specifically to the recommendations of ICRP. ICRP recommendations form the basis of radiological protection standards, legislation, programs, and practice worldwide.

AERB

The Atomic Energy Regulatory Board (AERB) was constituted on November 15, 1983 by the President of India by exercising the powers conferred by Section 27 of the Atomic Energy Act, 1962 (33 of 1962) to carry out certain regulatory and safety functions under the Act. The regulatory authority of AERB is derived from the rules and notifications promulgated under the Atomic Energy Act, 1962 and the Environmental (Protection) Act, 1986. The headquarter is in Mumbai.

The mission of the Board is to ensure that the use of ionizing radiation and nuclear energy in India does not cause undue risk to health and the environment. Currently, the Board consists of a full-time Chairman, an ex-officio Member, three part-time Members and a Secretary.

AERB is supported by the Safety Review Committee for Operating Plants (SARCOP), Safety Review Committee for Applications of Radiation (SARCAR) and Advisory Committees for Project Safety Review (ACPSRs) (e.g. nuclear power, light water reactor, and waste management projects). ACPSRs recommend to AERB issuance of authorizations at different stages of a plant of the Department of Atomic Energy (DAE), after reviewing the submissions made by the plant authorities based on the recommendations of the associated Design Safety Committees. The SARCOP carries out safety surveillance and enforces safety stipulations in the operating units of the DAE. The SARCAR recommends measures to enforce radiation safety in medical, industrial and research institutions which use radiation and radioactive sources.

AERB also receives advice from the Advisory Committee on Nuclear Safety (ACNS). ACNS is composed of experts from AERB, DAE and institutions outside the DAE. ACNS provides recommendations on the safety codes, Guides and manuals prepared for siting, design, construction, operation, quality assurance and decommissioning/life extension of nuclear power plants which have been prepared by the respective advisory committees for each of these areas. It also advises the Board on generic safety issues. ACNS examines and advice on any specific matter that are referred to it by AERB.

The administrative and regulatory mechanisms which are in place ensure multi-tier review by experts available nationwide. These experts come from reputed academic institutions and governmental agencies.

Divisions of AERB

AERB secretariat has ten divisions. The heads and directors of divisions constitute the Executive Committee which meets periodically with Chairman, AERB and Vice-Chairman, AERB to take decisions on important policy matters related to the management of the Secretariat of the Board.The different divisions of AERB are:

1. SSED : Siting and Structural Engineering Division
2. IPSD : Industrial Plants Safety Division
3. ITSD : Information and Technical Services Division
4. NPSD : Nuclear Projects Safety Division
5. OPSD : Operating Plant Safety Division
6. RSD : Radiological Safety Division
7. SADD : Safety Analysis and Documentation Division
8. SRI : Safety Research Institute, Kalpakkam
9. Administration Division
10. Accounts Division

Siting and Structural Engineering Division (SSED)

The primary responsibilities of SSED are:

a) Safety Review pertaining to Civil and Structural Engineering aspects of nuclear reactors, fuel cycle facilities, industrial and radiation facilities of DAE.

b) Site evaluation of nuclear facilities

c) Developing civil engineering safety criteria for design, construction and erection of NPPs

Industrial Plants Safety Division (IPSD)

The IPSD's primary reposnsibilities are:

a) Administration of The Factories Act, 1948 and The Atomic Energy (Factories) Rules, 1996 in DAE units viz front end fuel cycle facilities of IREL, UCIL, NFC and HWPs, Nuclear Power Plants/Projects, BRIT facilities, IGCAR facilities, ECIL facilities and DAE accelerator facilities of VECC and RRCAT.

b) Administration of The Atomic Energy (Radiation Protection) Rules, 2004 for enforcing radiological safety in front end fuel cycle facilities, DAE accelerator units and all Beach Sand Minerals Facilities of India.

c) Safety review of the above facilities during siting, construction, commissioning and operation.

d) Regulatory Inspection of the above facilities and special monthly regulatory inspection of major construction projects of DAE.

e) Industrial Safety, Fire Safety and Occupational Health Safety review of all DAE projects and plants (except BARC facilities).

f) Licensing of Operating Personnel in front end fuel cycle facilities.

Information & Technical Services Division (ITSD)
The ITSD takes care of:
a) Secretariat for AERB Board
b) Activities to promote and fund Safety Research Projects
c) International relations including interaction with other regulatory bodies
d) Public information and Media interaction including Website management
e) Editing and publication of AERB Annual Reports and AERB Newsletter
f) Human Resource Development
g) Response to parliament questions and queries under Right To Information Act
h) Knowledge Management and its development

Nuclear Projects Safety Division (NPSD)
The activities of NPSD include:
a) Safety Review of Nuclear Projects.
b) Regulatory Inspection & Enforcement in projects under construction.
c) Issue of authorizations at various stages of the projects as per established procedures and protocols.
d) Review of physical protection aspects in projects.
Operating Plants Safety Division (OPSD)

The responsibilities of OPSD are:
a) Safety Review and Safety Surveillance including Health Physics Aspects and Emergency
b) Preparedness of operating NPPs and Research Reactors
c) Regulatory Inspection and Enforcement in respect of all operating NPPs and Research Reactors
d) Conducting Periodic Safety Review and Renewal of Authorization
e) Licensing of the operating personnel and the management staff
f) Review of Physical Protection aspects in operating plants
g) Enforcement of Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987

h) Co-ordination with International Atomic Energy Agency (IAEA) for the International Nuclear Event Scale (INES) based reporting of events and for the Incident Reporting System (IRS) operated by IAEA/NEA
i) Function as secretariat of SARCOP

Radiological Safety Division (RSD)
The RSD has the responsibilities of
a) Licensing, Surveillance and Safety Review of BRIT facilities and Non-DAE Radiation Installations including Accelerators and Irradiators
b) Implementation of Atomic Energy (Radiation Protection) Rules, 2004 and enforcement of Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987 in non-DAE installations
c) Ensuring safety in Transportation of Radioactive Material in public domain
d) Function as secretariat for SARCAR (Safety Review Committee for Application of Radiation)

Safety Analysis and Documentation Division (SADD)
SADD's prime responsibilities include:
a) Safety Analysis and Safety Studies for nuclear facilities
b) Preparation of Regulatory Documents
c) Library and documentation services

Safety Research Institute (SRI), Kalpakkam
The major activities of SRI include research and development in areas of regulatory interest. Some of these areas are listed below:
I. Nuclear Plant Safety Studies
II. Radiation Safety Studies
III. Environmental Safety Studies
IV. Regulatory Inspection

JCAHO

The Joint Commission (TJC), formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), is a United States-based not-for-profit organization that accredits over 19,000 health care organizations and programs in the United States. A majority of state governments have come to recognize Joint Commission accreditation as a condition of licensure and the receipt of Medicaid reimbursement.

The declared mission of the organization is "To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value".

Although The Joint Commission was renamed Joint Commission on Accreditation of Hospitals in 1951, it was not granted deeming power for hospitals until 1965,when it was deemed that a hospital that met Joint Commission accreditation met the Medicare

Conditions of Participation. Recently, Section 125 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) removed The Joint Commission's statutorily-guaranteed accreditation authority for hospitals, to be effective July 15, 2010. At that time, The Joint Commission's hospital accreditation program will be subject to Centers for Medicare & Medicaid (CMS) requirements for accrediting organizations seeking deeming authority. To avoid a lapse in deeming authority, The Joint Commission must submit an application for hospital deeming authority consistent with these requirements and within a time frame that will enable CMS to review and evaluate their submission.CMS will make the decision to grant deeming authority and determine the term.

Operation

All health care organizations, other than laboratories, are subject to a three-year accreditation cycle. With respect to hospital surveys, the organization does not make its findings public. However, it does provide the organization's accreditation decision, the date that accreditation was awarded, and any standards that were cited for improvement. Organizations deemed to be in compliance with all or most of the applicable standards are awarded the decision of Accreditation.

The unannounced full survey is a key component of The Joint Commission accreditation process. "Unannounced" means the organization does not receive an advance notice of its survey date. The Joint Commission began conducting unannounced surveys on January 1, 2006. Surveys will occur 18 to 39 months after the organization's previous unannounced survey.

There has been criticism in the past from within the U.S. of the way the Joint Commission operates. The Commission's practice had been to notify hospitals in advance of the timing of inspections.A 2007 article in the Washington Post noted that about 99% of inspected hospitals are accredited, and serious problems in the delivery of care are sometimes overlooked or missed. Similar concerns have been expressed by the Boston Globe, stating that "The Joint Commission, whose governing board has long been dominated by representatives of the industries it inspects, has been the target of criticism about the validity of its evaluations". The Joint Commission over time has responded to these criticisms. However, when it comes to the international dimension, surveys undertaken by JCI still take place at a time known in advance by the hospitals being surveyed, and often after considerable preparation by those hospitals.

Preparing for a Joint Commission survey can be a challenging process for any healthcare provider. At a minimum, a hospital must be completely familiar with the current standards, examine current processes, policies and procedures relative to the standards and prepare to improve any areas that are not currently in compliance. The hospital must be in compliance with the standards for at least four months prior to the initial survey. The hospital should also be in compliance with applicable standards during the entire period of accreditation, which means that surveyors will look for a full three years of implementation for several standards-related issues.

As for the surveyors, the Joint Commission and JCI employ salaried individuals, people who generally work or have worked within health care services but who may devote half or less of their time for the accrediting organization. The surveyors travel to health care organizations to evaluate their operational practices and facilities (i.e., structure/input and process metrics) against established Joint Commission standards and elements of performance.

Substantial time and resources are devoted by health care organizations ranging from medical equipment suppliers and staffing firms to tertiary care academic medical centers to prepare for and undergo Joint Commission surveys. There is growing concern, however, over the lack of verifiable progress towards meeting the organization's stated goals. Although the Joint Commission increasingly cites and demands "evidence-based medicine" in its regulatory requirements, there is a relative paucity of evidence demonstrating any significant quality improvement due to its efforts, while there is a growing body of literature showing no improvement or actual deterioration in quality despite the increasingly stringent and expensive requirements.