

Guideline for Modifying Devices and Systems

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PREAMBLE

A medical technology is provided by a manufacturer to a health care entity in a completed form and with defined clinical benefit(s). On occasion, due to special patient needs, a medical device or system requires modification. On other occasions, modifications are requested by the medical staff for the purpose of a clinical investigation. Any modification of a manufactured device will result in the addition of a clinical benefit that was not originally intended by the manufacturer. Providing a modification carries the responsibility of assuring that the modification is safe and effective.

QUALIFICATIONS

The modification of medical devices and systems requires special qualifications and good judgment. Human factors knowledge, design safety, and circuit and component designs are just a few of the needed qualifications. The management of a modification requires lesser skills but demands a thorough understanding of the design changes and a keen judgment of the specialties required to review the design changes. A practicing and certified clinical engineer has the judgment and ability to manage modifications of a device or system.

GUIDELINES

Guideline #1-General

- Document a well reasoned need for the modification as well as the steps and decisions made along the path to the modification

Guideline #2- modification is needed...

- Discuss the modification with the clinical staff to assure that the need for a modification is real. Risk management and administration should also be consulted.
- If any readily available alternative exists, recommend it for consideration
- Review services manuals, standards, and other sources to determine if the modification is practical
- Discuss the modification with the manufacturer, ECRI and other sources with specialized knowledge, regarding the clinical benefit to be derived and the safety and effectiveness of the modification
- Consider possible liability for any modifications

Guideline #3-Making the modification...

- Request the original manufacturer to make the modification

- Clinical engineering judgment will be required to determine when a modification is minor and can be made by the health care entity. As always, safety and effectiveness should be the overriding concern.
- Software or Firmware modifications should be implemented by manufacturer or with their approval
- HIPPA requirements should be observed both in the modification of the device and with respect to its performance after modification
- Assure that the modification complies with the Medical Device Act of 1975 as currently enforced by the FDA; sections on off-label use, restricted and custom devices are of particular interest

Guideline #4-Subsequent to the modification...

- Include documentation of any modification with the original documentation of the device or system
- Assure that the operators of the medical device or system are properly educated and trained in safely achieving the new clinical benefit
- Assure that the appropriate preventive and corrective maintenance is established for the modification
- Monitor the use of the modified device; document, analyze and report unexpected events

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ADDENDUM