FDA Human Factors Draft Guidance Document:

Agency Expectations for Human Factors Data in Premarket Submissions

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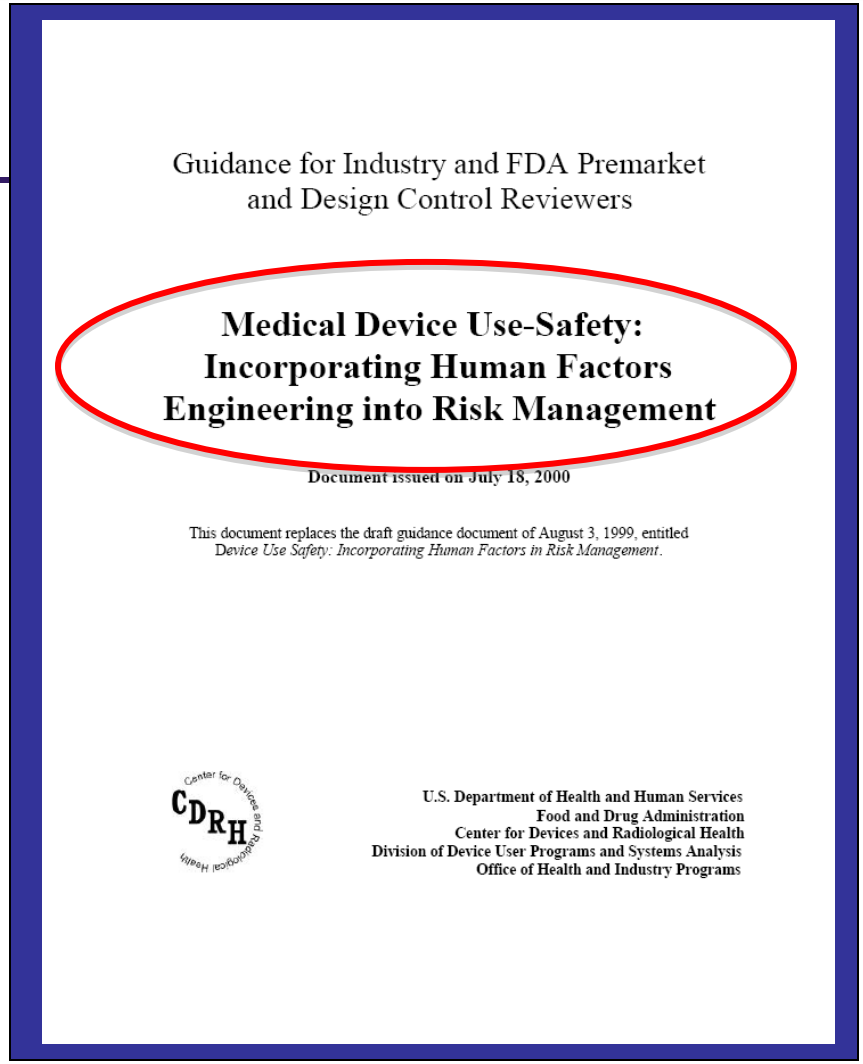
FDA HF Guidance

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm

- *NOTE: issued in 2000*



Guidance for Industry and FDA Premarket and Design Control Reviewers

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

Document issued on July 18, 2000

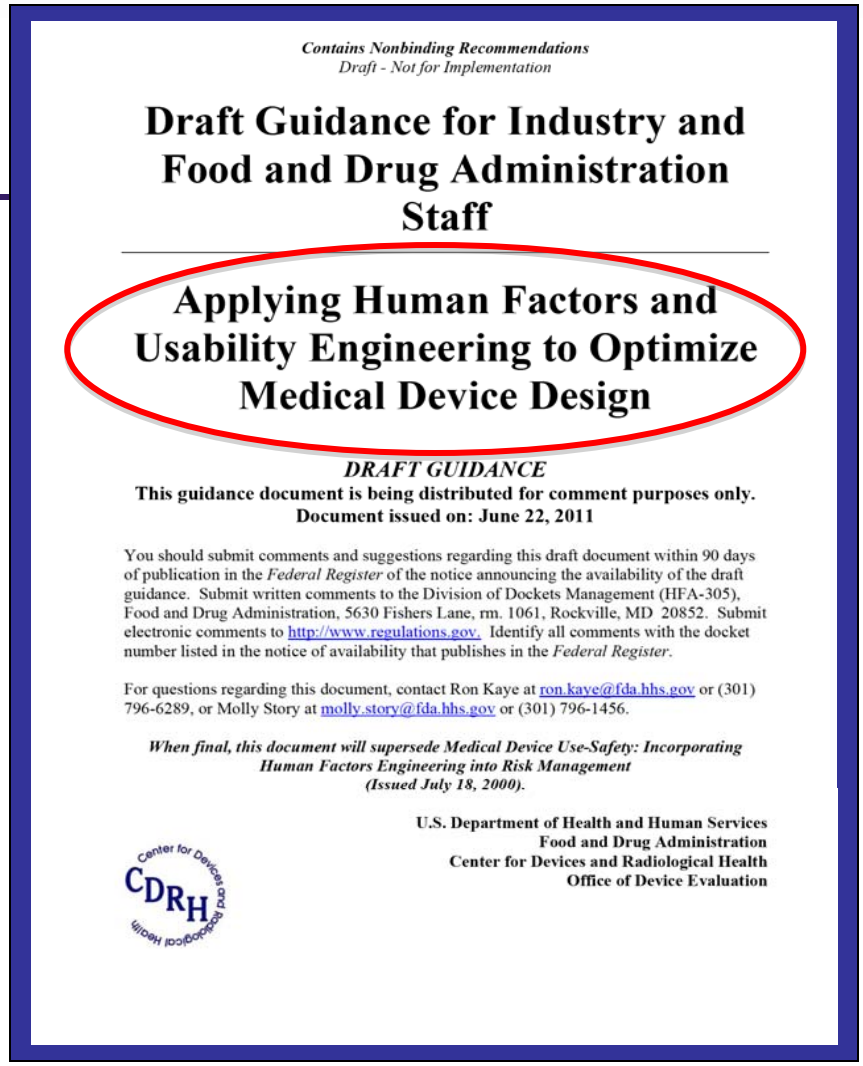
This document replaces the draft guidance document of August 3, 1999, entitled *Device Use Safety: Incorporating Human Factors in Risk Management*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs

Draft Guidance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm

- *NOTE: issued in 2011 – This guidance is **not yet in effect** but it reflects FDA-CDRH's current thinking and approach to human factors.*



Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

2011 *Draft* Human Factors Guidance

- Regulations, Guidance, Standards
- Considerations: Device Users, Use Environments and User Interfaces
- Preliminary Analyses and Exploratory HF/U Studies
- Risk Control and Design Iteration
- Human Factors/Usability Validation Studies

Regulatory Basis for HF at FDA

Quality System regulation:

21 CFR 820.30, Design Controls

– *The need for human factors is implied:*

c) **Design input** – includes "needs of the user and patient"

f) **Design verification** – performance criteria met

g) **Design validation –** "… devices conform to **defined user needs and intended uses** and shall include **testing of production units under actual or simulated use conditions.** Design validation shall include **software validation** and **risk analysis**…." [incl. use-related risks]

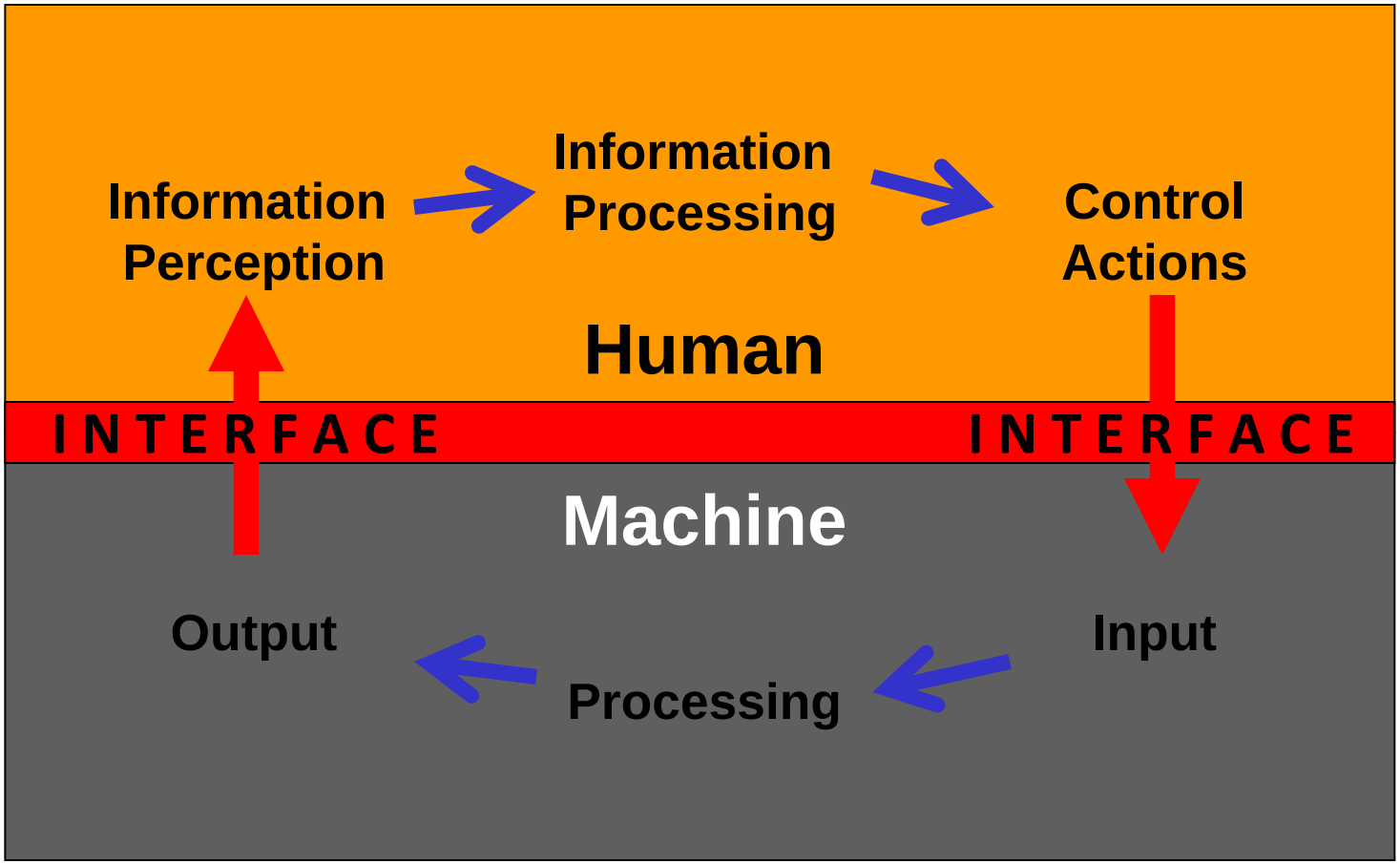
820.30(c) Design Input

- **User and Patient Needs**
  - **Relative to device *effectiveness***
    - Users can operate the device successfully for the intended uses
  - **Relative to device *safety***
    - Users can operate the device without injury or negative clinical consequences to either the user or the patient
  - **Potential use errors and failures have been eliminated or limited to the extent possible through appropriate application of human factors methods**

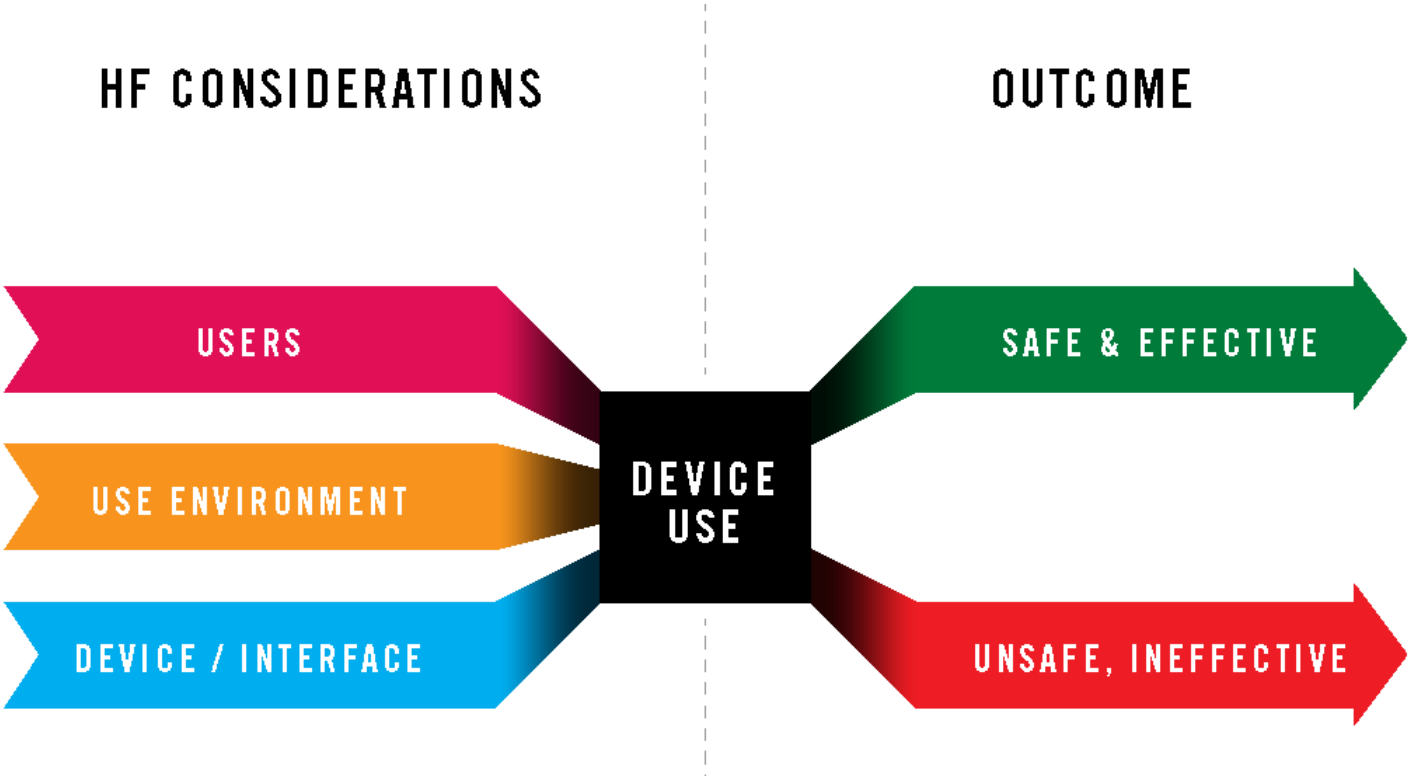
820.30(f) & (g) Design Verif. & Valid.

- **Design Verification:**
  - ***Did I make the product right?***
- **Design Validation:**
  - ***Did I make the right product?***

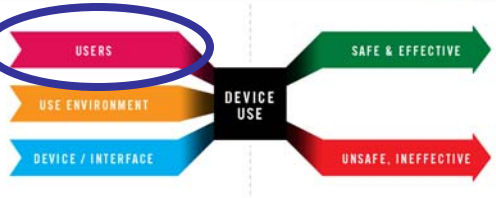
Device-User Interface



Human Factors of Device Use

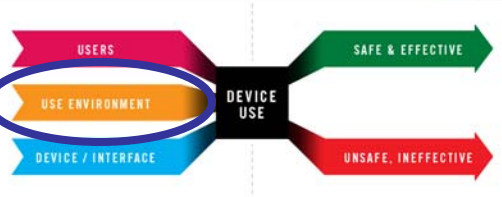


Users



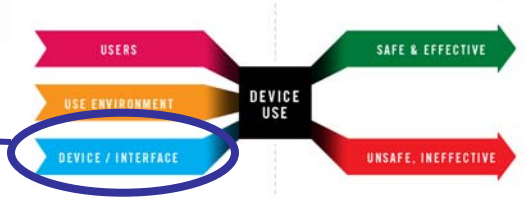
- **Professional or non-professional**
  - Job title and responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
  - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**

Use Environment



- **Clinical environment**
  - Hospital, clinic, etc.
- **Transitional care environment**
  - Rehabilitation, assisted living, long-term care, etc.
- **Home environment**
  - House, mobile home, townhouse, apartment, etc.
- **Community setting**
  - Office, school, retail, outdoors, etc.
- **Mobile environment**
  - Car, plane, train, bus, ambulance, medevac, etc.

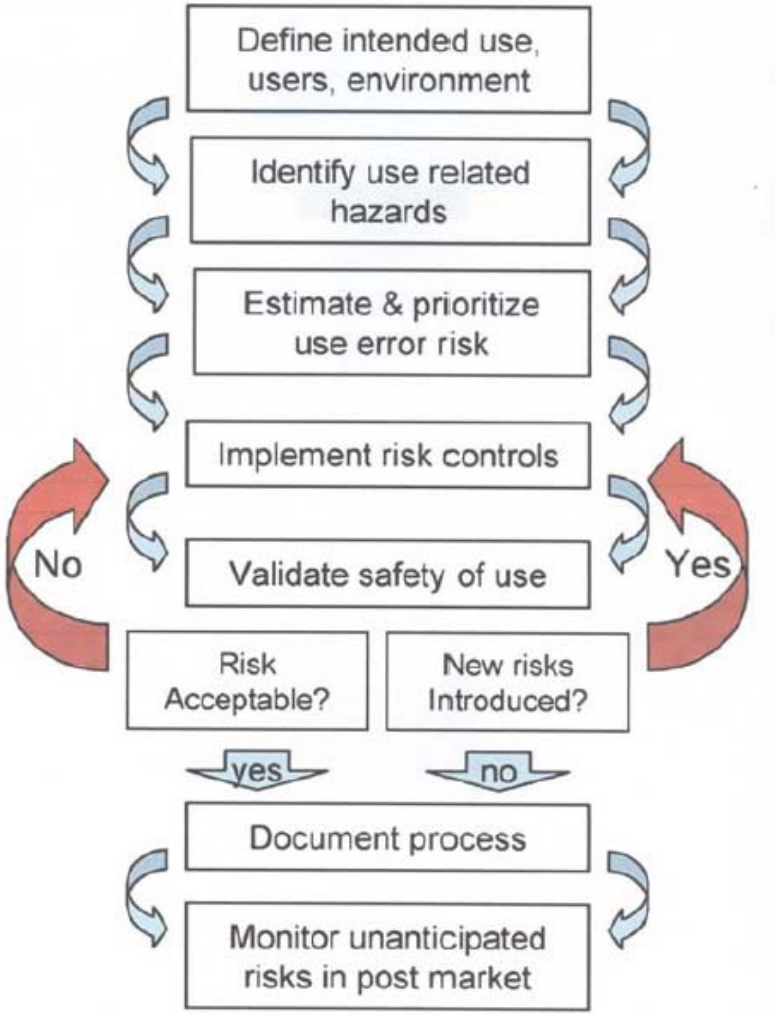
User Interface



- **Tasks**
  - Device set-up: installation, assembly, calibration, etc.
  - Device use: various aspects
  - Device cleaning, maintenance, disposal, etc.
- **Interactions**
  - Input
    - Connections, knobs/dials, switches, buttons, touch screens, etc.
  - Output
    - Visual: component status, displays, lights, etc.
    - Auditory: motors/fans, clicks, alerts/alarms, beeps, voice, etc.
    - Tactile: resistance, vibration, temperature, etc.

Human factor

process for medical devices



Source: ANSI/AAMI HE75:2009

Preliminary Analyses: Rationale

- Identify and analyze intended users and expected use scenarios and use environments
- Develop initial product concepts and prototypes
- Identify and explore potential device use-related hazards and risks and their potential clinical consequences
- Explore different design alternatives and identify the trade-offs between them

Preliminary Analyses: Methods

Two ways to discover use-related hazards:

1. **Analytical techniques**
   - To identify use-related hazards and risks
     - *Use-related hazards and user behavior can be difficult to predict*
   - To focus the process and prioritize resources
2. **Exploratory human factors/usability studies**
   - Conduct exploratory, hands-on, simulated-use testing to discover and explore unanticipated hazards
     - *Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations*

Preliminary Analyses: Methods (1 of 2)

- **Contextual inquiry**
  - User demonstrates; researcher observes, inquires
- **Interviews and focus groups**
  - Discussions are targeted; researcher is neutral
- **Function and task analyses**
  - Break down device use into discrete steps
  - Identify use-related hazards associated with each step of use
  - Identify potential causes and consequences of user encountering each hazard
  - Develop risk mitigation strategies, if needed

Preliminary Analyses: Methods (2 of 2)

- **Heuristic analysis**
  - Formally evaluate user interface against well-established design rules or heuristic guidelines
- **Expert review**
  - Use clinical and human factors experts
  - Experts provide personal opinions of usability and safety of user interface, based on professional knowledge and experience

Exploratory HF/U Studies: Rationale

- **Identify issues not findable through application of analytical techniques - e.g.:**
  - The use environment has negative effects
  - The demands associated with use of the device exceed the user's capabilities
  - Aspects of device use are inconsistent with the user's expectations or intuition
  - The device is used in unexpected ways
  - The device is used in inappropriate but foreseeable ways, for which adequate controls were not applied

Exploratory HF/U Studies (1 of 2)

- **Done while the device is under development**
  - Conduct studies iteratively to optimize the device design and ensure the human factors/usability validation testing results will be successful
  - Testing can involve simple product mock-ups or early prototypes, or even partial designs (e.g., components) operating in simulated-use modes
  - Test participants should be representative of the intended user population(s)
  - At early stages, use-related problems can be addressed more easily and less expensively

Exploratory HF/U Studies (2 of 2)

- **Conduct separate studies on labeling and training (recommended):**
  - Assess the clarity and effectiveness of all labeling (e.g., instructions for use, other documentation, packaging)
  - Determine the level and nature of training that will be necessary (if any)

Risk Control and Design Iteration

- **Develop risk mitigation strategies as needed:**
  - Modify the interface design, user instructions, and/or training to address the problems found
- **Re-test to assess whether mitigation strategies:**
  - Effectively reduced the known risks and
  - Did not introduce any new risks
- **Residual risk can be acceptable if it is:**
  - Reasonably limited, difficult to eliminate or further reduce, and outweighed by the device's benefits

Human Factors/Usability Validation

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**
  - By people who are representative of the intended users
  - Under expected use conditions
  - For essential and critical (high-risk) tasks

Test Populations

- **All intended user populations – e.g.:**
  - Healthcare professionals, engineers/technicians, home health care aides, family caregivers, patients
  - Pediatric and geriatric populations need careful consideration
- **Not company employees**
- **U.S. residents**

Device Testing Conditions

- **Use finalized device design and labeling**
- **Present within typical context of use**
- **Incorporate expected use conditions**
  - E.g., lighting, sound, and activity (distraction) levels
- **Allow realistic device-user interactions**
  - Provide participants with device as they would receive it (e.g., in its original packaging, with all documentation)
  - Allow participants to use the device as they normally would (e.g., without interference from test facilitator)

Selection of Tasks Tested (1 of 2)

- **Include in the HF/U validation study protocol and report a rationale for the tasks you choose to include in your testing**
  - Base task selection on results of preliminary analyses
    - E.g., task analyses and identification of use-related risks
  - Incorporate findings of exploratory HF/U studies
    - E.g., tasks found to be error-prone or difficult for users
  - Define criteria for task success prior to the test

Selection of Tasks Tested (2 of 2)

- **Tasks tested in validation do not necessarily include everything in the instructions for use**
  - Include *essential tasks* – i.e., tasks necessary for successful use of the device
  - Include *safety-critical tasks* – i.e., tasks on which users could make errors or could fail to complete, which would have negative clinical impact
    - All warnings and most caution statements in the device labeling imply safety-critical tasks
    - All tasks requiring responses to alarms are safety-critical

Instructions and Training

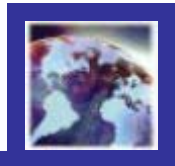
- **Participant interaction with instructions should approximate reality**
  - Labeling used in device validation should be final versions
  - Availability of labeling should represent realistic situation
- **Provision of training should approximate reality**
  - Training used in device validation study should be comparable to the training that actual users will receive
  - Consider integrating period of time for learning gained through training to “decay” before conducting device validation study, depending on actual conditions of use

Human Factors/Usability Data (1 of 2)

- **Objective (performance) data:**
  - Use errors, failures and difficulties are observed
    - Include details about performance – e.g.: success or failure, use error, reference to instructions for use, need for assistance, close calls, evidence of confusion
  - Measuring speed of task completion is only appropriate if it is clinically meaningful
  - Number of task attempts allowed varies by type of device and context of use
  - Facilitator should not interfere with independent and realistic use

Human Factors/Usability Data (2 of 2)

- **Subjective (narrative comment) data:**
  - Discuss user performance after use, particularly regarding perceived reasons for any essential and critical task errors, failures and difficulties
  - Solicit participant feedback on design of device, labeling and training
  - Forced-choice questionnaires or Likert rating scales collect limited information and can bias responses
  - Use of “think aloud” technique is inappropriate for validation because it does not reflect realistic use



Validation Data Analysis

- **Analyze all use errors and failures**
  - Determine root cause and consider potential consequences
  - Determine need to modify device, labeling, training
  - Identify true residual risks
- **Use errors/failures are not of equal importance**
  - Some might be frequent but inconsequential;
  - Some might be rare but reveal a hazardous design deficiency that was not previously recognized

Human Factors/Usability Eng'g. Rpt.

1. Intended device users, uses, environments
2. Device user interface
3. Summary of known use problems
4. Use task selection, characterization, priorities
5. Summary of preliminary evaluations
6. Validation studies
7. Conclusion

FDA Expectations for HF Data

- **Conduct a comprehensive risk assessment**
- **Identify and mitigate risks, including use-related**
- **Conduct human factors/usability validation testing on any strategies implemented to mitigate *significant* use-related risks**
  - Use representative users & realistic testing conditions
  - Fully describe testing protocols and results
  - Analyze and justify residual risks
- **Document everything in the Design History File**

Advice: Consult FDA Early

- **Discuss product development plans with FDA before your design is finalized (and changes would be difficult)**
  - Through a pre-submission mechanism
  - Interact with experts in CDRH (and CDER/CBER) who have advice to share based on experience
- **FDA will review human factors/usability validation study protocols on request**
  - *Before implementation is recommended!*

"Pre-IDE" Meetings

- **Can be used to interact with FDA regarding any future submission or application**
  - Can request a face-to-face meeting or teleconference or simple written response
  - Quicker turnaround: FDA often responds within 60 days
  - Can be used to request review of human factors validation study protocols
    - We try to turn these around within two weeks
- ***Guidance on IDE Policies and Procedures:***
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/ucm080202.htm

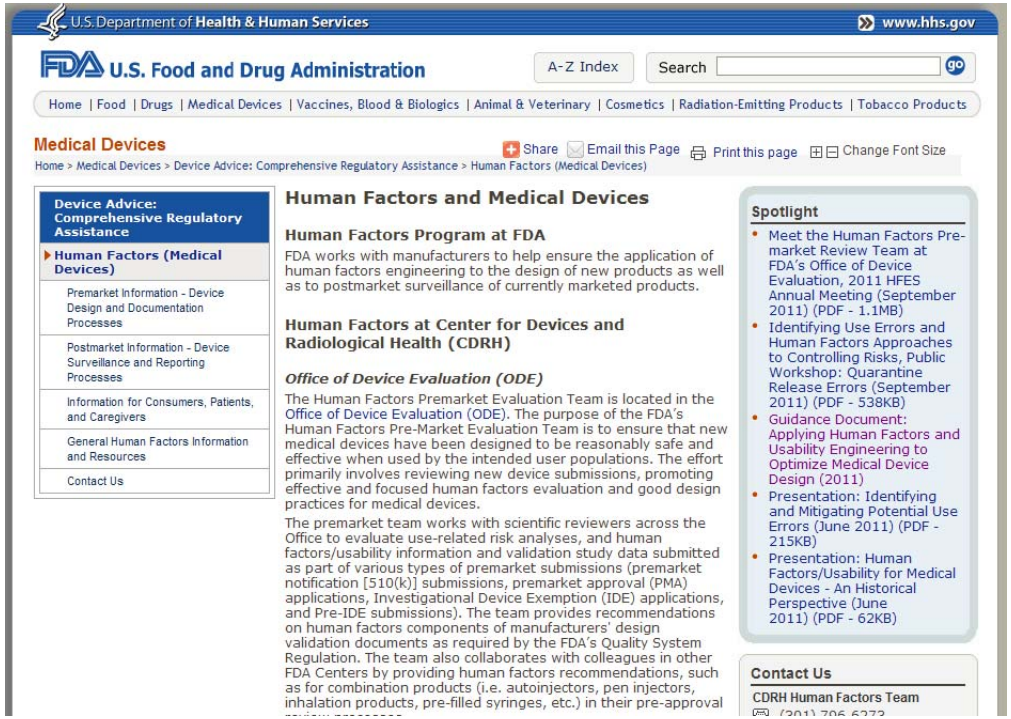
Status of Draft Guidance Document

- **Document issued June 22, 2011**
- **Comment period closed Sept. 19, 2011**
  - More than 600 comments were submitted
- **We are reviewing the comments**
  - Some are minor and easy to address
  - Some are significant and require ODE to establish new policies
- **We hope to finalize the document soon…**

FDA/CDRH Human Factors Program

http://www/fda.gov/humanfactors

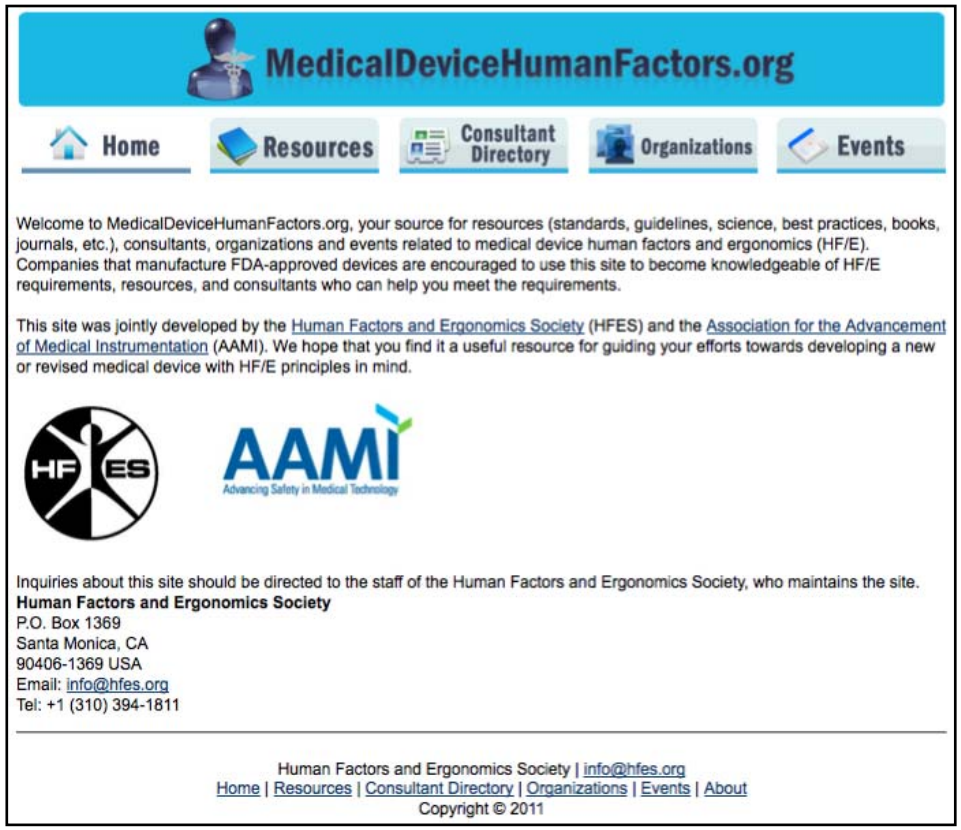
- Premarket Info
  - Design & Documentation
- Postmarket Info
  - Surveillance & Reporting
- Info for Consumers, Patients, Caregivers
- General Human Factors Info and Resources



New HFES-AAMI Web Site

http://www.medicaldevicehumanfactors.org

- Resources
- Consultant Directory
- Organizations
- Events



Questions

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FDA/HF web site: www/fda.gov/humanfactors