The FDA Perspective on Human Factors in Medical Device Software Development

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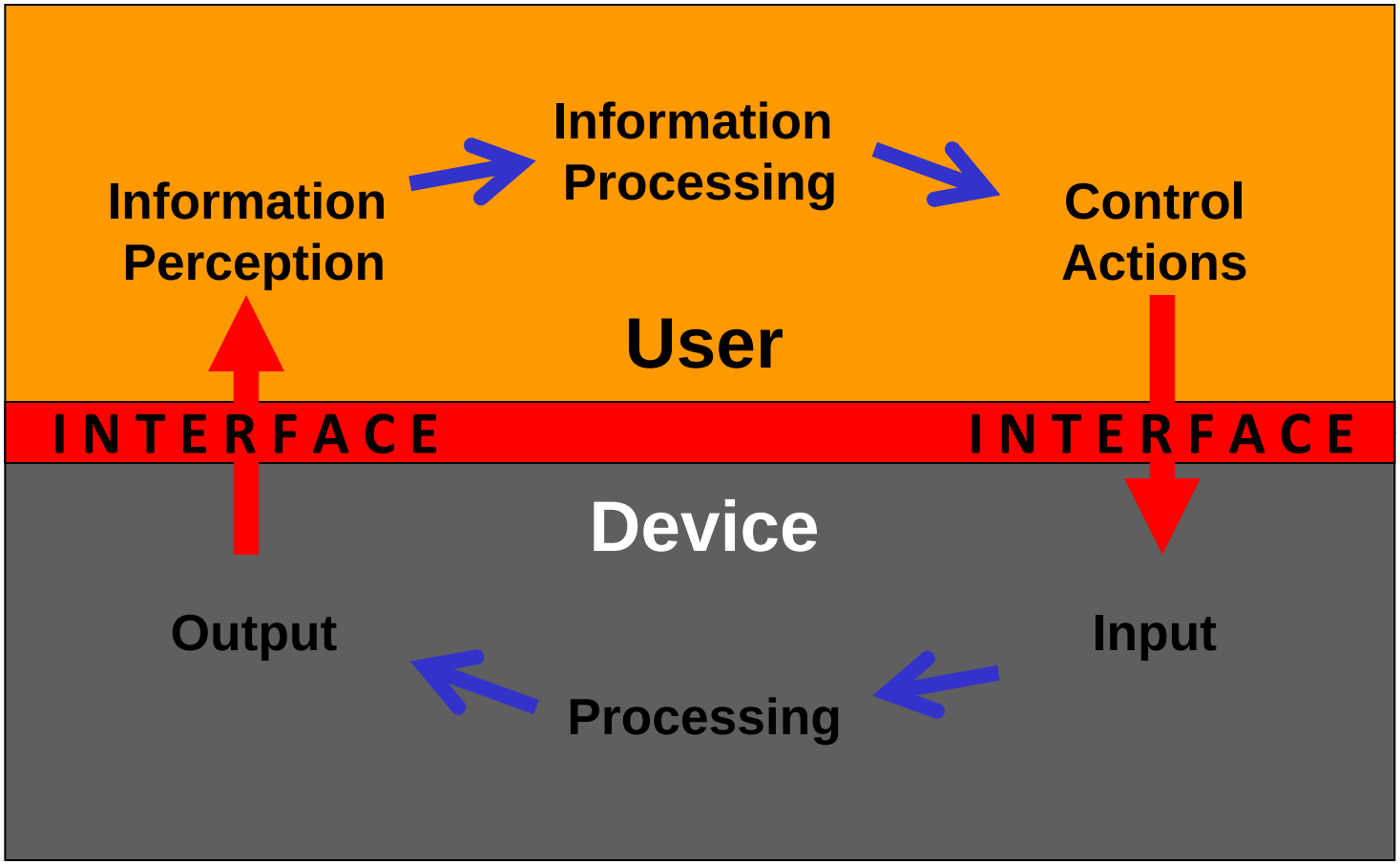
2012 IQPC Software Design for Medical Devices Europe
Munich, Germany – February 1, 2012

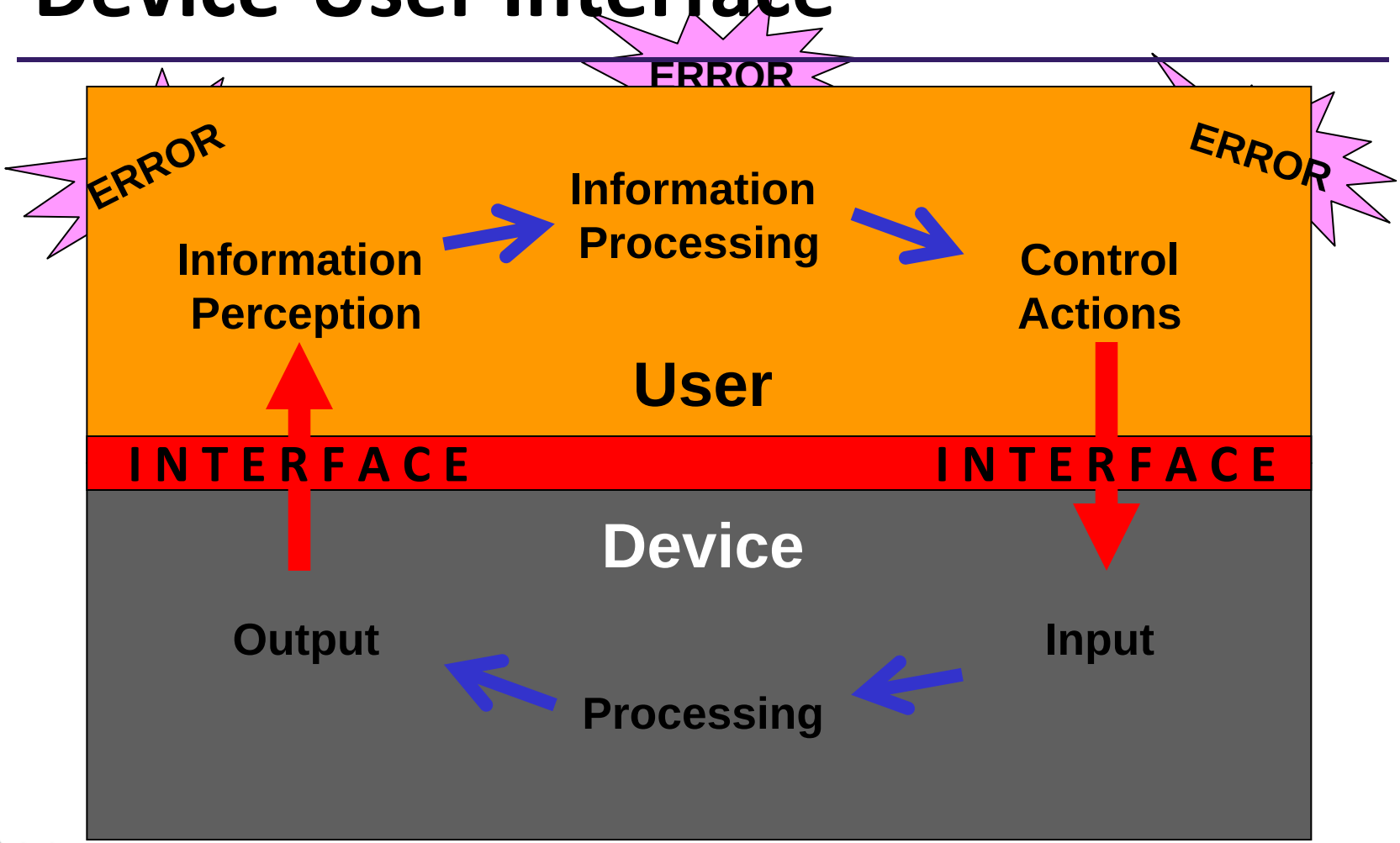
Overview

- Background
- Guidance for FDA premarket submissions involving medical device software
- Guidance for FDA premarket submissions involving human factors data
- Human factors/usability validation

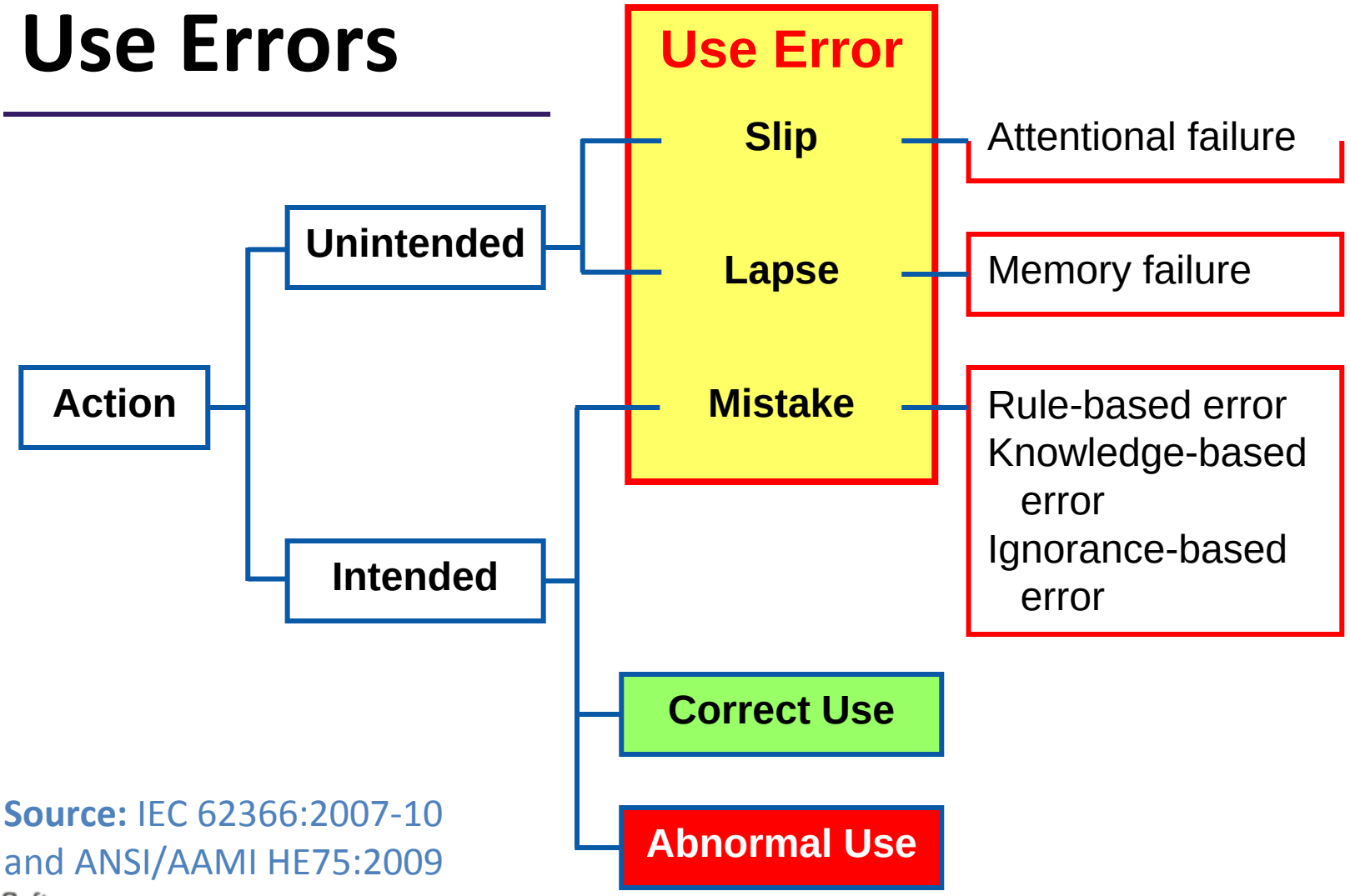
Device-User Interface



Device-User Interface



Use Errors



Source: IEC 62366:2007-10 and ANSI/AAMI HE75:2009

Common Reasons for Use Errors

- 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

Common User Interface (UI) Issues

- UI complexity causes user confusion, delay in use, or inability to use the device
- UI makes it difficult for user to correct data entry errors or modify device settings in a timely fashion
- UI falsely causes the user to believe a critical situation exists when it does not, or vice-versa
- UI does not draw attention to dangerous conditions of device operation or patient status
- UI does not prevent known, likely data input errors

Medical Device Software

- Primary standard recognized by FDA
- Guidance documents issued by FDA
- Guidance for FDA premarket submissions involving medical device software

Software Standard

IEC 62304:2006

Medical device software – Software life cycle processes

- **SW development**
- **SW maintenance**
- **SW risk management**
- **SW configuration management**
- **SW problem resolution**


NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI IEC 62304

Première édition
First edition
2006-05

Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel

Medical device software – Software life cycle processes

IEC ISO

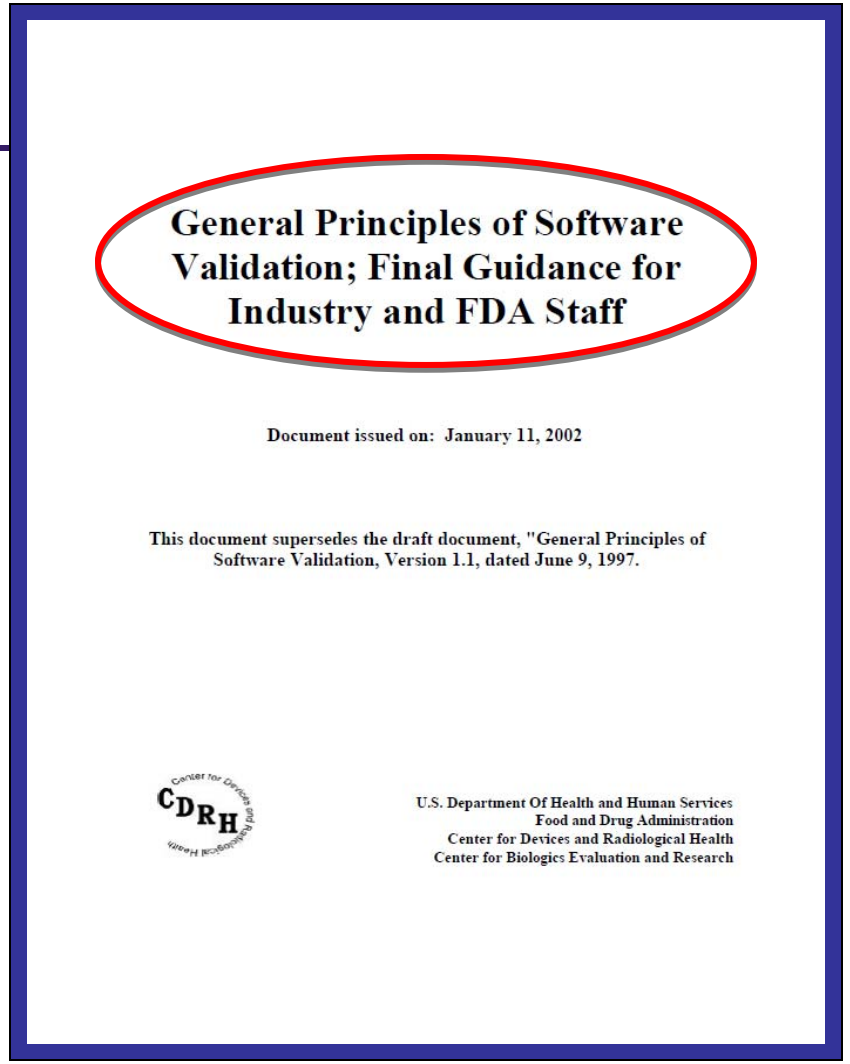
Numéro de référence
Reference number
CEI/IEC 62304:2006

FDA SW Guidance

General Principles of Software Validation

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

- *Note: issued in 2002*



General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Document issued on: January 11, 2002

This document supersedes the draft document, "General Principles of Software Validation, Version 1.1, dated June 9, 1997.

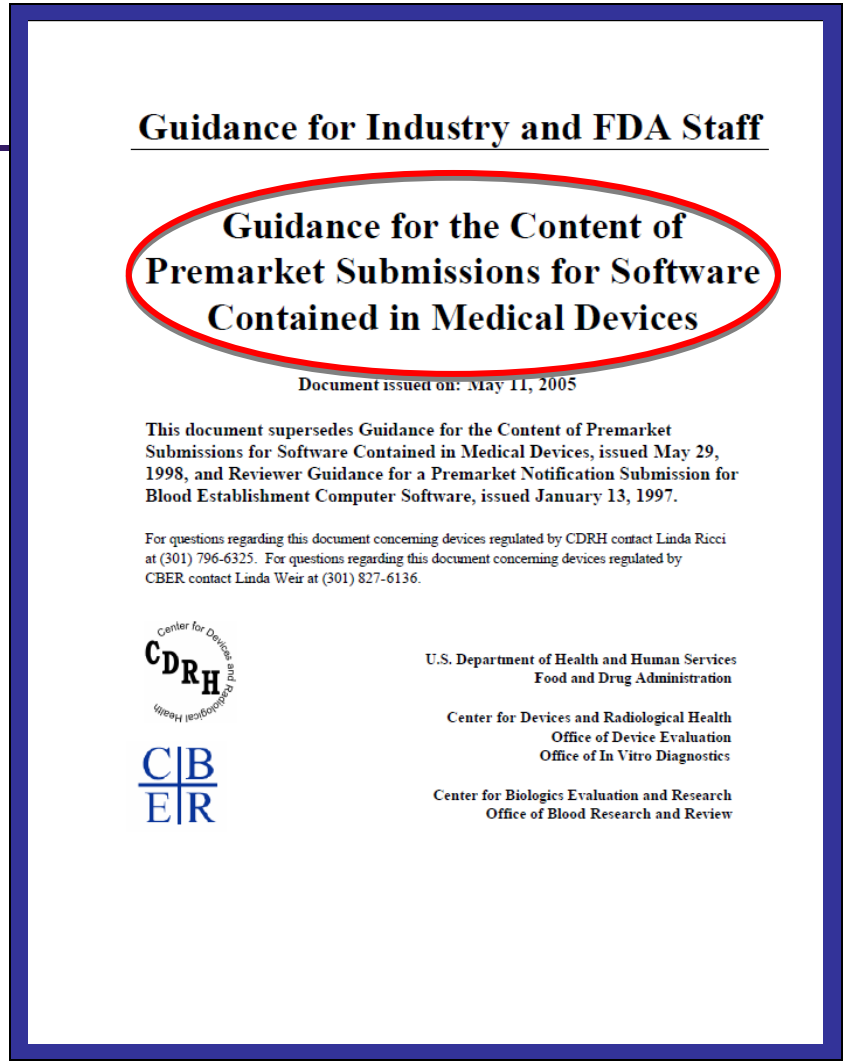
U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

FDA SW Guidance

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

- *Note: issued in 2005*



Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Document issued on: May 11, 2005

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 29, 1998, and Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software, issued January 13, 1997.

For questions regarding this document concerning devices regulated by CDRH contact Linda Ricci at (301) 796-6325. For questions regarding this document concerning devices regulated by CBER contact Linda Weir at (301) 827-6136.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics

Center for Biologics Evaluation and Research
Office of Blood Research and Review

FDA Software Guidance (1 of 7)

Device Hazard Analysis

- **Include all foreseeable software-related hazards**
  - Identification of the hazard
  - Severity of the hazard
  - Cause(s) of the hazard
  - Method of control (e.g., hardware, software, alarm)
  - Corrective measures (e.g., to eliminate, reduce, or warn)
  - Verification
  - Validation

FDA Software Guidance (2 of 7)

Software "level of concern"

- Estimate (in the absence of mitigations) of the **severity of injury** that a device failure or latent design flaw could permit or inflict, either directly or indirectly, on a patient or device operator:
  - **Major:** could directly result in death or serious injury
  - **Moderate:** could directly result in minor injury
  - **Minor:** unlikely to cause any injury

- **Documentation recommended for an FDA submission depends on the level of concern**

FDA Software Guidance (3 of 7)

Software-related documentation: Overview

- Describe the **design** of your device
- Describe how your design was **implemented**
- Demonstrate how the device, with your design implementation, was **tested**
- Show that you identified **hazards** appropriately and managed **risks** effectively
- Provide **traceability** to link the design, implementation, testing, and risk management

FDA Software Guidance (4 of 7)

Software-related documentation: Verification and Validation (V&V)

- **MINOR level of concern:**
  - Software functional test plan
  - Pass/fail criteria
  - Test results

FDA Software Guidance (5 of 7)

Software-related documentation: Verification and Validation (V&V)

- **MODERATE level of concern:**

  V&V activities at the unit, integration, and system level

  - System-level test protocol
  - Pass/fail criteria
  - Test results

FDA Software Guidance (6 of 7)

Software-related documentation: Verification and Validation (V&V)

- **MAJOR level of concern:**

  V&V activities at the unit, integration, and system level

  – Unit, integration and system-level test protocols
  – Pass/fail criteria
  – Test report, summary, test results

FDA Software Guidance (7 of 7)

Software design needs to address HF

- Weave human factors engineering into entire design and development process, including device design requirements, analyses, and tests
- Consider device safety and usability issues when developing flowcharts, state diagrams, prototyping tools, and test plans
- Perform task and function analyses, risk analyses, prototype tests and review, and full usability tests
- Include participants from the user population(s)

Medical Device Human Factors

- Standards recognized by FDA
- Guidance documents issued by FDA
- Guidance for FDA premarket submissions involving human factors data

Human Factors Standards (1 of 4)

AAMI/ANSI HE75:2009

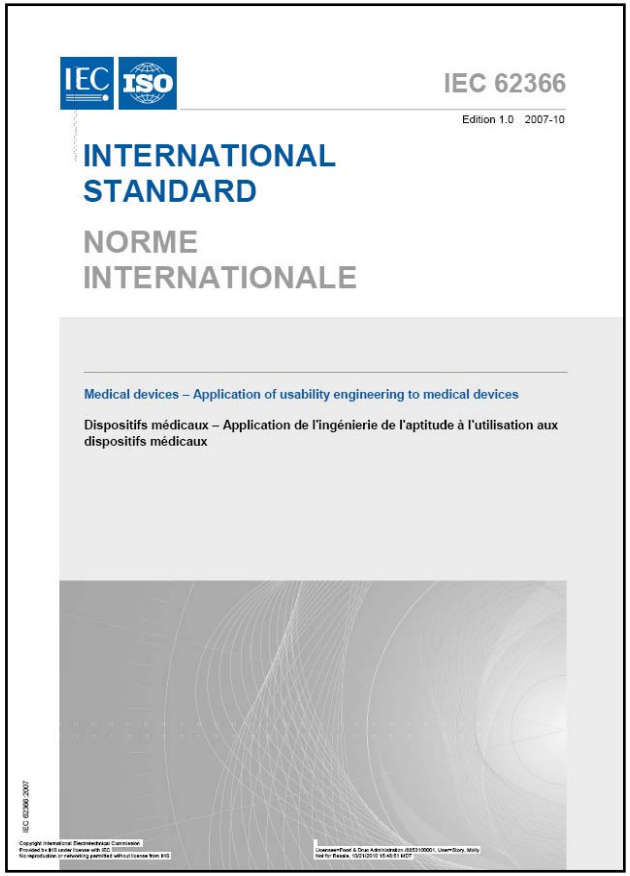
- **General considerations and principles**
  - Managing the risk of use error
  - Usability testing
- **Design elements**
  - Controls
  - Software
- **Integrated solutions**
  - Mobile medical devices
  - Home health care

Human Factors Standards (2 of 4)

ISO/IEC 62366:2007

Medical devices – Application of usability engineering to medical devices

- **Usability engineering process**
- **Accompanying document**
- **Training**

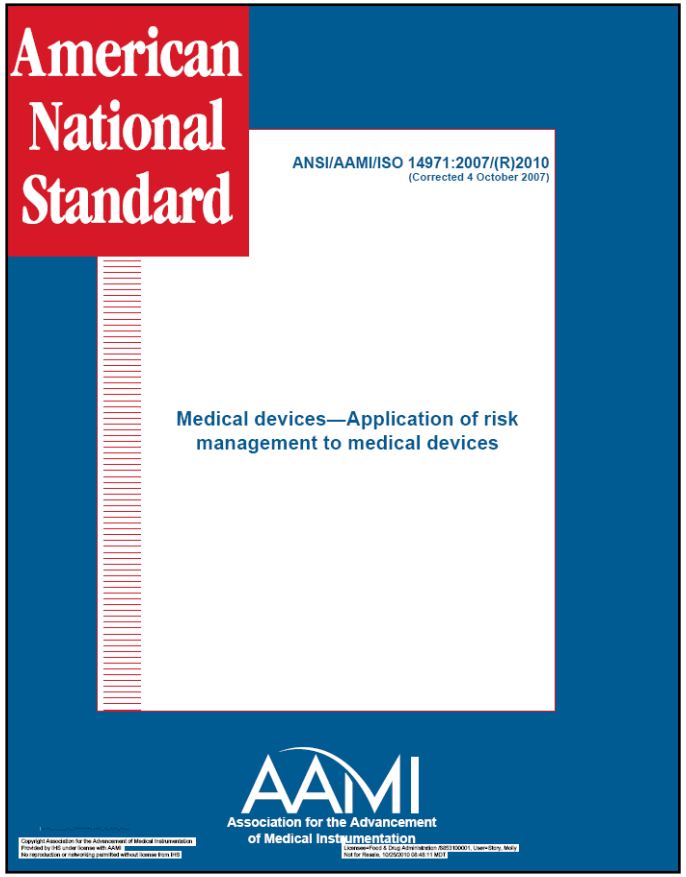


Human Factors Standards (3 of 4)

ANSI/AAMI/ISO 14971:2007

Medical devices – Application of risk management to medical devices

- **Risk management**
- **Risk analysis**
- **Risk evaluation**
- **Evaluation of overall residual risk acceptability**



Human Factors Standards (4 of 4)

IEC 60601-1-8:2006

Medical electrical equipment… Collateral standard: …alarm systems

- **Alarm systems**
  - Alarm condition
  - Generation of alarm signals
  - Alarm presets
  - Distributed alarm system
  - Etc.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI IEC 60601-1-8

Deuxième édition
Second edition
2006-10

Appareils électromédicaux –

Partie 1-8:
Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux

Medical electrical equipment –

Part 1-8:
General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC ISO

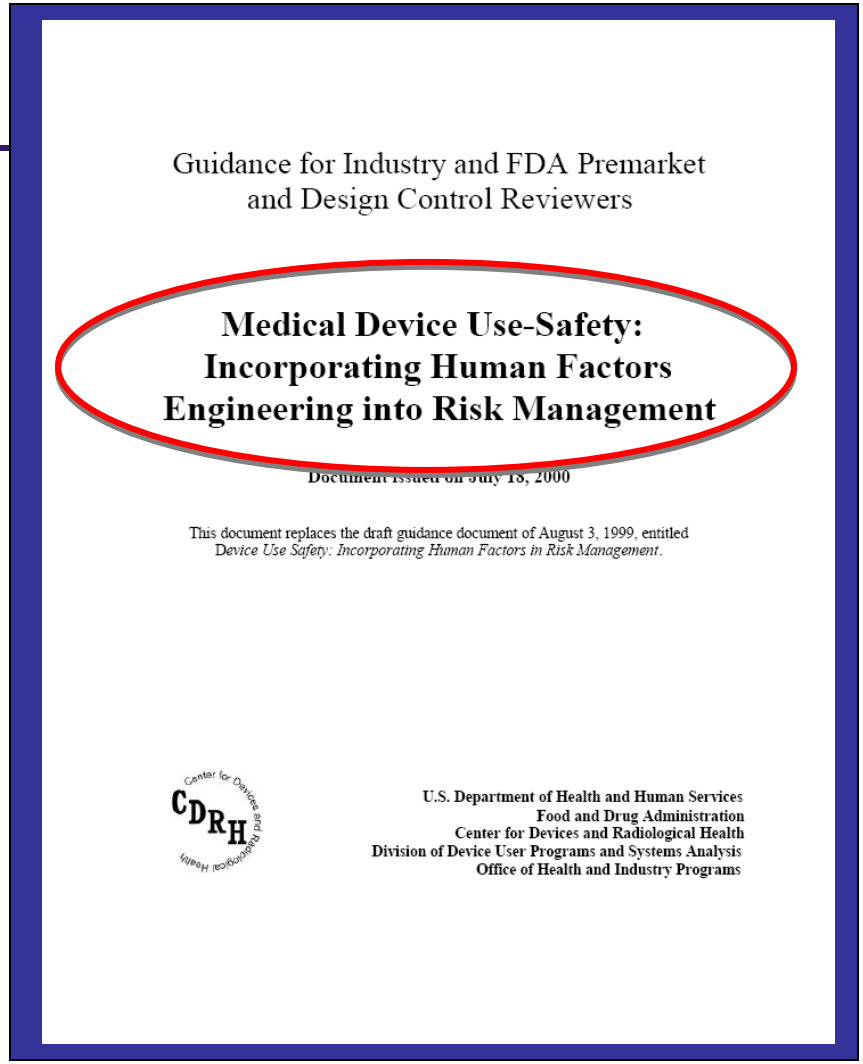
Numéro de référence
Reference number
CEI/IEC 60601-1-8:2006

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*.

CDRH Center for Devices and Radiological Health

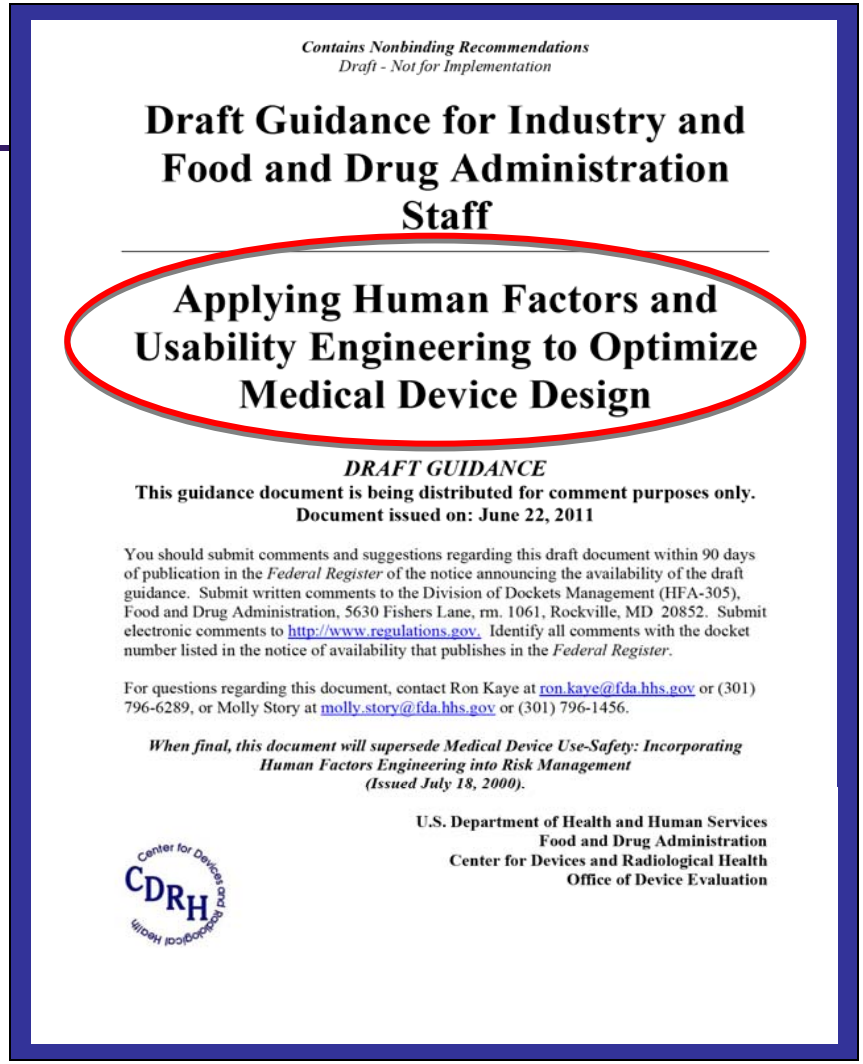
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs

FDA HF Guidance

Applying HF&UE to Optimize Medical Device Design

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

- *NOTE: issued in 2011 – It 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.

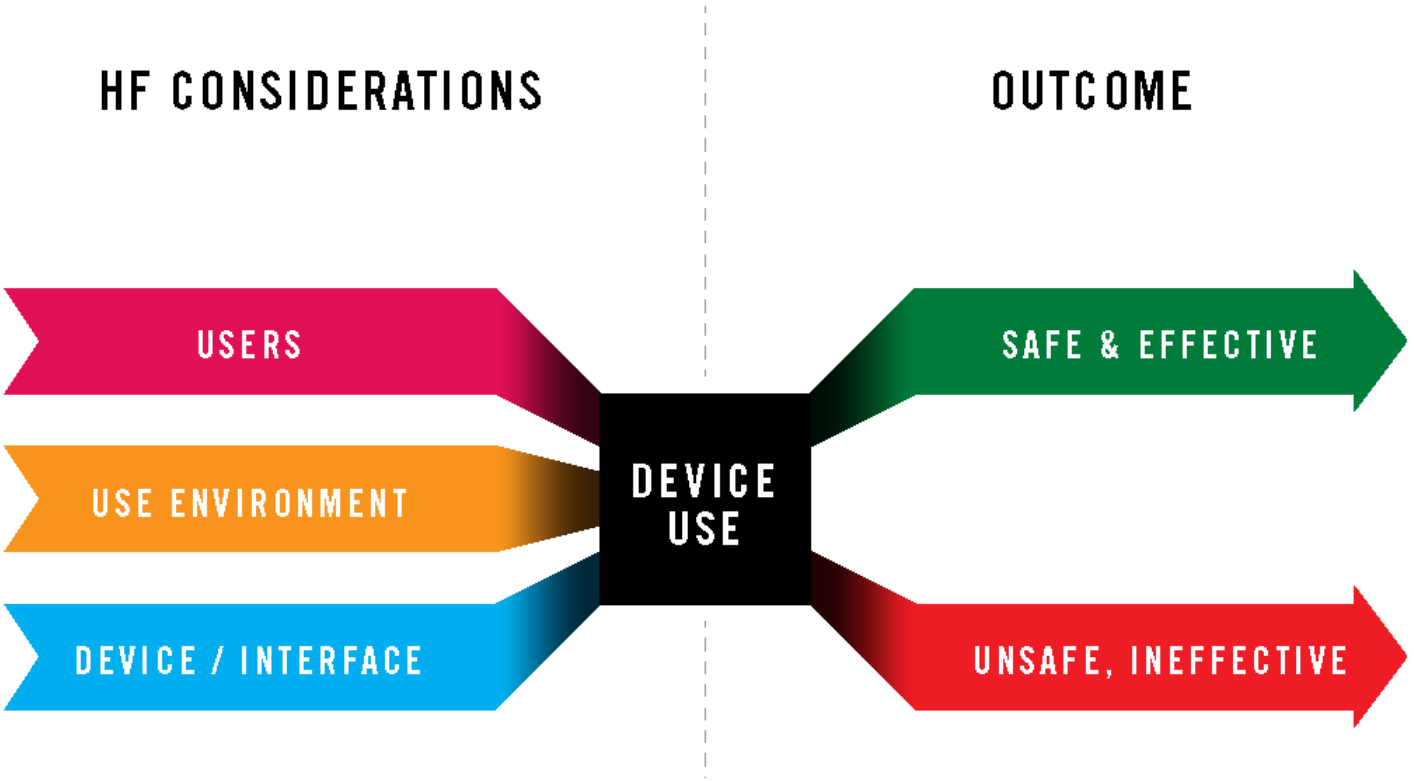
When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

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

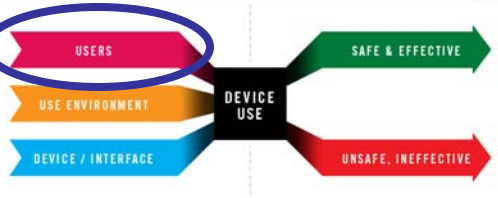
2011 *Draft* Human Factors Guidance

- Considerations: Device Users, Use Environments and User Interfaces
- Preliminary Analyses
- Exploratory HF/Usability Evaluations
- Hazard Mitigation and Control
- Human Factors/Usability Validation

Human Factors of Device Use

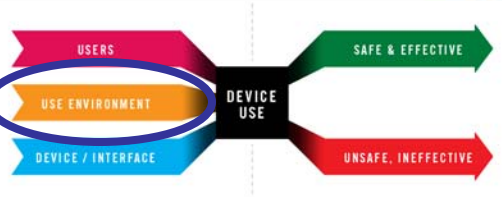


Users



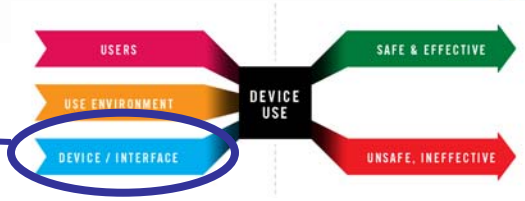
- **Professional or non-professional**
  - Job title and responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
  - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**

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



- **Example software interaction tasks**
  - Data entry (initial)
  - Data review
  - Data revision
- **Interactions (device hardware)**
  - Input
    - Knobs/dials, switches, buttons, keyboards, touch screens, etc.
  - Output
    - Visual: displays (GUI), lights, control settings, etc.
    - Auditory: alerts/alarms, beeps, voice, motors, fans, etc.

Regulatory Basis for HF at FDA

Quality System regulation:

21 CFR 820.30, Design Controls

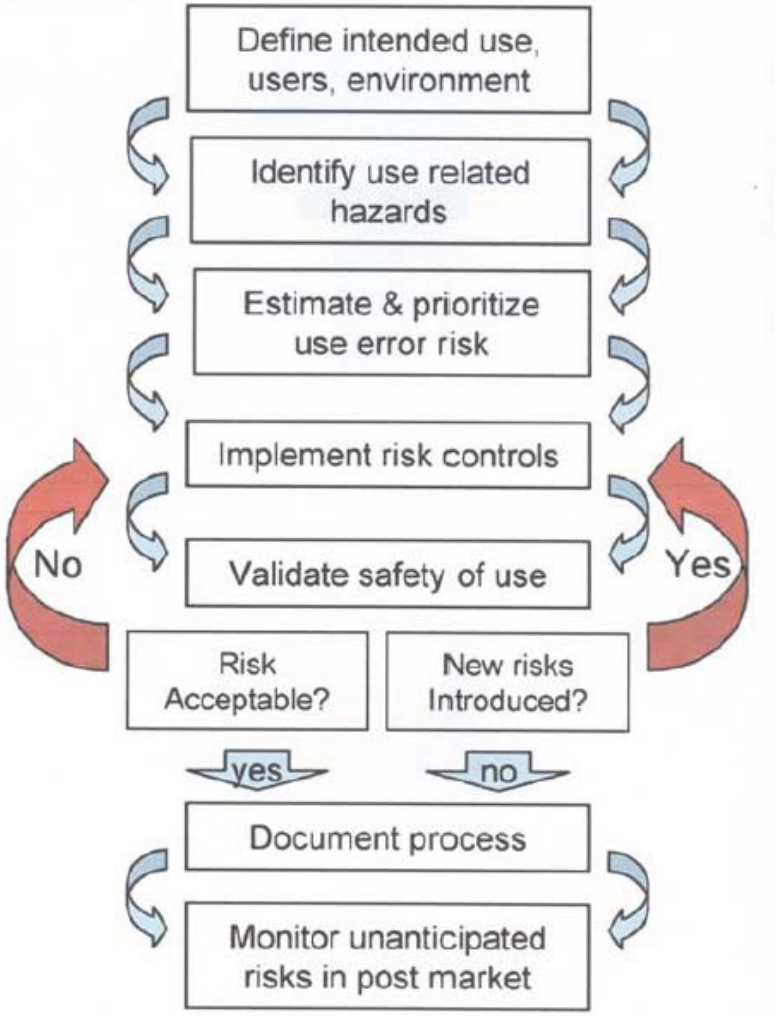
– *The need for human factors is implied:*

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]

Human factor engineering process for medical devices



Source: ANSI/AAMI HE75:2009

Preliminary Analyses: Inquiries

- **Analyze needs of current system users**
  - Who will use the system?
  - Where will they be working?
  - What tasks will they perform?
- **Analyze system-user interactions**
  - How will the users interact with the system?
  - What use errors and failures might occur?
  - How might errors and failures be prevented or the severity of any negative consequences be reduced?

Preliminary Analyses: Methods (1 of 3)

- **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 3)

- **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

Preliminary Analyses: Methods (3 of 3)

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. **Human factors/usability evaluations**
   - Conduct exploratory, hands-on testing to discover and explore unanticipated hazards
     - *Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations*

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:**
  - 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 Mitigation

- **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 is acceptable if it is:**
  - Reasonably limited, not capable of elimination or further reduction, and outweighed by the device's benefits

820.30(f) Design Verification

~~820.30(g) Design Validation~~

Design Verification:

- ***Did I make the product right?***

Design Validation:

- ***Did I make the right product?***

Source: Kimberly A. Trautman, FDA

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
- **Includes both objective and subjective data:**
  - Use errors and failures are observed and recorded
  - User feedback is collected after use regarding essential and critical task errors, failures and difficulties

Device Testing Conditions

- **Use finalized device design and labeling**
- **Identify 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 assessment of use-related risks
  - Incorporate findings of exploratory HF/U studies
    - E.g., tasks found to be problematic for users

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

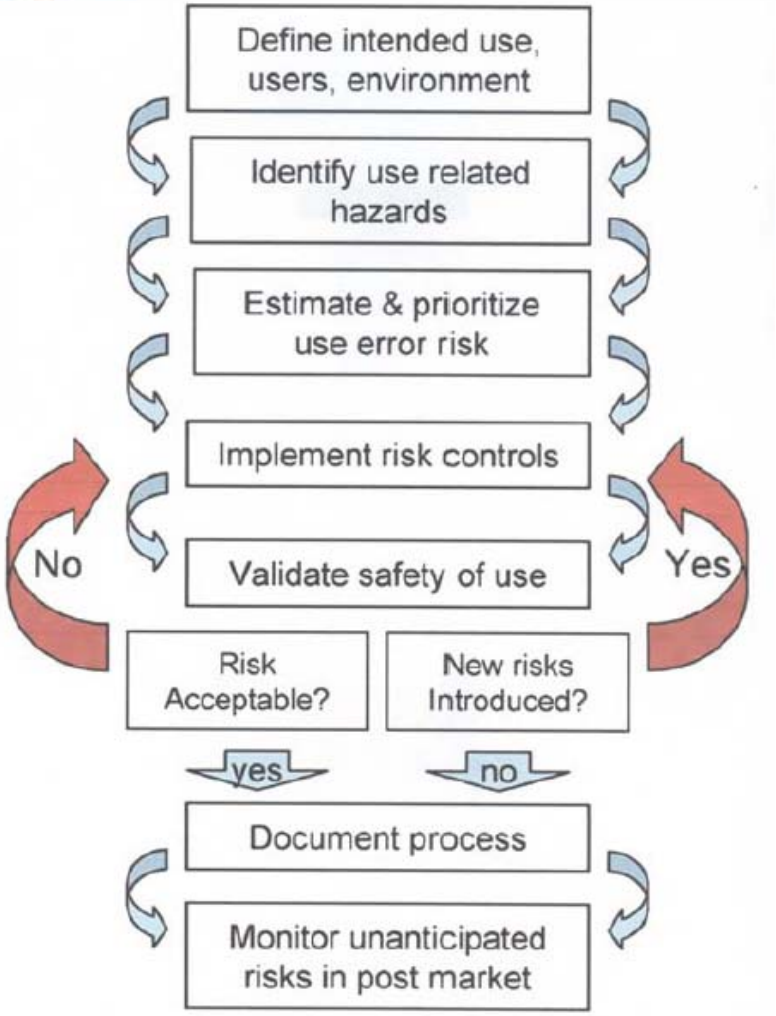
Instructions and Training

- **Participant interaction with instructions and training should approximate reality**
  - Labeling used in device validation should be final versions
  - Training used in device validation should be comparable to the training that actual users will receive

Validation Test Data

- **Assessment of device-user interactions**
  - User performance
    - Through observation, automated data collection, etc.
    - Essential and critical tasks
  - User knowledge
    - Through questionnaire or interview (worded neutrally)
    - Essential and critical knowledge
      - E.g., warnings and cautions
  - User subjective feedback
    - Through interview, after user has completed all test tasks
    - Overall use, essential/critical tasks, all performance failures

Human factor engineering process for medical devices



Source: ANSI/AAMI HE75:2009

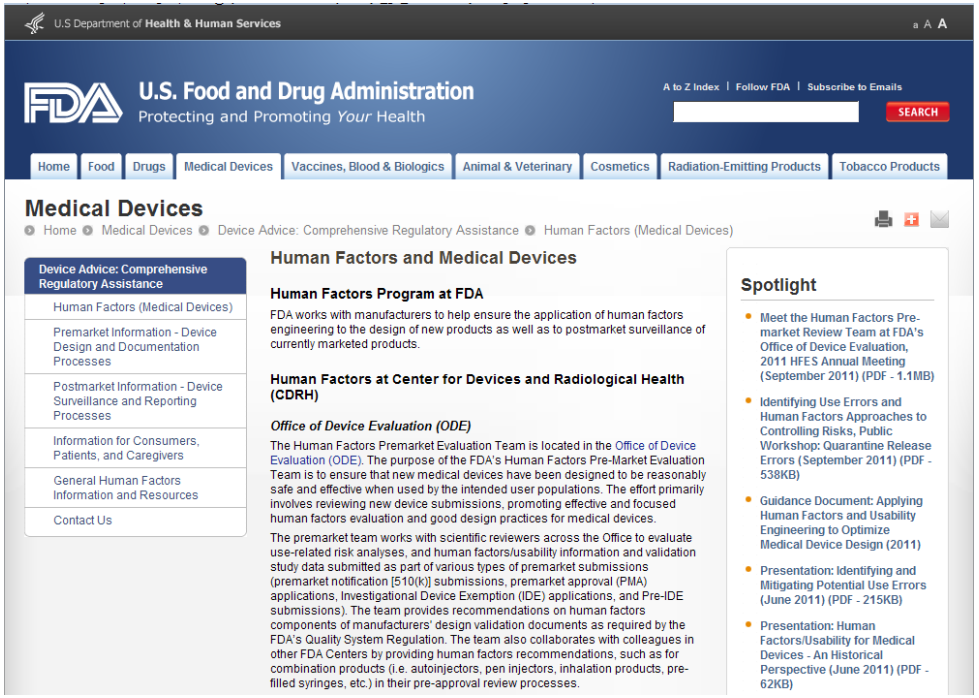
Advice: Consult FDA Early

- **Discuss product development plans with FDA before your design is considered "final" (and changes would be difficult)**
  - Staff in CDRH, CDER and CBER can advise
    - E.g., on software level of concern
  - FDA will review human factors/usability testing protocols on request
    - *Before implementation is recommended!*

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

Acknowledgment and Questions

My thanks to:

- Ron Kaye, FDA / CDRH / ODE / DAGID

Contact:

- Molly Follette Story: molly.story@fda.hhs.gov
- FDA/HF web site: www/fda.gov/humanfactors

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