

Guideline for Incident Investigators

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PREAMBLE

Clinical Engineers may be called upon to perform an investigation of technology-related incidents or accidents. Although the events may relate to staff or patients, investigative methods are much the same. The results of the investigation should be used to improve the performance and safety of health care systems and processes. To assure a complete and adequate investigation, the investigator must be qualified for the role, objective, unbiased, and follow ethical guidelines.

QUALIFICATIONS

- The investigator shall be either a Certified Clinical Engineer, licensed as a Professional Engineer or otherwise be qualified by education, training, and experience.
- The investigator should have received education and training in the techniques of accident investigation, systems and process analysis, human error theory, and human factors design.
- The investigator should have performed at least 5 investigations, while being mentored by an established investigator, i.e., professionally established and recognized investigator who has previously met the aforementioned requirements.

GUIDELINES

- As appropriate and as a minimum, the investigator should follow the guidelines established by recognized standard-setting bodies such as AAMI, ANSI, NFPA, ASSE, JCAHO, FDA, and ASTM.
- Investigators must be aware of pertinent legal and regulatory requirements of local, state, and federal agencies, as well as accreditation groups, as they apply to investigations
- To enhance patient safety, the investigator should publish or present case studies of their investigations to disseminate the lessons learned to the widest possible health care audience. The information shall be shared in such a manner as not to violate the confidentiality of the employer-investigator relationship.
- Conclusions should focus on the modification and improvement of health care technology systems and processes and not on blaming individuals working within the systems. Conclusions should be complete, impartial and ethical. When device failure or device design may be indicative of a systematic shortcoming by the device manufacturer, this information should be communicated to the manufacturer and the healthcare industry as an alert and in compliance with applicable laws and the guidelines of the institution affected.
- The investigator should be willing to submit investigative reports for peer review.

REFERENCES

- Standard Practice for Examining and Testing Items That Are or May Become Involved in Products Liability Litigation; ASTM designation: E 860-82
- Standard Practice for Evaluation of Technical Data; ASTM designation: E 678
- Standard Practice for Reporting Incidents; ASTM designation: E 1020
- Standard Practice for Collection and Preservation of Information and Physical Items by a Technical Investigator; ASTM designation: E 1188-95
- Standard Practice for Reporting Opinions of Technical Experts, ASTM designation E 620-85
- Guide for Fire and Explosion Investigation, NFPA-921
- The requirements of the Safe Medical Device Act should be followed where applicable and the policies of the institution on whose behalf the investigation is conducted must be honored

APPROVAL DATE (ACCE board)

January 27, 2006

REVIEW DATE

January 12, 2007

ADDENDUM