

A Sneak Preview of FDA's Human Factors Standard

HE 75 is the result of 20 years worth of effort to create best practices guidance in medical device human factors engineering.

Medical Device and Diagnostic Industry, January 2010

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For nearly two decades, the Association for the Advancement of Medical Instrumentation's (AAMI) human factors standard HE 48, "Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices" has been the only existing medical device user interface design standard. HE 48 contained general design best practices that have proved useful to industry. However, a standard with direct relevance to the healthcare industry was needed. With increased emphasis by global regulatory agencies on eliminating and controlling use error in devices, a new human factors standard with more direct relationship to healthcare contexts has been developed by the AAMI Human Factors Standards Committee.

HE 75, "Human Factors Engineering—Design of Medical Devices," is expected to be recognized as an industry best practice by FDA. This nearly 500-page document provides detailed human factors engineering (HFE) design guidance, examples, checklists, and case studies.

It is important that industry professionals understand how the document relates to existing human factors guidelines, such as HE 48 and HE 74. The documented use of the best practices in HE 75 provides regulators with evidence that a human factors design process has been adopted, and can improve usability and safety while making the development cycle more efficient.

HE 75? Why Now?

Although FDA began to include human factors in the approval process in the mid 1970s, the discipline did not gain importance until the Good

Manufacturing Practices (GMP) thrust was extended to include the entire device development process.

As FDA became aware of GMP's shortcomings, it broadened the spectrum of the guidelines to shift from "manufacturing" to "life cycle process," i.e., the entire design process. The result was the publication of *Code of Federal Regulations (CFR) 820.3, Quality System Regulation*, which covered all aspects of device design, not just manufacturing. The regulation now includes *CFR 820.30, Design Controls*—a process for ensuring that a design ultimately would meet the needs of the end-user.

As devices have become more complex and technically advanced, problems associated with use error have continued. According to comments from an FDA spokesperson at the AAMI conference, June 2005, Washington, DC, more than one third of medical device incident reports involve use error, and more than one half of the recalls due to design problems can be traced to the design of the user interface. To improve its review of devices, FDA's Center for Device Radiological Health (CDRH) moved its human factors team to the Office of Device Evaluation (ODE).

HE 48, HE 74, HE 75—What's the Difference?

HE 75 will eventually replace HE 48, which provided only very general guidance on the design of displays, controls, consoles, and equipment based on the body of knowledge accumulated from aerospace, defense, and other industries. HE 75 focuses on the unique user interface challenges of the medical industry, and provides general good practices for the design of human-machine interfaces.

HE 48 was written in the 1990s, explains Ed Israelski, program manager, human factors, corporate regulatory and quality science with Abbott Laboratories, who cochaired the AAMI human factors engineering committee that developed HE 75. He says that technology has advanced and that the environment and user profiles have changed dramatically. According to Israelski, HE 48 was an good first attempt, but it was never intended to be comprehensive. And even though it is almost 500 pages, Israelski says HE 75 is still not all-

inclusive.

HE 75 will complement ANSI/AAMI HE 74-2001, "The Human Factors Design Process for Medical Devices," which focuses on the process of analysis, evaluation, and testing methods manufacturers should follow to integrate HFE throughout the design of medical devices. Simply stated, HE 74 covers what needs to be done and when along the product development process. HE 75, on the other hand, is a design document and a look-up encyclopedia where manufacturers can find specific answers on how devices should be designed and built for certain situations. It defines the desired outcomes of the studies and analyses required by the process outlined in HE 74.

HE 75 is a resource for human factors professionals and for engineers who might know only a little about HFE. Israelski says it gives specific advice on design principles. For example, the section on hand tools covers grip, ergonomic principles, friction on holding a device, weight, fit and finish, strength needed to operate, and more. Rather than scouring the HFE literature, engineers can look up the design principles in HE 75. It should save time, but the HFE process must still be applied in conjunction with incorporating the design principles from HE 74, says Israelski.

Kevin Keegan, director, home cardiology with Inverness Medical Innovations, says that the guidelines on incorporating HFE into the product development process are important because they may eliminate some of the guesswork.

Although primarily a design principle handbook, HE 75 does include two process-oriented sections. One section, called Use Error Risk Management, discusses the process of discovering potential use errors, along with recommendations of methods and steps for managing their risk (see the sidebar, "When Usability Isn't Enough," on p. 96). This section is patterned after the FDA guidance document *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management* by Ron Kaye and Jay Crowley. It found its way into HE 75 because the writers of the standard wanted to stress the need for HFE to be a part of an overall device risk management plan. FDA expects

device manufacturers to do the following:

- Treat use error as a risk to be understood and controlled.
- Identify and understand foreseeable use error risk.
- Assess the clinical severity of use errors.
- Control or mitigate use error risk in design.
- Validate risk mitigation effectiveness through testing with users.
- Document risk management efforts.
- Monitor use errors after device is in use.

Another section, *Test and Evaluation Methods*, summarizes material covered in HE 74, but has more-specific information about testing practices and when they are appropriate. The section covers topics such as the number of test subjects and how to set up test protocols.

How to Use HE 75

HE 75 looks to be a powerful tool in all stages of the design life cycle. In the design input stage, it can be used to narrow design requirements by identifying the HE 75 sections that apply to the human interface design aspects of a device and to apply the general and specific considerations contained in those sections. The *Test and Evaluation Methods* section can be used to plan interface evaluations that can inform the design team early about challenges with user interaction in design inputs and help with formal or summative study design applicable in design validation. In the design verification phase, the standard becomes a way of documenting that the device was built following best practices for human interface parameters. Device OEMs can point to the criteria they used to build the device correctly.

Although HE 75's page count may seem overwhelming, it is not designed to be read and followed cover to cover. In fact, the HFE and usability standards of HE 74 were applied to the creation of the HE 75 document itself. Israelski recommends reading the introductory material first to get an idea of how to use the standard. HE 75 is a set of design principles rather than a pure process standard that must be followed every step of the way. The greater the complexity of the

design, the more HFE work will be required, he says.

Structure

HE 75 was conceived as a companion to HE 74 (which has since become the foundation of ISO/IEC 62366) to provide the details necessary to design safe, effective, efficient and satisfying medical devices of all types, says Matthew Weinger, MD, cochair on the AAMI HFE committee. He says that to make the document usable for the various intended users, it was divided it into three sections. The first section, General Considerations, provides an overview of the topic. It addresses many of the human factors design principles that are generic across a range of devices and applications, he says. The second section, Design Elements, covers specific attributes of the user interface, with chapters intended primarily for designers who have a specific design question (e.g., which type of ___ should I select for my device and what are the design attributes of ___ that I must consider?). The final section, Integrated Solutions, contains chapters about integrating several user interface design elements, generally for specific applications. Originally this component was envisioned to be a larger section, but the committee decided to limit the number of chapters in the interest of publishing the standard more quickly, Weinger says.

Human Factors Trends

Home Devices. Devices intended for home use make up the fastest-growing segment of the medical device industry. This section in HE 75 covers the design of medical devices that are used outside of a typical clinical environment by lay caregivers and patients. Designers for professional-use devices often make numerous design-relevant assumptions that simply cannot be made about the lay user. Laypersons are very different in terms of their capabilities, limitations, and training. The environments laypersons use the device in are often much less controllable than professional settings.

Most standards that apply to the design of the user interface of medical devices and equipment are also based on research and data collected from able-bodied users. These data may not be appropriate

for user populations with varying capabilities and limitations. FDA has singled out devices for use by laypersons as an important aspect of patient safety.

The challenge for OEMs is to balance the guidance documents with good business strategy to meet the objectives of innovating and launching cutting-edge products, which provide more individual choices, and foster prevention and wellness, says Keegan. OEMs with products aimed at use by patients in their homes or by lay users in decentralized settings have to overcome potential risks of use error, data interpretation error, and connectivity error. HFE is increasingly important in those product development processes, he says. Incorporating formative, usability and risk analysis studies into the feasibility stage may be a key way to handle such challenges, Keegan says.

Mobile Devices. Although other document sections cover information important to the design of mobile devices and portable equipment, Mobile Devices zeroes in on the unique challenges and potential risks associated with this equipment. For the first time, manufacturers will have a specific set of medically oriented design principles and best practices for designing ambulatory and body-borne devices, and FDA will have a means to direct the designer towards relevant design points for consideration. A manufacturer that presents an ambulatory infusion pump for FDA approval, for example, is expected to have reviewed and considered the guidelines provided in the Mobile Devices section. If a product or device shows a certain level of human interaction that could impact safety, FDA's human factors team must have the means to ask pointed questions in reference to HE 75's best practices.

Automated Devices. This section is one of the most important in HE 75 due to the proliferation of automated devices in the marketplace and because automation cuts across many different types of devices. A plethora of automated, computerized, and integrated devices are currently being advertised under the promise of making it easy for users. They may be easy, but the question is, are they safe? A brand-new design using the latest technology requires much more HFE work

than a low-risk, routine design using proven technology, says Israelski.

The section on automated devices clearly states the thought process manufacturers must go through to ensure that devices are safe as users interact with them in their automatic modes. A computer may be able to act as caregiver by monitoring all of a patient's medical devices in the home and automatically sending the information to the doctor, but imagine the potential for use error in such a sophisticated device. With HE 75, FDA now has guidelines for the design of safe and complex automation.

User Documentation. The section on user documentation (i.e., labeling and training) sets high expectations for the efficacy of instructions and training. In the past, manufacturers tested instructions, if at all, by relying on computerized assessments of grade-reading levels and multiple-choice tests. FDA has seen problems associated with poor labeling and training among both lay and professional users. HE 75 emphasizes observational testing of training materials and user guides to validate the utility of the material in performing user tasks.

Cross-Cultural Considerations. This long-overdue focus deals with designing products for use outside the United States and outside Western environments. Currently, many devices designed for the U.S. population are launched into international markets with little consideration for cultural differences that could affect their safety. The dos and don'ts for marketing devices in such environments go far beyond linguistic considerations. Although getting the language right is of course important, use of the right colors, for example, is equally critical. For example, in western cultures, the color red is generally understood (or accepted) to mean stop, danger, or emergency. However, in eastern cultures, the color red can signal celebration, luck, or happiness. Even shape, size, look, and feel of devices may have culture-specific implications. The guidelines also apply to manufacturers from other countries that want to market their devices in the United States.

Weinger states that HE 75 was developed as one-stop shopping for medical device industry developers to incorporate human factors into their design process. It also helps medical device industry quality and regulatory personnel to ensure the devices their companies develop are usable and safe. Interested clinicians and healthcare facilities can make sure they are purchasing devices that are maximally safe and usable.

Israelski expects that AAMI will soon offer courses to help manufacturers understand and apply HE 75 and its related standards. In the meantime, he says that if OEMs don't want to have their own human factors people on staff, they should hire consultants to make sure that the standards are properly applied.

What HFE Is Not

Everyone involved in the design and development process should know what human factors is and what it is not, says Israelski. He says that sometimes manufacturers get in trouble because they only apply market research principles to the evaluation of device usability. HFE is a separate discipline. It focuses on usability and behavior, while market research is interested in attitudes, perceptions, and opinions. Focus groups and other forms of market research are never sufficient to assess usability, warns Israelski.

People in a usability test are often observed to struggle with a device, he says. They make mistakes, take too much time, or even fail to complete the task. And yet, when queried about their experience after the test, they will say the device was easy to use, the instructions were clear, and that they had no difficulty with the task. Perhaps they want to save face or please the moderator, Israelski suggests. Whatever the reason, the conclusion is simple, he says: people's subjective ratings cannot be taken as a sole indicator. The best data on usability come from direct observation in a usability test.

Although usability as a market discriminator is not the rationale behind HE 75, easy-to-use devices are certainly good for business. As more manufacturers compete in the home market, a user-friendly device can mean a greater market share because people will gravitate toward

a product that is easy to use. Although recent incidents involving consumer products may help fuel demand for more risk-free devices, it is unclear whether efforts to add greater safety will make devices more attractive to the home healthcare market.

Medical devices engineered for home use represent a merger between consumer and medical products, says Keegan. Therefore, he says, medical device manufacturers that are planning to launch products into the home environment would do well to assimilate the consumer product design model to meet their audience's expectations for simplicity of use, durability, reliability, clear instructions, and a very low error rate.

Human behavior presents a tremendous design challenge to the device manufacturer due to the vast individual differences in experience, knowledge, physical and mental capabilities, and motivation. As nearly every section of the standard mentions, applying HE 75 design principles cannot ensure optimal and totally safe user-device interaction. Therefore, rigorous user testing is recommended to validate design in most instances. HE 75, technically, is listed as a recommended practice, not a standard in the strict sense of the definition.

Note that a *Handbook of Human Factors in Medical Device Design* is being published as a supplement to HE 75 (CRC Press, expected publication date: March 2010; for further information, visit www.crcpress.com).

HFE for Safety and Profit

HE 75 provides detailed design guidance to those who are responsible for HFE work in medical device companies. The standard is an easy-to-use reference on human interface design principles, design criteria, and guidelines specifically focused on the medical device industry. Manufacturers that use the information provided in HE 75 throughout their product design and development process will design and manufacture devices that minimize use-related errors and reduce training time. The inclusion of HFE principles in the design and development process will ensure that the user's voice is heard. As a

result, devices will not only be safer but will also offer the enhanced user experience that improves marketability and therefore the manufacturer's profitability.

When Usability Isn't Enough

Usability is often associated with Web design and general product design, for which ease-of-use is the primary driver. In the medical industry, usability is important, but the primary objective is to identify and control use-related errors in the interaction of the user with the device. This requires an understanding of risk management and mitigation practices, which are foreign concepts to many usability science engineers. The HE 75 section, *Managing the Risk of Use Error*, emphasizes the importance of having methods in place to control and manage the risk of use error. It describes the difference between standard usability testing and the type of testing required to identify how a design may contribute to use errors that can endanger patient safety.

A usability test of a nonmedical consumer product might indicate that 95% of users are able to successfully complete a given task. However, for a medical device, 95 out of 100 may not be good enough. If 5% of users cannot correctly set up and use a heart monitor, for example, it can lead to false conclusions about their cardiac state resulting in incorrect diagnosis and treatment decisions. HE 74 defines use error as an "act or omission of an act that results in a different outcome than intended by the manufacturer or expected by the user, which may result from a mismatch situation between user, man-machine interface, task, and/or environment."

The term user error is no longer used officially in favor of the less blameful use error, but even the term use error may be a misnomer. Failure to use a medical device correctly is not always about human fallibility. It is about the device not fully supporting a certain percentage of the user's sensory, cognitive, and physical requirements at a given moment in time. The manufacturer has several options: eliminate the task, redesign the user-device interaction, improve the labeling and documentation, or redesign the training to call attention

to difficult and error-prone tasks.

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