CRCST Self-Study Lesson Plan
Lesson No. CRCST 129 (Technical Continuing Education - TCE)

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ROLE OF HUMAN FACTORS IN MEDICAL DEVICE DESIGN

LEARNING OBJECTIVES
1. Explain the concept of human factors engineering.
2. Discuss the evolution of human factors engineering.
3. Review how medical device manufacturers incorporate human factors concerns into their products.
4. Discuss how human factors apply to quality system regulations.
5. Describe the importance of device use environments.

HUMAN FACTORS CONCERNS DURING MEDICAL DEVICE REPROCESSING represent a relatively new concept in Central Service (CS) departments; however, their recognition can help improve departmental efficiencies while reducing the worker fatigue, injuries and errors that can occur while processing devices. Manufacturers are incorporating human factors engineering into their instrument designs by focusing on the interactions between users and devices. This self-study lesson will provide a basic understanding about human factors engineering and its impact of CS personnel.

OBJECTIVE 1: EXPLAIN THE CONCEPT OF HUMAN FACTORS ENGINEERING

Human factors engineering (HFE) involves the application of knowledge about human physical, sensory, emotional, and intellectual capabilities and limitations to the design and development of tools, devices, systems, environments, and organizations. The process involves the use of behavioral science and engineering methods in support of design and evaluation concerns.

The successful development of safe and optimally usable medical devices and systems requires the application of HFE principles and processes throughout the entire product design cycle. For example, when HFE is used, the consideration of how medical devices are to be cleaned will occur at the beginning of the design phase, not as an after-thought. Doing so can help reduce user error, improve patient outcomes, enhance patient and user safety, improve product usability, performance, and efficiency, and increase user satisfaction. HFE-based design also facilitates recovery from user error, improves the ability of instrumentation to be cleaned, decreases training time, and improves job satisfaction.

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MARCH / APRIL 2013  Communiqué
Human factors engineering (HFE) involves the application of knowledge about human physical, sensory, emotional, and intellectual capabilities and limitations to the design and development of tools, devices, systems, environments, and organizations.

reduces product liability risks, facilitates the regulatory approval process, and increases the chance of commercial success.

There has been significant manufacturing and academic research and practical experience which have generated a substantial base of knowledge about people and their interactions with each other, technology and their environment. There is also extensive data available about the size and shape of the human body, and how people sense the world, think and act.

Knowledge of HFE methods and principles is critical to the design of safe and effective medical devices. It allows device designers to select wisely from among design alternatives. It also allows them to validate that a design is appropriate for use in a clinical context. Those who incorporate HFE concerns into device design must understand the factors that affect human performance, the nature of human error and fallibility, the role of humans in complex systems, and the causes of use errors.

The main purpose of HFE for medical devices is to ensure their safe use. Medical devices that are not designed with usability in mind are frequently unsafe, prone to user error, difficult to learn to use and actually use, and may reduce user efficiency and satisfaction.

HFE applies to all aspects of a device and to all of the tasks that might be performed with the device including its general use, cleaning and sterilization and all of the hardware and software interfaces that support user tasks. Primary usability questions include:

- How easy is it to learn to use the device?
- How soon will the intended user feel comfortable using it?
- Once learned, how efficiently can the device be used?
- Do users remember how to use the device after several days, weeks or months of non-use?
- Does the device prevent users from making errors or help users recover from their errors?
- Are users satisfied with the device?
- Is the device design appropriate for user capabilities and limitations?

**OBJECTIVE 2: DISCUSS THE EVOLUTION OF HUMAN FACTORS ENGINEERING**

The U.S. Food and Drug Administration (FDA) conducted an analysis of device recalls and adverse reactions between 1985 and 1989. Its representatives reported that about one-half of all reported medical device failures involved traditional good manufacturing practice (GMP) problems. Its recall database indicated that approximately 50% of all device recalls stemmed from poor product design including problems with software. Congress tasked the FDA to identify enforcement mechanisms to address the issue. In response, FDA indicated that design controls or enhanced GMP controls were needed. As a result, Congress passed the Safe Medical Devices Act (SMDA) of 1990, which gives FDA the authority to require good manufacturing practices necessary to ensure proper device design.

The FDA revised GMP requirements for medical devices and incorporated them into a Quality System Regulation that was released as a final rule in 1996. It includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing medical devices intended for human use. The regulation requires manufacturers to establish and maintain procedures to control and verify device design to ensure that design requirements are met. It also requires manufacturers to establish and maintain plans that describe or reference device design and development activities and indicate responsibility for their implementation. It further requires manufacturers to establish and maintain procedures to ensure that design requirements relating to a particular device are appropriate and address its intended use, including the needs of users and patients. Note: the human factors aspect regarding cleaning and sterilization activities is part of this regulation.
OBJECTIVE 3: DISCUSS HOW MEDICAL DEVICE MANUFACTURERS INCORPORATE HUMAN FACTOR CONCERNS INTO THEIR PRODUCTS

A medical device's purpose, use and human factor concerns should be incorporated into the design planning process. Three major components of the device-user system are important considerations in the development of medical devices: (a) device users, (b) device use environments and (c) device user interfaces.

To ensure medical devices are safe for use, manufacturers must eliminate or reduce design-related use problems that contribute to or cause unsafe medical treatments. The ability to thoroughly clean an instrument is a safety feature that reduces the risk of harm when it is used. Instruments that are difficult to clean can cause patient harm, and this would be classified as a "use error," which is assessed as a risk. Medical devices must undergo a risk analysis before they become available in the market place. To develop medical devices that are safe and reliable for their intended uses, manufacturers consider the possibilities of hazards arising from use of and failures of the device and its components. Hazards traditionally considered in risk analysis include:

- Inability to thoroughly clean an instrument
- Chemical hazards, such as toxic chemicals
- Thermal hazards, such as high temperature components
- Electrical hazards, such as electrical shock
- Use-related hazards, such as one's ability to perceive, read, interpret, or recognize and act on information from monitoring or diagnostic testing devices, and improper treatment for devices that provide medical treatment

Use-related hazards occur for one or more reasons such as:

- Device use requires physical, perceptual or cognitive abilities that exceed users' abilities
- The use environment affects the device's operation, and this effect is not recognized or understood by the user
- The use environment impairs the user's physical, perceptual, or cognitive capabilities when using the device to an extent that negatively affects the user's interactions with the device
- Device use is inconsistent with a user's expectations or intuition about device operation
- Devices are used in ways that were not anticipated
- Devices are used in ways that were anticipated, but inappropriate and for which adequate controls were not applied

Based on risk potential, there are three essential considerations that should be incorporated into the medical device design, development and risk management processes. These relate to the need to (a) identify anticipated and unanticipated use-related hazards and determine how hazardous use situations occur, (b) develop and apply strategies to mitigate or control use-related hazards, and (c) demonstrate safe and effective device use through human factors validation testing.

OBJECTIVE 4: DISCUSS HOW HUMAN FACTORS APPLY TO QUALITY SYSTEM REGULATIONS

Medical device manufacturers must comply with the FDA Quality System Regulation, which contains a section on design controls. It is within this section that human factors considerations are addressed in the design process.

DESIGN INPUT

Manufacturers must establish and maintain procedures to ensure that the design requirements relating to a medical device are appropriate and address the intended use of the device, including the needs of the users and patient. This is best done by systemic consideration of human factors in the development of the device. This includes all aspects of the device,
including its labeling, use (operation) and processing.

**DESIGN VERIFICATION**

Human factors verification is undertaken as medical device manufacturers establish and maintain procedures for verifying the design input. The design verification process shall confirm that the final design meets requirements of the device.

As a medical device progresses through the design phase, human factors relevance is assessed by medical device manufacturers. These activities can include task/ function analyses, user studies, prototype tests, and mock-up reviews.

**DESIGN VALIDATION**

Design validation ensures that medical devices conform to defined user needs and intended uses, and it shall include testing of production units under actual or simulated use conditions. Design validation is used to demonstrate that the potential for use error that can lead to patient injury has been minimized. The regulation requires testing the device under actual or simulated use conditions.

Realistic use conditions are carried out by test participants. These participants represent a range of typical intended users in terms of their ability to acquire information from, manipulate, and maintain the device and understand the accompanying labeling. Design validation also includes a risk analysis.

**OBJECTIVE 5: DESCRIBE THE IMPORTANCE OF DEVICE USE ENVIRONMENTS**

The environments in which medical devices are used may present a range of complexities because they are used under variable environmental attributes including space, lighting, noise levels, and activity. Examples of environmental hazards in the clinical setting include:

- The lighting level can be low, making it hard to see device displays or controls.
- The noise level can be high, making it hard to hear device operation feedback or audible alerts and alarms.
- The room can be busy with other people and activities, providing distractions that can confuse the device operator.

The CS decontamination room is an example of a difficult condition in which to clean instrumentation. The room is cluttered and difficult to maneuver. Lighting may be low, the processing equipment is noisy, and the instrumentation adds to the noise. The constant flow of work into the room includes, for example, items from nursing units and surgery, along with the receipt of loaner sets. Technicians must wear personal protective equipment (PPE), which further hampers their dexterity and vision.

**CONCLUSION**

Incorporating human factors design during every phase of a medical device design and development, from initial conceptualization through post-market surveillance, helps yield safe and effective medical devices. Addressing the ability to thoroughly clean a device and disinfect or sterilize it at the initial design phase reduces the risk of a processing error during actual use. This, in turn, results in reducing use error, enhancing patient and user safety, improving product usability and efficiency, and increasing user satisfaction.

**ADDITIONAL READING**


Human Factors Implications of the New GMP Rule: Overall Requirements of the New Quality System Regulation: [http://www.fda.gov/Medical-Devices/DeviceRegulationandGuidance/Human-Factors/ucm119215.htm#.ULLDxmjspnc.email](http://www.fda.gov/Medical-Devices/DeviceRegulationandGuidance/Human-Factors/ucm119215.htm#.ULLDxmjspnc.email)