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of today's participants.*

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Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and FDA Staff

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Overview

- Relevant regulations and standards
- FDA's Human Factors guidance
- List of highest priority devices for human factors review - draft guidance

Regulatory Basis for HF at FDA

21 CFR 820.30...

(c) **Design Input...** design requirements “address the intended use of the device, including the needs of the user and patient” ...

(f) **Design Verification...** “confirm that the design output meets the design input requirements” ...

(g) **Design Validation...** “ensure that 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, where appropriate.”

Regulatory Basis for HF at FDA

Medical Devices; Current Good Manufacturing Practice (cGMP); Quality System Regulation Preamble to Final Rule 21 CFR Parts 808, 812, and 820 (61 FR 52502)

i.72. ...“when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed..”

i.159. ... “FDA emphasizes that any death, even if the manufacturer attributes it to user error, will be considered relevant by FDA and will have a high risk potentially associated with it. User error is still considered to be a nonconformity because human factors and other similar tools should have been considered during the design phase of the device.”

Human Factors Standards

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

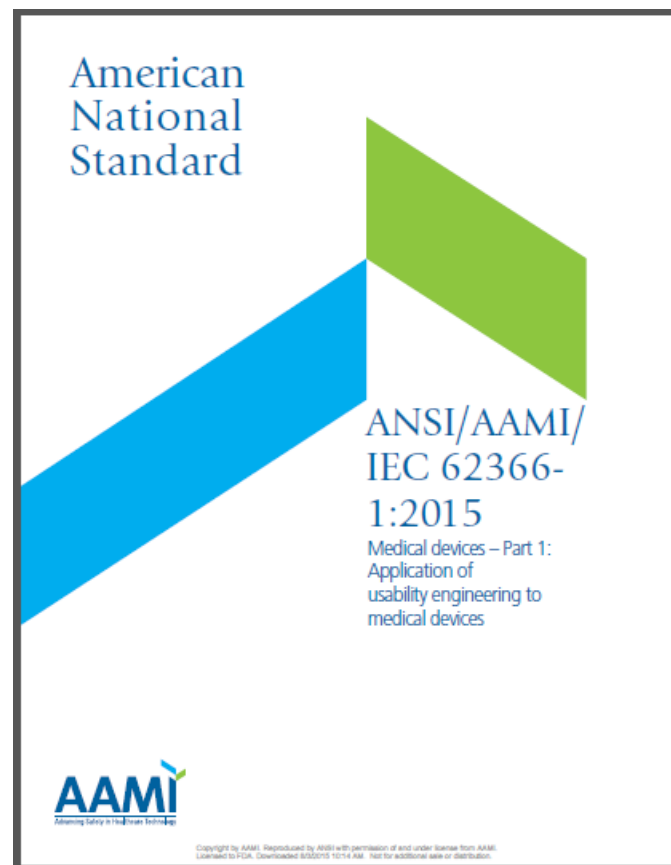


Human Factors Standards

ANSI/AAMI/IEC 62366 1:2015

*Medical devices – Part 1:
Application of usability
engineering to medical devices*

- Usability engineering process
- Accompanying document
- Training



Human Factors Standards

ANSI/AAMI/ISO 14971:2007 [R2010]

*Medical devices -
Application of risk
management to medical
devices*

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



2015 FDA HF Guidance

Applying Human Factors and Usability Engineering to Medical Devices

As of April 3, 2016, this document supersedes “Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management” issued July 18, 2000.

Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices


Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes “Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management” issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.



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

Overview of changes from the 2011 Draft HF Guidance

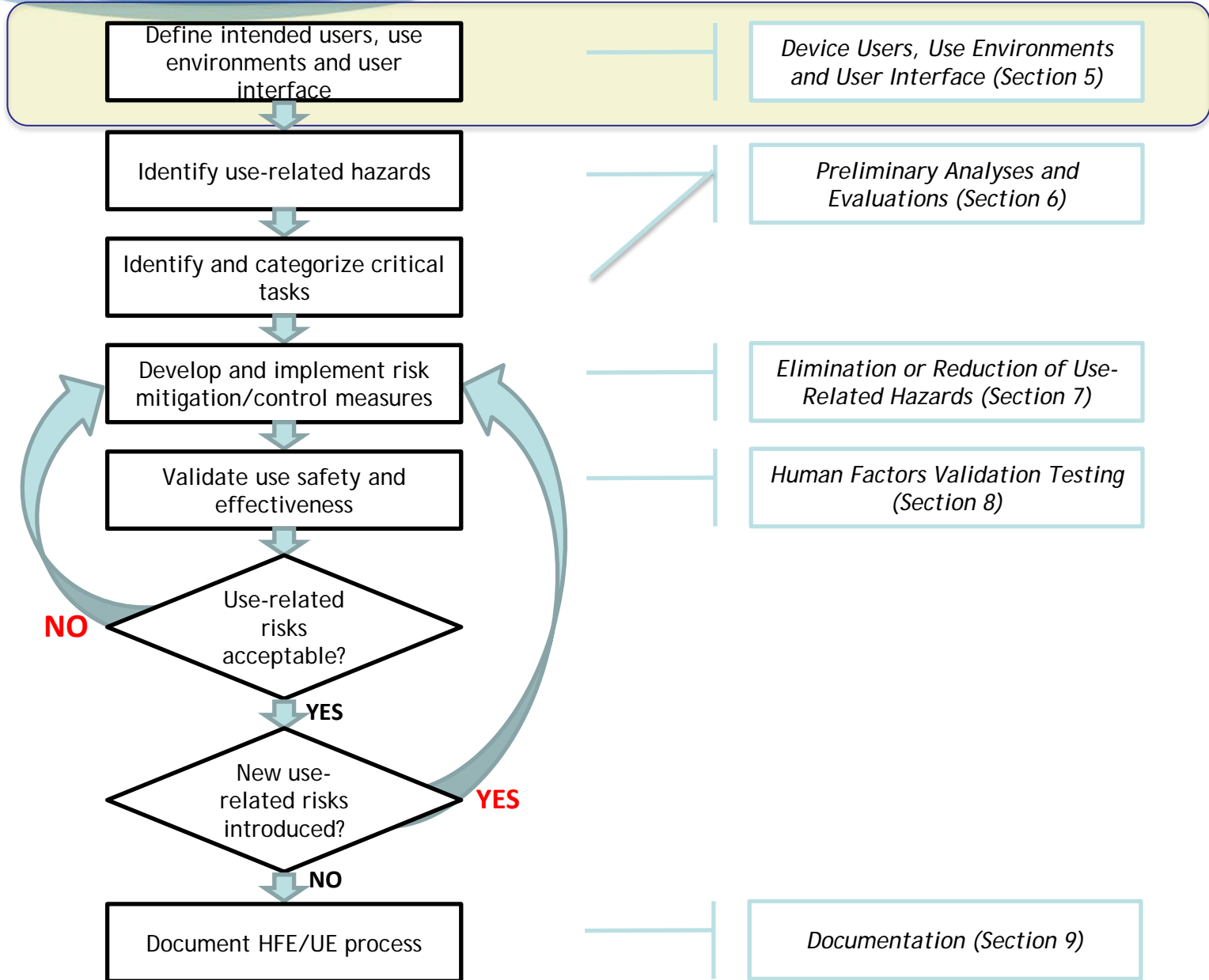
Scope aims to clarify expectations around when to submit a HF report with a premarket submission

“CDRH recommends that manufacturers consider human factors testing for medical devices as a part of a robust design control subsystem. CDRH believes that for those devices where an analysis of risk indicates that users performing tasks incorrectly or failing to perform tasks could result in serious harm, manufacturers should submit human factors data in premarket submissions (i.e., PMA, 510(k)).”

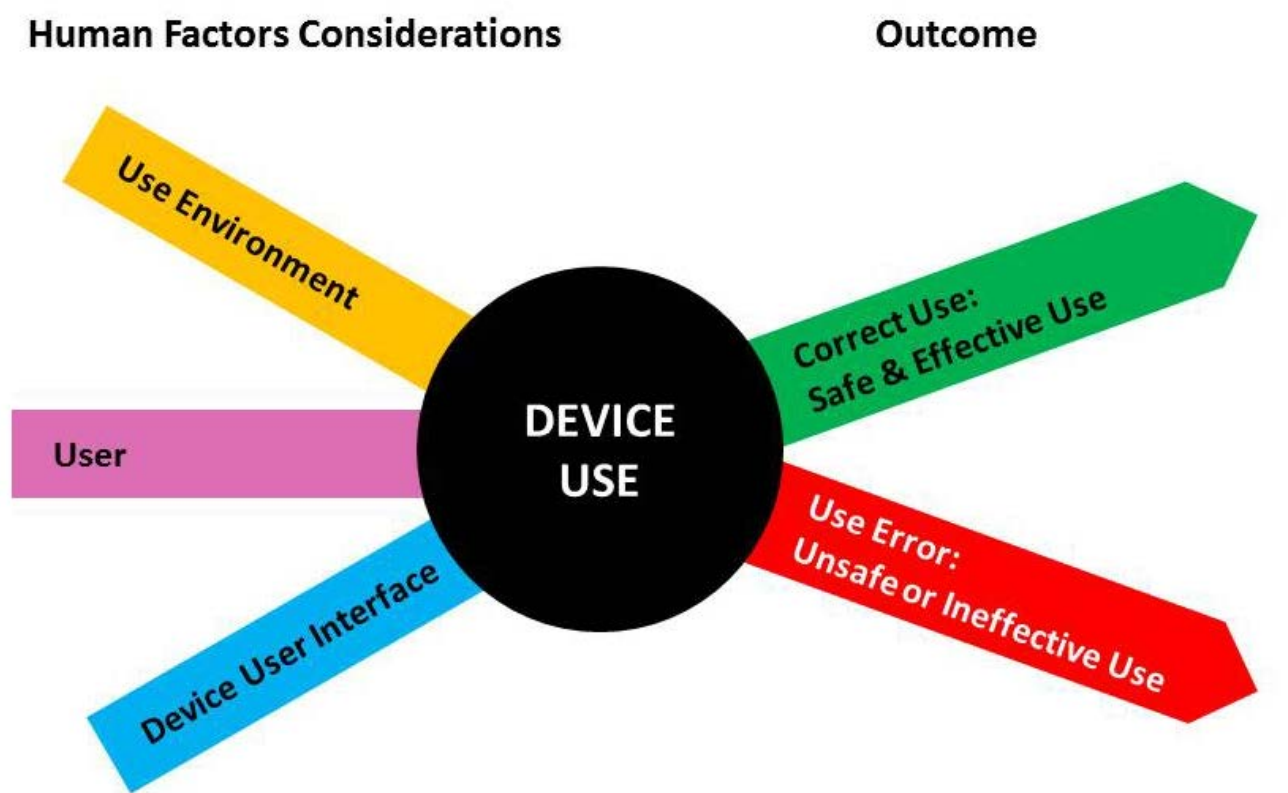
Overview of changes from the 2011 Draft HF Guidance

Key terms (from Section 3 Definitions):

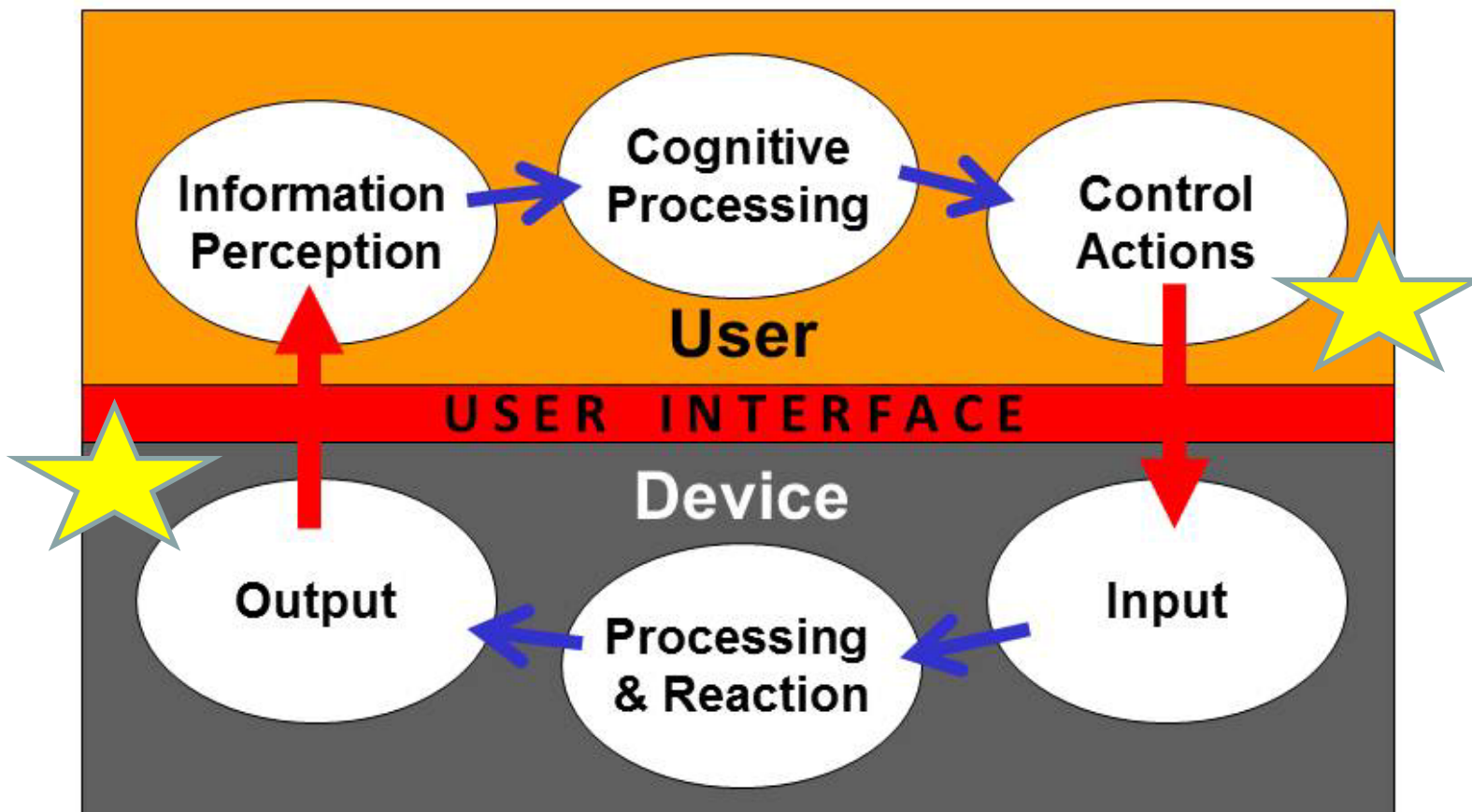
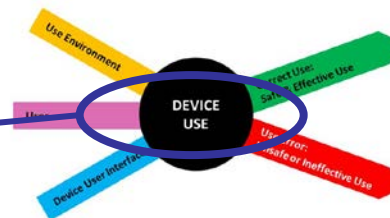
- Critical task - A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.
- User interface - All points of interaction between the user and the device... (including packaging, labeling, and training) and all physical controls and display elements...

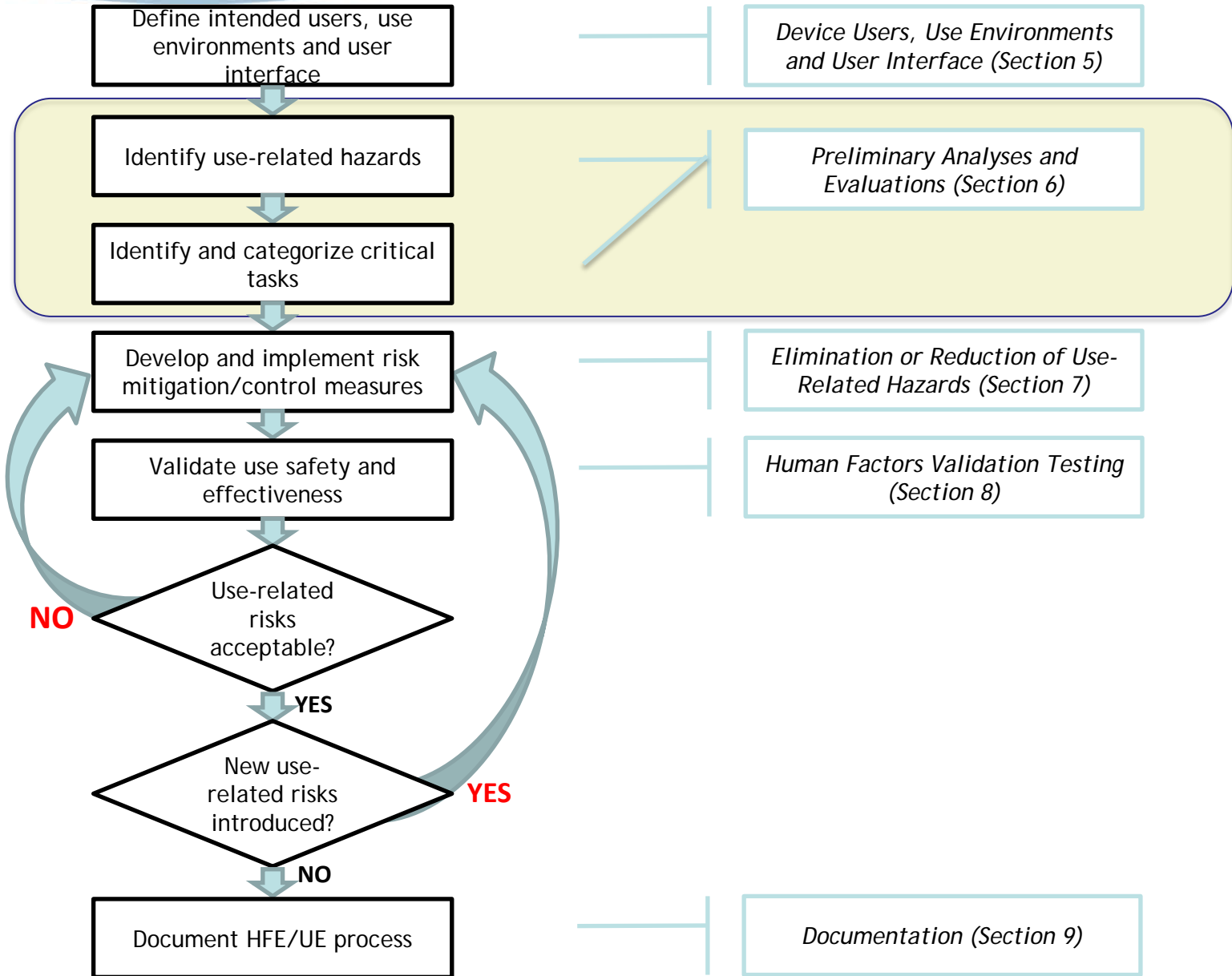


Human Factors of Device Use



Device Use





Preliminary Analyses and Evaluations

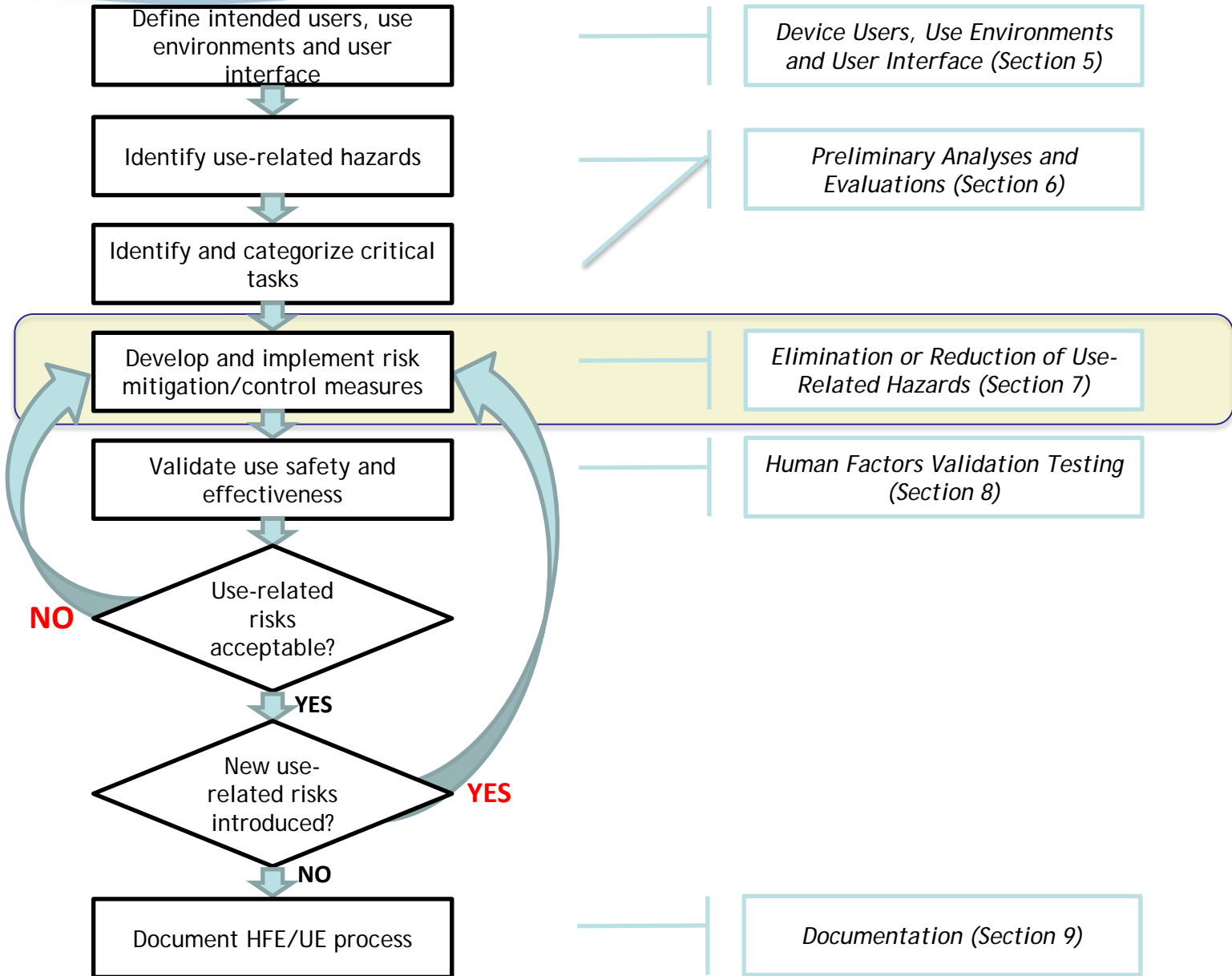
- Critical tasks identification and categorization:
 - Categorize the user tasks based on the severity of the potential harm
 - Warnings, precautions and contraindications in the labeling should be included in the risk assessment
 - Examples of risk analysis tools
 - Failure mode effects analysis (FMEA)
 - Fault tree analysis

Preliminary Analyses and Evaluations

- Sources of known use-related problems
 - Customer complaint files, knowledge of training and sales staff familiar with use-related problems
 - Previous HFE/UE studies
 - Current device users, journal articles, relevant internet sites, such as:
 - FDA's Manufacturer and User Facility Device Experience (MAUDE) database
 - FDA's MedSun: Medical Product Safety Network
 - CDRH Medical Device Recalls

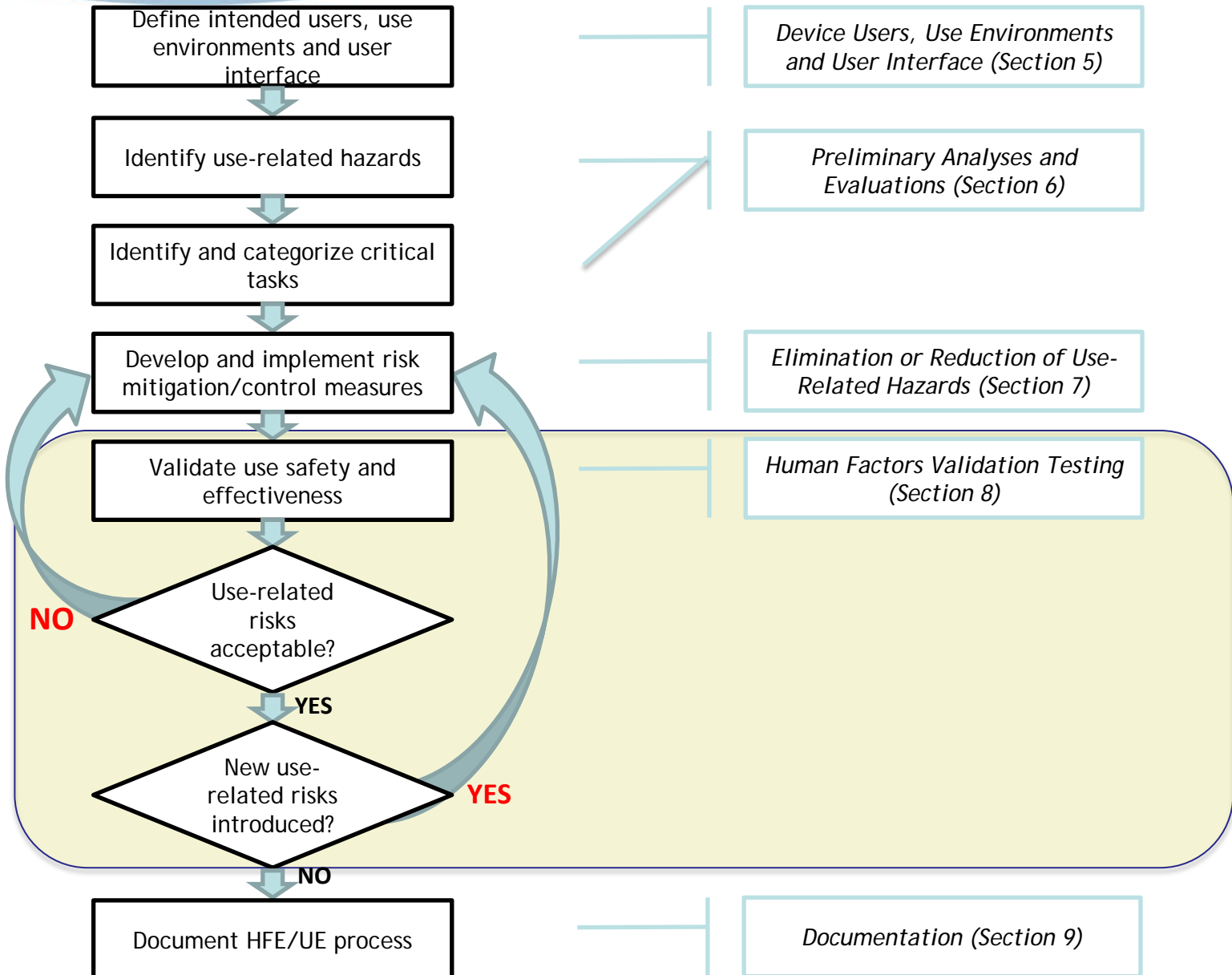
Preliminary Analyses and Evaluations

- Analytical approaches involve review and assessment of user interactions with the devices
 - Task analysis
 - Heuristic analysis
 - Expert review
- Empirical approaches derive data from users' experiences interacting with the device or device prototypes or mock-ups
 - Contextual inquiry
 - Interviews
 - Formative evaluations (e.g. cognitive walk-through, simulated-use testing, etc.)



Elimination or Reduction of Use-Related Hazards

- Address use-related hazards by applying risk management strategies
 - Inherent safety by design
 - protective measures
 - information for safety
- Design modifications are generally the most effective means for controlling eliminating or reducing use-related hazards
- Test to assess whether mitigation strategies:
 - Effectively reduced the known risks and did not introduce any new risks



Human Factors Validation Testing

- Demonstrates that the device can be used by the intended users, under expected use conditions, without serious use errors or problems
- Testing should be designed as follows:
 - The test participants represent the intended (actual) users of the device.
 - All critical tasks are performed during the test
 - The device user interface represents the final design
 - The test conditions are sufficiently realistic to represent actual conditions of use

Test Participants

- Test participants should represent the population of intended users
- In general, the minimum number of participants should be 15 for each distinct population;
 - examples of distinct populations: Pediatric and adult, Healthcare providers and lay users
- Your employees should not serve as test participants
- The test participants should reside in the U.S. Exceptions to this are considered on a case-by-case basis.

Tasks and Use Scenarios

- Tasks that logically occur in sequence when using the device can be grouped into use scenarios
- Use scenarios in the testing should be organized to represent a natural workflow
- Prior to testing, you should define user performance that represents success for each task
- Critical tasks that have a low frequency of occurrence require careful consideration and should be included in the testing

Instructions for Use

- The labeling used in the human factors validation testing should represent the final designs
- The human factors validation testing can indirectly assess the instructions for use for the device, but only in the context of use of the device
- Stating that you mitigated the risks by modifying the instructions for use is not acceptable, unless you provide additional test data demonstrating that the modified elements were effective in reducing the risks to acceptable levels

Participant Training

- The training provided to the human factors validation test participants should approximate the training that actual users would receive
- Stating your intention to mitigate the risks by providing “additional training” is not acceptable unless you provide additional data that demonstrates that it would be effective in reducing the risks to acceptable levels
- Minimum one hour training decay should be included; longer time would be appropriate when it is necessary to evaluate training decay as a source of use-related risk

Data Collection (Objective)

- Observational data
 - observations of participants' performance of all the critical use scenarios (which include all the critical tasks)
- Knowledge task data
 - Comprehension of interface components involved in knowledge tasks are usually the user manual, quick start guide, labeling on the device itself, and training

Data Collection (Subjective)

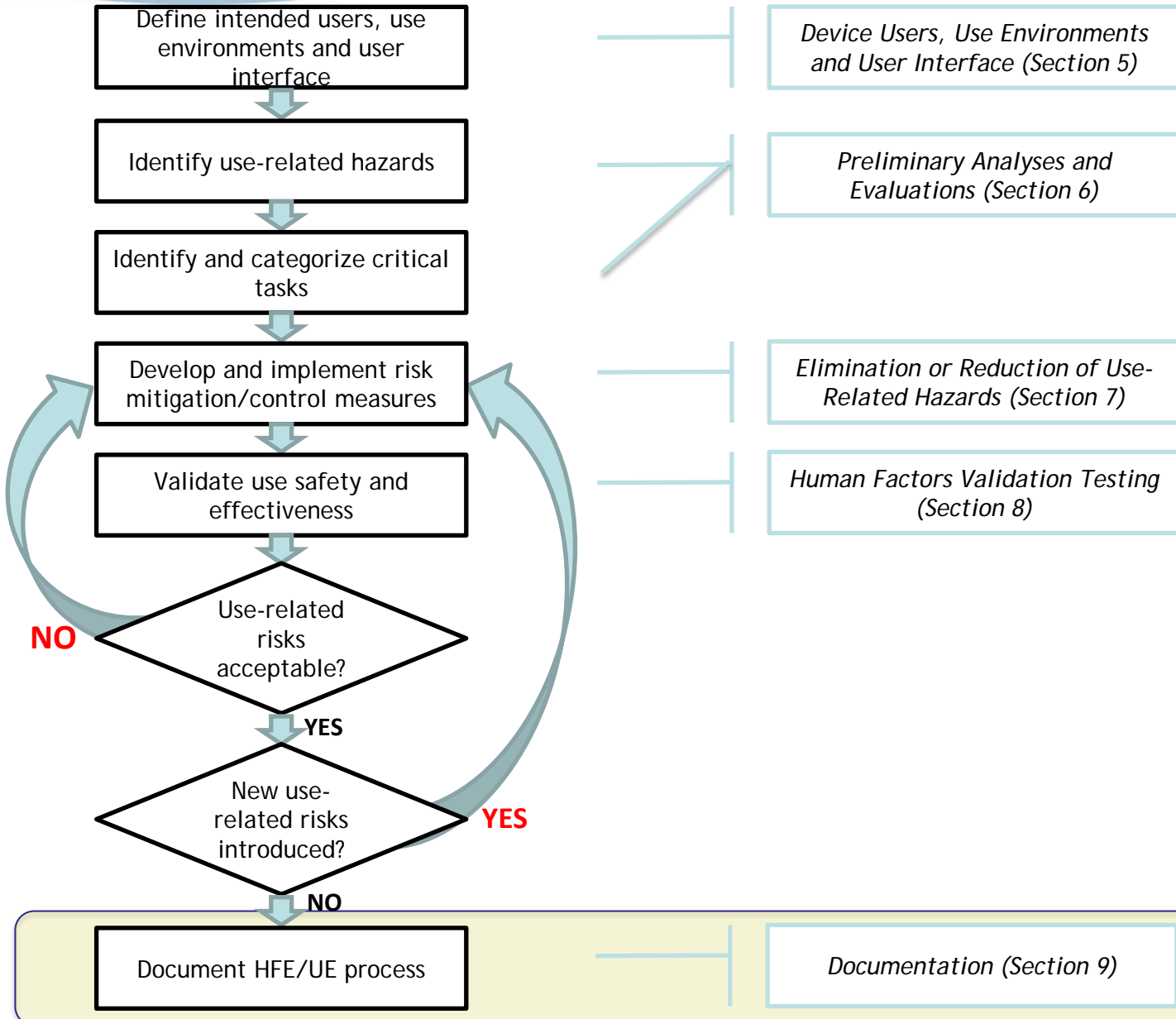
- Interview data
 - Participant feedback considering the overall device and then focused on each critical task or use scenario
 - Participant assessment of any use difficulties, confusions or errors that were experienced during the test
 - Participant assessment of root cause for any observed or participant reported use difficulties, confusions or errors

Analysis of Human Factors Validation Test Results

- Analyze qualitatively by aggregating objective and subjective data to:
 - Identify potential use errors
 - and determine the root causes
- Address use errors and problems through risk management strategies
- Conduct human factors (re-)validation testing on the modified user interface elements

Actual Use Testing

- When actual-use testing is determined to be necessary (rare) to ensure safe use of the proposed device, an Investigational Device Exemption (IDE) may be required.
 - Actual-use testing can also be conducted as part of a clinical study.
 - it is inadequate to depend solely on self-reports data since these data can be incomplete or inaccurate



Human Factors Recommended Report Outline

1. Conclusion
2. Description of Intended device users, uses, environments and training
3. Description of device user interface
4. Summary of known use problems
5. Analysis of risks associated with use of the device
6. Summary of preliminary analyses and evaluations
7. Description and categorization of critical tasks
8. Details of human factors validation testing

When to submit...

From the 2015 HF Guidance scope:

“In an effort to make CDRH’s premarket submission expectations clear regarding which device types should include human factors data in premarket submissions, CDRH is issuing a draft guidance document *List of Highest Priority Devices for Human Factors Review, Draft Guidance for Industry and Food and Drug Administration Staff*. When final, this document will represent the Agency’s current thinking on this issue.”

List of Highest Priority Devices for Human Factors Review Draft Guidance

- FDA is issuing this guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions (i.e., for PMA, 510(k) and related Pre-submissions).
- For devices that should include human factors data in premarket submissions, as listed here, manufacturers should provide FDA with a human factors report

List of Highest Priority Device Types

- Ablation generators (associated with ablation systems, e.g., LPB, OAD, OAE, OCM, OCL)
- Anesthesia machines (e.g., BSZ)
- Artificial pancreas systems (e.g., OZO, OZP, OZQ)
- Auto injectors (when CDRH is lead Center; e.g., KZE, KZH, NSC)
- Automated external defibrillators (e.g., MKJ, NSA)
- Duodenoscopes (on the reprocessing; e.g., FDT) with elevator channels
- Gastroenterology-urology endoscopic ultrasound systems (on the reprocessing; e.g., ODG) with elevator channels
- Hemodialysis and peritoneal dialysis systems (e.g., FKP, FKT, FKX, KDI, KPF, ODX, ONW)
- Implanted infusion pumps (e.g., LKK, MDY)
- Infusion pumps (e.g., FRN, LZH, MEA, MRZ)
- Insulin delivery systems (e.g., LZG, OPP)
- Negative-pressure wound therapy (e.g., OKO, OMP) intended for use in the home
- Robotic catheter manipulation systems (e.g., DXX)
- Robotic surgery devices (e.g., NAY)
- Ventilators (e.g., CBK, NOU, ONZ)
- Ventricular assist devices (e.g., DSQ, PCK)

How this List Should be Used for Premarket Submissions

- For device types on the list: Any premarket submission for the device types listed above should include either a human factors test report and data or should provide a detailed rationale that supports the conclusion that human factors data are not necessary.

How this List Should be Used for Premarket Submissions

- For device types not on the list: ODE may also determine that human factors data are needed in a specific premarket submission on a case-by-case basis when one or more of the following apply:
 - Submission type
 - User interface modification
 - Different users
 - Recalls, adverse events, and problem reports
 - Device modifications

Advice: Consult FDA Early

- Discuss product development plans with FDA before your design is finalized (and changes would be difficult)
- FDA encourages manufacturers to submit a draft of the human factors testing protocol prior to conducting the test. The premarket mechanism for this is a Pre-submission.

Questions





Questions?

General questions about human factors and usability engineering processes?

Contact CDRH's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov, 1-800-638-2041, or 301-796-7100

Questions about following appropriate human factors and usability engineering processes in a specific device?

Contact CDRH Human Factors team at HFPMET@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

<http://www.fda.gov/training/cdrhlearn>

Under “Specialty Technical Topics” Heading