This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

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Human Factors Points to Consider for IDE Devices

"One of the most important lessons of abnormal events, ranging from minor incidents to serious accidents, is that they have so often been the result of incorrect human actions."
International Atomic Energy Commission, 1988

Purpose

This enclosure is intended to help sponsors of an Investigational Device Exemption (IDE) determine how much attention to pay to human factors during the premarket review and analysis process and future device design and development. Included in this document is a brief explanation of human factors engineering and the human factors engineering process.

The extent to which human factors is considered, both by the sponsor and the Office of Device Evaluation (ODE), for any device should be governed by the complexity of the device and the risks associated with its use. The goal is to assure that the device meets the users' expectations, both stated and implied, so that the likelihood of user error is minimized. To be effective, human factors must be an integral part of the product development process from concept through production. The objective is to produce a device with an effective, efficient and safe user-device interface.

For more information, please contact one of our human factors specialists at 301-443-2436 or by FAX at 301-594-0067.

Background

In the premarket review, ODE will verify that a manufacturer adequately considered the user and the use environment in the design and development of its medical device. The recently published Quality System Regulation (formerly known as Good Manufacturing Practices) requires most medical device manufacturers to "maintain procedures to control and verify the design of the device in order to ensure that specified design requirements are met. Manufacturers are required to establish and maintain procedures:

- To ensure that the design requirements are appropriate and address the intended use of the device, including the needs of the user and patient, and
- For verifying and validating the device design, to ensure that devices conform to the users needs and intended uses."

This will require that manufacturers have in place a process that ensures adequate consideration of human factors in the design and development of medical devices. *The premarket review will examine the products of this process, for example the results of task analyses and usability testing, to verify that the device design adequately addresses the users' needs and intended uses.*

Human Factors Engineering

Human Factors is the science of human-machine interaction. Human Factors Engineering is the application of this science to improve this interaction, or more specifically, the user-device interface. Three key areas to consider during the premarket review and analysis process and future device design and development are:

Users and the Use Environment:

A device may have many users. The operator is one of the users; other users include the patient, the prescriber of the device, clinicians who interact but do not operate the device (e.g., take readings, check status), hospital personal who support the device, and personal who install and maintain the device.

Medical devices are being used in a wider variety of environments; including operating rooms, emergency rooms, patient units, critical care facilities, clinics and homes. There are also many external environmental factors that influence device use - including light, sound levels and other devices in close proximity.

Some questions to ask yourself:

1. Who is the user?
2. Can operator (use) error lead to death or serious injury?
3. How busy will the user of the device be?
4. How likely is the user to be distracted?
5. What is complexity of the use environment?
6. What is the user's level of cognitive stress?
7. How skilled is the typical user?
8. How diverse are the users of the device?
9. What is the user's understanding of the device?
10. How important to safe use are the user's vision, hearing, dexterity and strength?

The User Interface:

The user-device interface is the link between the designer's intended use of the device and the user, who ultimately decides, either intentionally or unintentionally, how the device will be used. The user interface includes all aspects of a device that users operate, read, use or come in contact with in the course of interacting with the device. The user interface includes the device's controls and displays, alarms, operating logic, and all manuals, labeling and training necessary to install, operate and maintain the device.

For each of the questions below, ask yourself, Can the design be simpler, more intuitive, less demanding or more forgiving of user error?

1. How much user adjustment or manipulation is required?
2. How many variables does the user have to interact with?
3. How rapidly and accurately does the user have to interact?
4. How complex are the displays and controls?
5. How complex or varied are the alarms?
6. Can alarms/feedback detect errors/fault conditions?
7. Can the device be misassembled/misattached?
8. How much training will the user need to operate the device?
9. How much maintenance will the device require?
10. How difficult is the device to maintain/service?

Device Design:

Relying on the user to adjust and compensate for problems presented by a poorly designed user interface is the least desirable alternative, and one that is bound to fail in time. The designer has a responsibility to produce a device that:

1st - preclude the opportunity for mistakes, or if that can't be done, then
2nd - make mistakes less likely to occur (e.g. interlocks), or
Finally - mitigates or limits the consequences when a mistake is made.

The goal is to design devices that are easy to use (user-friendly) and minimize the chance for users to make mistakes. In addition, since it is not possible to predict and prevent all errors, the design must also be error tolerant.

The most common cause of human factors problems is the failure of the device designers and developers to anticipate and deal with the characteristics of the people who interact with the device and the nature of these interactions. Including:

- Unusual or unexpected device operation - Know your user's understanding of the device, and make sure that your device operates accordingly.

- Lack of protection against incorrect use - Can your device be connected to the wrong device, to the wrong part of a device or in the wrong way?

- Confusing or complex controls, labeling or operation - Is your device easy to use by the intended user? Avoid reliance on training or manuals - the best devices are those that do not require specific user training.

- Defeatable or ignorable safety features - Again, understand your user and the environment. Do you have a silenceable alarm that can be permanently defeated?

Human Factors Engineering Process

Human factors engineering is part of a systematic, iterative process which must be properly coordinated and integrated into a structured engineering design and development process to ensure that the resulting product can be demonstrated to be safe and effective and adequately addresses the user's needs and intended uses. The Quality System Regulation will require most medical device manufacturers to establish and document procedures for the control of design input and output, design review, verification and validation, design transfer into production specifications and design changes. At a minimum human factors engineering activities will need to be identified in the general design control plan and in the procedures governing design input through design validation.

Human factors methods and tasks used during device design and development include:

Information Review:

A review of the literature, incident report and recall data on similar devices, and applicable codes, standards and regulations will help identify the necessary information for the other design processes. The literature review should include human factors articles, technical reports and textbooks, and a thorough and critical review and analysis of the appropriate medical literature to uncover the problems reported by users. A review of reports from the Medical Device Reporting (MDR) system as well as hospital incident reporting systems will often uncover user problems that have not been reported in the medical literature.

User Studies:

Designers should know their users firsthand. It is critical for those involved in the design to spend time in typical environments in which the device will be used. This includes visiting a number of facilities that span the range of the use environments (e.g., hospitals, nursing homes, home-use) to see how the device will be used and talking to users to understand their priorities, skills and limitations. In addition, valuable information can be gained by conducting interviews, holding focus groups, using questionnaires or conducting usability tests of early prototypes. Those who

supervise and train users can be an especially valuable source of information on the users needs. The use environment must be closely evaluated, defined and understood.

Analyses:

A structured and critical examination of the device functions, the tasks the user needs to perform and the procedures to set up, check, use and service the device along with an analysis of the hazards and risks resulting from possible user error are essential human factors tasks. Analysis of the device functions, the users tasks and hazards of user error can often be carried out as a single integrated activity. Medical devices are becoming increasingly multi-functional to accommodate a wider range of users and to provide additional utility. The added device complexity, if not carefully designed to address the users' capabilities, can adversely impact ease of operation, increase the possibility of user error and effect patients safety.

Usability Testing:

The proof that the design actually meets users' needs and intended uses can **only** be verified by observing typical users operating the device under real use (or closely simulated) environments. Most significant user interface problems can be found by conducting usability tests with representative users to observe how quickly, easily and safely they can set-up, check and operate the device. This testing should be conducted as early in the development cycle as practical. Limited usability tests can begin even before the first prototype has been constructed by employing mock-ups and computerized models. As design and development progresses, and the prototypes increase in fidelity, the usability tests can be more confidently relied on to validate that the design will meet the users' needs and intended uses.