Find Answers. Prevent Recurrence.

Accidents happen in healthcare. When an accident or serious adverse event occurs in your healthcare facility you want to know how it occurred, the root causes, whether the incident must be reported, and how to prevent recurrence. For many types of accidents, investigation is critical to restoring operations, minimizing interdepartmental conflict, and maintaining staff confidence in the affected technology.

This course will provide a detailed curriculum on medical device accidents, hazards, and problems focusing on applicable investigation techniques, problem reporting, management, and information resources. Risk management strategies for reducing harm and potential liability will be explored, along with case examples and hypotheticals, with a focus on identifying and managing device related risks. This course is intended to help attendees perform investigations more effectively and efficiently.

Trainer Profile

James P. Keller, Jr., MS
Vice President, International Market Development, ECRI Institute

James Keller is responsible for the integration of ECRI’s international operations with its headquarters. He leads ECRI headquarters efforts to support the mission, business operations, business development, planning, and overall growth for its international programs and services. He serves as a member of ECRI Institute’s Executive Committee, which is responsible for overall governance of ECRI Institute’s operations. Prior to taking on his international role, Mr. Keller spent nearly twenty years directing ECRI Institute’s Health Devices evaluation program that provides independent judgment and guidance to help hospitals and health systems select and manage medical devices. The program was referred to by the New York Times as the “country’s most respected laboratory for testing of medical products.

Mr. Keller is a recognized expert and frequently invited speaker on a wide range of health technology-related topics. These include patient safety, equipment management, strategic planning and forecasting, device utilization, incident investigation, surgical laser safety, and the convergence of medical devices and information systems. He has been an invited keynote at national conferences in Australia, Italy, Canada, and multiple venues in the US. He is also routinely sought out by the news media for his expertise on a variety of health technology concerns.
### Course Outline

- Why Medical Device Accidents Happen
- Accident Investigation Overview
- Information Resources for Accident Investigation
- Device Inspection and Testing
- Human Factors Considerations in Accident Investigation
- Interviewing Techniques
- Investigation Reports
- Concluding the Investigation Process
- Medical Device Problem Reporting Programmes
- Technology Management and Preventive Measures
- Vendor Investigations of Medical Device Accidents
- Medical Device Safety & Handling of Near Misses
- Monitoring Technologies
- Gas Embolism Accidents
- Medical Device Fires
- Skin "Burns" from Medical Devices
- Patient harm from Drug Delivery Pumps
- Electrosurgical Units (Surgical Diathermy)
- Surgical Instrument Breakage
- Defibrillators
- Respiratory Care & Anesthesia Equipment
- Warming Devices
- Radiographic/Imaging Equipment
- Simulated investigations based on actual medical devices accidents or reported problems

Special bonus section on surgical laser accidents and surgical laser safety