ECRI INSTITUTE ACCREDITATION OF
BEST PRACTICES IN BIOMEDICAL
ENGINEERING

Introduction and Background

ECRI Institute is a non-profit 501(c)(3) organization committed to improving the safety and cost-effectiveness of patient care. Headquartered in suburban Philadelphia, it has been in continuous operation since 1968, has an interdisciplinary full time staff of 385 and offices in Australia, Malaysia, the United Kingdom and the United Arab Emirates.

Patient safety in healthcare facilities has become a much debated and critical discipline. It demands detailed analysis of adverse events, reporting and, above all development and implementation of systems to prevent harm.

Medical devices are a vital element of modern healthcare and provide great benefits, but are also implicated in 5% of accidental injuries and deaths in U.S. hospitals. (Source: First National Summit on Medical Errors and Patient Safety sponsored by the United States Quality Interagency Coordination Task Force and the Agency for Healthcare Research and Quality). Risks are higher in high technology environments where the use of intrinsically dangerous equipment and procedures is routine and more devices are in use and often interconnected.

Hospitals usually try to minimize such adverse events through a formal structured system for medical equipment management and demand the same from their outside equipment service providers. The biomedical engineering department is the hospital locus for this responsibility. However, many hospitals throughout the world rely heavily on third party equipment service organizations, also known as independent service organizations (ISO’s). ISO’s may or may not be supervised or managed effectively by hospital biomedical engineering departments or, in the case of hospitals which lack such departments and outsource all equipment service, by hospital administration.

ECRI institute has pioneered device related patient safety for over 44 years and has been the prime mover in the area of medical device safety. We developed and published in 1971, the first protocol for medical equipment management and safety. It included a specific process for related accident investigation. That protocol is the foundation for medical equipment management and safety for healthcare facilities worldwide. We have also operated an international device problem reporting system since 1971 and since 1977 have made available an extensive database, Health Devices Alerts, used worldwide.
Over the past forty years our Accident and Forensic Investigation Group has investigated more patient and staff injuries and deaths related to medical devices than any government or private institution worldwide. Our databases of adverse device related events are also the standard reference throughout the world and our training programs related to medical device safety have been provided to health professionals and biomedical engineers in North America and Latin America, Asia and Europe.

Our knowledge base in this area is also based on hundreds of hospital biomedical engineering surveys and consultation projects undertaken over the past 40 years in North America, Europe and Asia. Our three year program on behalf of the Ministry of Health of Malaysia, focused on biomedical service quality monitoring, has also contributed to development of our auditing tools.

Our work has led to recognition of ECRI Institute worldwide for its role in device related patient and staff safety programs. The U.S. Government has designated ECRI Institute as a Patient Safety Organization (PSO), and an Evidence-Based practice Center. ECRI institute has been a Collaborating Center of the World Health Organization for decades.

As a Patient Safety Organization (PSO) we identify key processes and systems that will make the operating environments in hospitals and healthcare institutions safer. A formal process of evaluation of these key processes by a systematic auditing process to identify weaknesses and encourage hospitals to identify their own weaknesses through a systematic framework. A formal accreditation program based on demonstration and acknowledgement of the healthcare facility's adherence to accepted Standard Operating procedures and quality systems for management of Medical Devices Safety is therefore a natural progression.

As Biomedical or Clinical Engineering Departments usually are responsible for this activity, this naturally leads to accreditation and/or certification of the Biomedical or Clinical Engineering Departments of the Hospital or Healthcare Institution. Our new Accreditation for Best Practices in Biomedical and Clinical Engineering program is based not only on our recognition of need but on requests for such a service from the bioengineering community.

Currently ISO 9001 is the standard usually used for certification of engineering services. However this is only a process standard and relies on the assumption that good processes design assures good outcomes. Our accreditation program is intended to both ensure adherence to optimum processes and to measure related outcomes.

Our Accreditation for Best Practices in Biomedical and Clinical Engineering program underwent its first trials in Germany where we accredited three organizations, namely:

- CFM Charité Facility Management GmbH, responsible for biomedical and clinical engineering in the Charité, the biggest University Hospital in Europe
- Klinik Medizintechnik Eppendorf GmbH responsible for biomedical and clinical engineering in the University Hospital of Hamburg-Eppendorf
- VAMED Management and Service GmbH Deutschland, one of the biggest third party medical equipment service providers in Germany
Our accreditation program is currently being made available in the GCC Region as well as Europe. In 2013 we plan to extend its availability to North America.

**Anticipated Outcomes of the Accreditation Process**

What additional benefits, beyond improvements in quality of care and patient safety do we expect to achieve?

- Accreditation of best practices in biomedical and clinical engineering would help assure hospital management and governing boards that what they perceive is an arcane black box is in fact functioning properly and contributing to their patient safety goals.
- An accredited biomedical/clinical engineering department would help assure hospital or healthcare system management executives that both cost effective and high quality maintenance for their medical equipment assets are being provided. (That equipment often account for over 30% of their hospital’s total capital investment).
- An accredited biomedical engineering department will enhance recruitment of a higher quality of engineering talent, since it assures that the accredited biomedical engineering facility is focused on continuous development of its human resources.
- An accredited organization will help assure management and stakeholders of the priorities and the focus of the organization to provide an environment and culture of patient safety and quality processes in a critical area of modern medicine - where technology is a key component.
- Accreditation of ISO's will eliminate a significant gap since neither ISO9001 or JCI cope effectively with outsourced services provided to a hospital.

**Our Accreditation for Best Practices in Biomedical and Clinical Engineering Program**

Our multistep accreditation process has now undergone practical testing and includes:

**Education:**

Education of the management and leadership of the candidate biomedical engineering department to understand the benefits, process and schedule for examination and accreditation.

**Baseline assessment, Gap Analysis and Action Plan:**

Our evaluators critically and objectively assess each area and conduct a detailed baseline assessment of the organization’s current adherence to the standards and each measurable element. We conform to ISO 17021 in terms of following best practice guidelines in assessment and audits of biomedical/clinical engineering departments. Our educators and evaluators are completely independent of our auditors.

In those hospitals which have been assessed for ISO 9001 or by the Joint Commission, the relevant sections on Medical Equipment Management are useful but we supplement them with far more
intensive assessments in many key areas, specifically related to biomedical and clinical engineering, medical device management and device safety.

The findings of the baseline assessment lead to development of a detailed plan for improvement. This serves as a gap analysis which, in turn, leads to an action plan for corrective action. In addition to an overall project plan, we compile a list of all required policies and procedures that will need development or revision.

Final Audit and survey
This final accreditation survey is based on an evaluation of the organization’s elimination of previously identified gaps and its performance of functions and processes aimed at continuously improving Biomedical/Clinical Engineering Management.

This assessment is accomplished through evaluating an organization’s compliance with the applicable standards based on the following:

- Documents provided by the organization
- Responses to our inquiries
- Audit of medical equipment by asset
- On-site observations and interviews by auditors
- Audit of computerized medical equipment management system

Performance measurement requirements
We have integrated a measurement process that incorporates data on core performance measures that facilitates improvement of Biomedical/Clinical Engineering Management. While this data will be consistent with the requirements of key healthcare quality organizations like Joint Commission and CMS, it is far more detailed.