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FDA Human Factors Submission Requirements: 2026 eSTAR Map

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Executive Summary

The U.S. Food and Drug Administration (FDA) issued the final guidance "Content of Human Factors Information in Medical Device Marketing Submissions" on May 29, 2026 (www.fda.gov), replacing a revised draft dated December 9, 2022. It sets a risk-based framework for the human factors (HF) content of 510(k), De Novo, premarket approval (PMA) and humanitarian device exemption (HDE) submissions (www.fda.gov). The document is nonbinding: FDA describes it as "not binding on FDA or the public" (www.fda.gov), and "should" means suggested or recommended, not required. FDA's June 1, 2026 eSTAR update carries the guidance content into the templates (www.fda.gov), and FDA did not generally expect the newly recommended information in submissions received before August 1, 2026 (www.fda.gov).

The operational core is one category per submission (www.fda.gov). **Category 1** applies when the user interface, users, uses, environments, training and labeling are unchanged. **Category 2** applies when no critical tasks exist, or none are new or impacted, or when a rationale replaces validation data (www.fda.gov). **Category 3** requires a comprehensive HFE/UE (human factors engineering / usability engineering) report with validation testing (www.fda.gov). Decision Point D, the fourth decision point, asks whether validation data should be submitted at all (www.fda.gov). FDA staff said this is where "there is the most discretion" (www.fda.gov).

For eSTAR, FDA says the template offers a "Guide Me" route or direct category selection (www.fda.gov), and that fillable boxes should tell reviewers where evidence sits (www.fda.gov). eSTAR use is mandatory for 510(k) and De Novo submissions and voluntary for PMAs (www.fda.gov). FDA's page lists nIVD and IVD eSTAR Version 7.1 as current. Because FDA verifies dropdown answers and may place a submission on technical screening hold for up to 180 days (www.fda.gov), category selection is a quality-controlled step, not a formality.

The practical decision for regulatory and human-factors teams is whether an existing usability-engineering file is submission-ready. This report maps each category to report sections, eSTAR prompts and internal artifacts, separates recommendations from legal duties, and provides a planning calculator (an illustration, not an FDA benchmark). Device-specific questions belong in a Pre-Submission. Several items could not be verified and are listed in the Conclusion.

Introduction and Background

Human factors content has long been a common topic of premarket dialogue, but the question "what do we actually put in the submission?" lacked a published structure. FDA's final guidance fills that gap by describing the level of documentation, not the development process: the guidance states it is not intended to inform manufacturers how to perform a human factors evaluation (www.fda.gov), and it complements the existing guidance "Applying Human Factors and Usability Engineering to Medical Devices" (www.fda.gov). In the town hall, FDA put it directly: the category determines the level of documentation, "not what human factors processes should be applied" (www.fda.gov).

This report is written for regulatory affairs leads, human-factors engineers, product owners and software teams preparing a 510(k), De Novo, PMA or HDE after the August 1, 2026 implementation point. As of November 21, 2026, the key dates are: guidance issued May 29, 2026 (Federal Register notice 91 FR 32061 (www.federalregister.gov)); eSTAR update June 1, 2026 (www.fda.gov); town hall July 22, 2026 (www.fda.gov); and the companion 2016 guidance reissued with a date of August 3, 2026 (www.fda.gov).

The report's distinctive contribution is a traceability map from guidance sections to eSTAR prompts and internal evidence. It is deliberately not a primer on usability-engineering principles. Throughout, statements are tagged as FDA recommendation, legal requirement, or this report's planning assumption. Nothing below is regulatory advice. Teams should consult qualified regulatory counsel and their FDA review division for device-specific decisions.

Key Changes: From the May 29 Guidance to the June 1 eSTAR

Change 1: A risk-based framework with a fourth decision point

The final guidance states its purpose as providing a risk-based framework (www.fda.gov). FDA's Federal Register notice says it added risk-based factors for determining the HF Submission Category, new examples and appendices, and scope clarifications after comments (www.federalregister.gov). A law-firm commentary identifies Decision Point D as the notable substantive change (www.thefdalawblog.com), and notes the draft had appeared to expand the number of submissions requiring HF data (www.thefdalawblog.com). A practitioner summary says that, after the change, not all devices with new or impacted critical tasks automatically require added validation testing (emergobyul.com), a view echoed by another certification body's commentary (www.nsf.org). The same law-firm post cautions that in its author's experience CDRH review teams expect to review HF study results (www.thefdalawblog.com), so the framework should not be read as a general relaxation.

Change 2: Examples and report outlines

Practitioners report the examples now take three times the page count of the draft's (emergobyul.com). Trade press describes three appendices, one per category (www.raps.org), and scenarios including a duodenoscope and a stereotaxic navigation system (www.raps.org). In the guidance itself, Appendices A, B and C give report outlines for the three categories (for example Table A-1 for Category 1 (www.fda.gov)).

Change 3: Transition treatment

FDA recognized that the Agency and industry might need at least 60 days to operationalize the policies (www.fda.gov), and said it did not generally expect the newly recommended information in pending submissions or those received before August 1, 2026, while still intending to review such information if submitted at any time (www.fda.gov). The Federal Register notice carries the same language (www.federalregister.gov). This differs from the 2022 draft's notice, which referred to up to 60 days after publication of the final guidance (www.federalregister.gov). At the town hall, FDA confirmed a 60-day transition with implementation on August 1 (www.fda.gov), and added that earlier submissions are not expected to use the new eSTAR version (www.fda.gov). One consultancy summarizes the result as FDA having implemented the new recommendations on August 1, 2026 (www.freyrsolutions.com). Trade press also dated FDA's publication as May 28, while FDA's own documents say May 29; this report uses FDA's date (www.raps.org).

Change 4: eSTAR incorporation

FDA's eSTAR page carries an update dated June 1, 2026, stating the nIVD and IVD eSTARs now include the human factors content guidance (www.fda.gov). FDA describes a major version update as significant template revisions (www.fda.gov). The page currently lists nIVD and IVD eSTAR Version 7.1 (www.fda.gov). A trade-press report, based on the template at release, describes Version 7.0 released June 1, 2026 with a transition date of August 3, 2026 (www.emergobyul.com). The two dates describe different events: August 1, 2026 is when the content guidance takes effect, while the trade report gives August 3, 2026 as the eSTAR template transition date. The sources also differ on version number (7.0 versus 7.1); FDA's page carries no release notes for 7.1, so teams should open the current template and read its version history before filling it in. The same trade report says the template adds a Human Factors and Usability section within Performance Testing (www.emergobyul.com).

Change 5: Companion guidance reissued

The 2016 guidance file now reads "Document issued on August 3, 2026" and "originally issued on February 3, 2016" (www.fda.gov). Its revised text directs readers to the content guidance for what belongs in a submission (www.fda.gov). FDA staff also said they intended minor updates to the older guidance for consistency (www.fda.gov). The 2026 reissue is not compared here against the 2016 original, so the participant-number figures cited below are from the current text only.

Scope, Legal Status and Combination Products

Recommendation versus requirement

A reliable crosswalk separates what FDA recommends from what the law requires. FDA's good guidance practices regulation says guidance documents do not establish legally enforceable rights or responsibilities (www.law.cornell.edu), and that a sponsor may choose a different approach that complies with the relevant statutes and regulations (www.law.cornell.edu). The guidance itself says FDA guidances "should be viewed only as recommendations" unless specific regulatory or statutory requirements are cited (www.fda.gov), and an alternative approach is allowed if it satisfies the applicable statutes and regulations (www.fda.gov). Practically, four layers apply:

- **Recommendation layer:** the category framework, the HFE/UE report outline and the comparative analysis. These are "should" statements (www.fda.gov).
- **Process-record layer:** the guidance recommends retaining HF information whether or not it is submitted (www.fda.gov), and notes records must be kept as required by applicable law, including the Quality Management System Regulation (QMSR) (www.fda.gov). The QMSR took effect February 2, 2026 (www.fda.gov) and governs the design and labeling controls for finished devices intended for human use (www.law.cornell.edu); records are generally to be made available to an FDA investigator on request (www.fda.gov). FDA said at the town hall that fulfilling QMSR design-validation requirements is outside the guidance's scope (www.fda.gov).
- **Regulatory-text layer:** the content duties sit in the regulations, not the guidance. A 510(k) "shall contain" the information listed in 21 CFR 807.87 (www.law.cornell.edu), and FDA may request additional information it needs for a substantial equivalence finding (www.law.cornell.edu). A PMA's technical sections must contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval (www.law.cornell.edu). HDE (www.law.cornell.edu) and De Novo (www.law.cornell.edu) content rules each allow an omission only if justified. In the text reviewed, 21 CFR 807.87, 814.20, 814.104 and 860.220 do not name human factors, so the category framework is FDA's recommended way to meet general sufficiency duties, not a separately codified requirement.
- **Submission-mechanics layer:** the statute directs that device submissions, including those under the 510(k), De Novo and PMA provisions, be made in the electronic format FDA specifies in final guidance (www.law.cornell.edu). FDA's electronic-submission pages state eSTAR is required for 510(k) from October 1, 2023 (www.fda.gov) and for De Novo from October 1, 2025 (www.fda.gov). FDA's eSTAR page lists PMA use as voluntary (www.fda.gov), so the statute and the program page should be read together for PMA planning.

The guidance also does not decide when a marketing submission is required: it points to the change-assessment provisions for 510(k)s, HDE supplements and PMA supplements, and FDA said at the town hall that submitters should use the relevant 510(k) guidance documents for that decision (www.fda.gov). Device-specific guidances take precedence (www.fda.gov).

Submission types

The guidance covers 510(k)s, De Novo requests, PMAs and HDE applications (www.fda.gov), and also applies to modifications of 510(k)-exempt devices (www.fda.gov). FDA's landing page describes the framework as intended to promote consistency and facilitate efficient review (www.fda.gov). The eSTAR picture is narrower than the guidance scope, as *Table 3* in the Data Analysis section shows: eSTAR is mandatory for 510(k) and De Novo, voluntary for PMA (www.fda.gov), and the program page does not list HDE under either group. FDA's slides nonetheless state the guidance applies to HDEs (www.fda.gov).

Combination products

Combination products are excluded: the guidance says their additional risks and considerations are not addressed (www.fda.gov), and a footnote points to a separate combination-product human factors Questions and Answers document (www.fda.gov). The town hall echoed this: the two HF guidances are for medical devices "but not for combination products" (www.fda.gov). Separately, the eSTAR page states that mandatory

eSTAR use extends to 510(k) and De Novo submissions for combination products sent to CDRH or CBER (www.fda.gov). Reading both together, a combination-product team must use eSTAR where it applies yet should not assume the Category 1/2/3 framework governs its human factors package; confirm with the lead Center and review division.

Choosing Human Factors Submission Category 1, 2 or 3

The decision flow

FDA recommends one category per marketing submission (www.fda.gov), and, where a device has several modifications, that submitters consider them collectively (www.fda.gov). The flowchart has four decision points. *Table 1* below restates them with the evidence each outcome implies.

Decision point	Question (paraphrased)	Outcome	Evidence implied
A	Is this a modification of an existing authorized device (510(k), PMA, HDE or De Novo)? A new device can answer yes if it leverages the same or a similar user interface of the submitter's own marketed device (www.fda.gov).	Does not itself yield a category (www.fda.gov).	Establishes the comparison baseline for later analyses.
B	Have the user interface, intended users, intended uses, use environments, training or labeling changed (www.fda.gov)?	"No" gives **Category 1** (www.fda.gov).	Conclusion and high-level summary, with a statement that modifications do not affect HF considerations (www.fda.gov).
C	Does the use-related risk analysis (URRA) show critical tasks (new device) or new or impacted critical tasks (modified device)?	"No" gives **Category 2** (www.fda.gov).	Rationale for why the answer is no (www.fda.gov); report sections 1 to 4 (www.fda.gov).
D	Given user interface history of use (www.fda.gov), complexity (www.fda.gov) and adequacy of existing risk controls (www.fda.gov), should validation data be submitted (www.fda.gov)?	"No" gives **Category 2** with a rationale; "Yes" gives **Category 3** (www.fda.gov).	Detailed rationale (www.fda.gov) or comprehensive HFE/UE report with validation (www.fda.gov).

Table 1 shows why category selection is evidence-driven. Decision Point A is a framing step, not a verdict. Decision Point B is a change screen: any change to the six listed elements moves the file past Category 1. Because FDA counts a change in the number of steps in a critical task as potentially impacting that task (www.fda.gov), even a "small" workflow edit can change the answer at Decision Point C. FDA also recommends running the URRA on the final finished device, not only on the change, so upstream and downstream tasks are not missed (www.fda.gov).

Where discretion sits

Decision Point D is where FDA said sponsors have the most discretion (www.fda.gov). FDA declined to define a complex interface, calling complexity resistant to binary categorization (www.fda.gov), and described the considerations as a totality-of-evidence assessment (www.fda.gov). Validation data are likely needed for

complex interfaces or device types historically associated with use errors, with infusion pumps given as an example (www.fda.gov). FDA may also require data if there is a significant difference from similar devices (www.fda.gov) or an increase in severity of potential harm from use error (www.fda.gov). For impacted critical tasks with unchanged controls, a rationale needs objective evidence that the controls remain effective (www.fda.gov). One consultancy reads the final text as meaning a "no" at Decision Point D no longer necessarily points toward Category 3 (humanfactors.ca). FDA told submitters unsure whether a rationale will suffice to seek Pre-Submission feedback (www.fda.gov).

Evidence Inventory and eSTAR Crosswalk

The four building blocks

- **Use-related risk analysis (URRA):** systematic use of information to identify use-related hazards and estimate use-related risk (www.fda.gov). FDA's presenters said it should include all user tasks (www.fda.gov) and the guidance calls it a living document (www.fda.gov). The URRA document itself belongs in the Category 3 report (www.fda.gov).
- **Critical tasks:** tasks that, if performed incorrectly or not at all, would or could cause serious harm to the patient or user (www.fda.gov). The report should categorize them by severity of potential harm (www.fda.gov).
- **Comparative use-related risk analysis:** for modified devices, a comparison of the modified and existing URRAs (www.fda.gov), covering at minimum all tasks in the use scenarios relevant to the modifications (www.fda.gov). FDA said it identifies change in risk and can support categorization, particularly Category 3 (www.fda.gov).
- **HF validation testing and the HFE/UE report:** validation is one portion of design validation (www.fda.gov); FDA notes "summative testing" is sometimes used for it, with differing definitions (www.fda.gov). HFE and UE are treated as interchangeable terms (www.fda.gov).

Report sections by category

Table 2 below crosswalks the report sections to the categories and to the eSTAR prompts that FDA's slides describe. The eSTAR column is built from FDA's slides, transcript and a trade report; the template PDF itself was not reviewed, so on-screen field names should be confirmed in the current template.

HFE/UE report section	Cat. 1	Cat. 2	Cat. 3	Typical internal source document	eSTAR note
1. Conclusion and high-level summary, including residual risk discussion (www.fda.gov)	Yes (www.fda.gov)	Yes	Yes	Design validation summary; risk management report	Category dropdown or "Guide Me" (www.fda.gov); Category 1 is conclusion and summary only (www.fda.gov)
2. Intended users, uses, environments, training (www.fda.gov)	Summary level only	Yes	Yes	Intended-use and user-profile documents	Cross-reference allowed where already in the device description (www.fda.gov)

HFE/UE report section	Cat. 1	Cat. 2	Cat. 3	Typical internal source document	eSTAR note
3. Device user interface description, with comparison to the existing device for modified devices (www.fda.gov)	Summary level only	Yes	Yes	UI specification, labeling, screenshots	Fillable boxes should point reviewers to where information sits (www.fda.gov)
4. Known use problems (www.fda.gov)	Summary level only	Yes	Yes	Post-market surveillance review; predicate and prior-model literature	State explicitly if none are known
5. Preliminary HFE/UE analyses and evaluations (www.fda.gov)	No	No	Yes	Formative evaluation reports	Documented locations in eSTAR
6. URRA, with comparative URRA for modified devices (www.fda.gov)	No	Underlying analysis supports the Decision Point C answer	Yes	URRA / hazard analysis traceability matrix	Living document
7. Critical tasks (www.fda.gov)	No	Basis for "no critical tasks" claim	Yes	Critical task list with severity categories	Severity scale described in the report
8. Validation testing of the final design (www.fda.gov)	No	No (rationale instead)	Yes	Validation protocol, scripts, forms, results	Full protocol and sample scripts appended (www.fda.gov)

Table 2 should be read as a minimum map, not a checklist of everything FDA might ask. For Category 2, the content is a rationale rather than a report, and FDA recommends a "detailed rationale for why human factors validation should not be" submitted. For Category 1, only a conclusion and high-level summary are recommended. Previously reviewed HFE/UE evaluations should not be resubmitted; a cross-reference may help (www.fda.gov). The report summarizes evaluations and does not typically include all raw data from validation testing (www.fda.gov).

Validation testing expectations

The final content guidance defers testing method to the companion guidance. Section 8 of the report asks for a rationale for test type (simulated use, actual use or clinical study) (www.fda.gov). The current text of the companion guidance states that validation is generally conducted under simulated use (www.fda.gov), that participants represent intended actual users (www.fda.gov), that all critical tasks are performed (www.fda.gov), and that the testing should include at least 15 participants from each user population (www.fda.gov). Pediatric and adult users of one device are treated as distinct populations (www.fda.gov). "Think aloud" is acceptable in formative evaluation but not in validation testing (www.fda.gov). Manufacturer employees should generally not serve as participants (www.fda.gov), participants for U.S. users should reside in the U.S. (www.fda.gov), training given should approximate real-world training (www.fda.gov), and testing should not follow training immediately because retention decays (www.fda.gov). Critical task performance is measured by observation (www.fda.gov), while knowledge tasks can be assessed by questioning participants (www.fda.gov).

For modified devices, FDA says the validation test may be limited to aspects of users' interactions affected by the modification (www.fda.gov), consistent with the companion guidance that testing can focus on modified aspects of use (www.fda.gov). The need for additional validation depends on the risk analysis of the modification (www.fda.gov).

Implementation Considerations and Process Changes

Gap-assessment workflow and document controls

A practical workflow for an existing usability-engineering file has six steps. Each step produces a controlled record; the numbering below is this report's suggestion, not an FDA sequence.

- **Step 1, baseline the device:** identify the authorized device, or the same-submitter device whose user interface is leveraged. Record the submission number and report section for any earlier HFE/UE evaluation you intend to cross-reference.
- **Step 2, run the change screen:** list every change to the user interface, users, uses, environments, training and labeling. Consider changes collectively.
- **Step 3, refresh the URRA on the finished device:** update the URRA across all tasks and re-categorize critical tasks by severity. Count step additions or removals as potential impact.
- **Step 4, assess Decision Point D:** document history of use, complexity and control adequacy, and the objective evidence for any rationale.
- **Step 5, assemble by category:** populate report sections per *Table 2* and decide where each lives in the submission; FDA wants locations documented in eSTAR.
- **Step 6, release gate:** a regulatory lead signs that the eSTAR category selection, attached documents and report conclusion agree. This matters because FDA intends to verify the accuracy of responses (www.fda.gov) and an eSTAR can be placed on technical screening hold for up to 180 days (www.fda.gov).

Document-control points: keep one controlled copy of the HF information regardless of whether it is submitted; version the URRA as a living document; retain the evidence behind each Category 2 rationale; and keep attachment names within the 124-character limit (www.fda.gov), with attachments under 1GB each and 4GB per eSTAR (www.fda.gov). FDA does not expect a properly prepared eSTAR to go through Refuse to Accept review, but technical screening still applies (www.fda.gov). If a team prepared a submission on a prior eSTAR major version, FDA says previous versions may continue where major changes do not affect the device (www.fda.gov); given that the human factors section is new, check this against the specific template.

An evidence-gap tracker needs only six columns: evidence item, category it supports, guidance section, owner (role), status (not started, drafted, reviewed, filed) and eSTAR location. Typical gaps found when a legacy file is mapped to *Table 2* are a URRA that covers only the changed function, a Section 4 known-use-problem summary that was never written, and a rationale with no objective evidence.

Worked examples

FDA's own examples anchor the three scenarios requested by software teams, device engineers and new-device sponsors.

- **Software user interface change.** In FDA's anesthesia gas machine example, a font size increase from 12 to 14 with a larger screen leaves layout and format unchanged and no critical task impacted, so it is Category 2 with a rationale that may rest on formative data (www.fda.gov). An algorithm-only change to a lesion-detection device with no user interface change is Category 1 (www.fda.gov). Contrast an augmented reality interface added to a stereotaxic navigation system, which FDA treats as more complex than existing 2D interfaces, so validation data are needed (www.fda.gov).
- **Physical control change.** In the same gas machine, replacing a physical knob with a digital slider changed the interaction (www.fda.gov); FDA judged the interface complex enough that validation data should be submitted, making it Category 3 (www.fda.gov). Adding a new user group (for example pediatric users) triggers Category 3 even with no interface change (www.fda.gov).
- **New device.** A blood lancet with critical tasks but low-complexity, long-established interface components is Category 2 (www.fda.gov). A guided ultrasound whose intended users include professionals unfamiliar with the technique is Category 3 (www.fda.gov). A new stent delivered by an unchanged balloon catheter system is Category 1 because the delivery system is the same as approved (www.fda.gov).

(Hypothetical Example) A team plans a mobile app update that reorders the screens of a dose-confirmation workflow, adds a pediatric caregiver user group, and leaves hardware unchanged. Decision Point B is "yes" (interface and user group). The URRA likely shows impacted critical tasks (dose confirmation), and a new user group is a pattern FDA illustrates as triggering validation, so the planning assumption would be Category 3 with a validation cohort for each distinct user population. This illustration is the report's, not FDA's.

Review gates and questions for FDA

FDA says device-specific questions go through the Pre-Submission pathway (www.fda.gov). A Pre-Submission is not a pre-review of a submission or of data (www.hhs.gov). The Q-Submission guidance (current copy dated May 29, 2025 (www.hhs.gov)) includes sample HF questions: whether a validation protocol is adequate (www.hhs.gov), whether the participant recruitment plan is adequate (www.hhs.gov), and whether the URRA plan is adequate (www.hhs.gov). Written feedback is due 70 calendar days after receipt in the MDUFA V commitment (www.fda.gov), or 70 days or 5 days before the meeting, whichever is sooner (www.hhs.gov). A consultancy recommends using the program when there is uncertainty about category selection or testing expectations (www.exponent.com). Good questions to pose: whether FDA agrees with the proposed category, whether a Category 2 rationale is sufficient, which tasks FDA considers critical, and which participant populations should be separate.

How practitioners read the framework

Independent commentary is largely consistent with FDA's text, with differences of emphasis. These are secondary sources and should not replace the guidance.

- **Decision Point D:** consultancies call it the most impactful structural change (mdxcro.com) and say the rationale should directly address the applicable decision point (gardner.law). Another describes category assignment as still requiring sponsor judgment (novapharmanews.com).

- **Category 2 scope:** a human-factors consultancy notes some modified devices may fall into Category 2, which does not require validation testing (www.loring-hf.com). A caution from another consultancy: choosing not to submit validation data does not make the underlying work optional (mflrc.com).
- **Comparative analysis:** commentators say comparative analyses may help support reliance on prior information (gardner.law) and that FDA gave added instruction on the comparative URRA for modified devices (www.loring-hf.com). One goes further and calls a Table 3 style comparative URRA the new norm for any modification (www.cosmhq.com); the guidance itself recommends it for modified devices but frames it as a recommendation.
- **The URRA as backbone:** several sources treat the URRA as the backbone of the submission (mdxcro.com) or the engine of the process (mflrc.com), and say the URRA and critical-task rationale become the load-bearing documents (hfdesignworks.com). FDA's own advice is to assess the URRA on the whole finished device, echoed in practitioner summaries (medqair.com).
- **Justification and evidence:** a regulatory consultancy says a rationale should include objective evidence that risk controls remain effective (www.donawa.com), tracking the guidance text, and another says a clear rationale supported by a URRA is required (www.cloudtheapp.com).
- **Process advice:** commentators recommend planning human factors work earlier (www.cloudtheapp.com), keeping one controlled record early in submission planning (intelasolve.com), and recording the decision points for every software release (medqair.com). The last of these matches the document-control step proposed in this report.
- **eSTAR:** one consultancy says the templates now require a category selection (www.lexim.ai) and another calls the category a mandatory eSTAR field (meddeviceguide.com). FDA's own materials describe a "Guide Me" or direct-selection route; the template should be checked directly to see which fields block submission.
- **Pre-Submission:** commentary points submitters toward the Pre-Submission program rather than guessing (www.lexim.ai), consistent with FDA.

A cautionary note on dates: one practitioner advises planning as though August 1, 2026 is the effective date (www.cosmhq.com), and another describes the transition as covering submissions already under review or received before that date (www.loring-hf.com). Both match the guidance's wording (www.fda.gov).

Standards and non-U.S. context

FDA's content guidance aligns its user interface definition with ANSI/AAMI/IEC 62366-1 (www.fda.gov), and the FDA recognition database lists the IEC 62366-1 Edition 1.1 consolidated version (www.accessdata.fda.gov). The IEC store describes the standard's process as evaluating the usability of a medical device as it relates to safety (webstore.iec.ch), notes that the consolidated edition combines the 2015 first edition and its 2020 amendment (webstore.iec.ch), and states that it does not assess or mitigate risks associated with abnormal use (webstore.iec.ch). A 2025 edition of the companion AAMI human factors standard is described by ANSI as covering general principles and attribute-specific principles (blog.ansi.org). Teams should confirm in FDA's database which editions are currently recognized, because the guidance points readers there for current editions.

Regulators elsewhere express related expectations in different forms, which matters for global filers reusing a usability-engineering file. EU Medical Device Regulation Annex I sets duties for reducing risks related to use error (eur-lex.europa.eu) and refers to design for lay, professional, disabled or other users (eur-lex.europa.eu). The UK MHRA's human factors guidance states it does not represent a compliance requirement (assets.publishing.service.gov.uk) and asks summative studies to include representatives from all identified user groups (assets.publishing.service.gov.uk). Australia's TGA guidance expects human factors testing with a representative sample of intended users where applicable (www.tga.gov.au). None of these replaces the FDA category decision, and no equivalence of category logic across jurisdictions is claimed here.

Data Analysis and Evidence

Scope and eSTAR status by submission type

Table 3 below consolidates the scope facts.

Submission type	In guidance scope	eSTAR status (FDA program page)	Notes
510(k)	Yes	Mandatory since October 1, 2023	Applies to modifications of 510(k)-exempt devices too
De Novo	Yes	Mandatory since October 1, 2025	Must use the CDRH Portal (www.fda.gov)
PMA	Yes	Voluntary	nIVD and IVD eSTARs cover PMA (www.fda.gov)
HDE	Yes (www.fda.gov)	Not listed on the program page as mandatory or voluntary	Slides state HDEs are in scope
Combination products	Not addressed	eSTAR mandatory for 510(k) and De Novo combination products	Contact Center and review division

Table 3 highlights a three-way mismatch for HDE and PMA teams: the guidance applies, but the eSTAR mechanics are voluntary or unlisted. Those teams should still follow the framework in the narrative section of their submission and confirm format expectations with their review division.

Review clocks and volumes

Available FDA data give context for planning. The MDUFA V commitment letter sets goals of a decision within 90 FDA days for 95% of 510(k)s (www.fda.gov), 150 FDA days for 70% of De Novo requests (www.fda.gov), and 180 FDA days for 90% of PMAs without advisory committee input (www.fda.gov). FDA's fiscal 2025 report lists 4,151 510(k)s received against a five-year average of 3,881 (www.fda.gov), and 4,502 Pre-Submissions, 26% above average (www.fda.gov). These figures describe FDA workload, not the share of submissions with human factors content; FDA did not publish such a share in the sources reviewed.

Planning calculator (assumptions, not an FDA benchmark)

The only numeric participant figure in the sources is the companion guidance's minimum of 15 per user population. The calculator in *Table 4* multiplies it by the number of distinct populations; the 10% recruitment buffer is an assumption of this report, not an FDA recommendation, and the critical-task counts are invented inputs.

Scenario (Hypothetical Example)	User populations (U)	Minimum participants = 15 × U	Recruit with 10% buffer (assumption)	Critical tasks (C)	Critical-task observations = min. participants × C
Single professional group	1	15	17	8	120
Lay user plus caregiver	2	30	33	10	300
Pediatric, adult and clinician	3	45	50	12	540

Table 4 is a sizing aid for budgeting and scheduling. Use environments, training arms, repeat devices and any FDA feedback may change the real number. The statistical rationale in the companion guidance's appendix is that a sample of 15 detected a minimum of 90% and an average of 97% of problems in the cited study (www.fda.gov), with 30 users detecting less than 2% more (www.fda.gov). Independent literature shows the limits of this logic: a resampling study of 60 users found sets of 5 found between 55% and 99% of problems and sets of 20 reached at least 95% (pubmed.ncbi.nlm.nih.gov); earlier work reports diminishing returns with sample size (pubmed.ncbi.nlm.nih.gov); and a 2022 analysis argues the decision rule used to size usability tests has statistical limitations (pubmed.ncbi.nlm.nih.gov), with the expected net benefit of sampling reaching zero after 90 participants in their example (pubmed.ncbi.nlm.nih.gov). A peer-reviewed review argues that no a priori cohort size can guarantee a reliable assessment (research.utwente.nl). A peer-reviewed paper restates that usability testing is mandatory for market access (pmc.ncbi.nlm.nih.gov), though that statement is the authors' framing, not FDA's wording. A published example of a summative test with 15 intended users shows the common practice in the literature (humanfactors.jmir.org), and the literature describes formative testing as primarily conducted during design and development (humanfactors.jmir.org).

Implications and Future Directions

For teams filing after August 1, the main shift is that evidence packaging is now explicit and tied to a category dropdown. The framework rewards a living URRA and a maintained comparison against the existing device, since both determine Decision Points C and D. It also moves effort from "run a study by default" toward "justify the decision either way", which raises the value of objective evidence for rationales.

Open points to monitor as of November 2026:

- **Version drift:** FDA lists eSTAR 7.1 while a trade report describes 7.0 at release. Check release notes before each submission.
- **Newer Q&A:** only the town hall transcript and slides were identified, with no separate FAQ document issued afterward; the search was not exhaustive.

- **Companion guidance revisions:** FDA said it intended to update the older guidance, and its file now carries an August 2026 date.
- **HDE and PMA mechanics:** eSTAR status for these types is voluntary or unlisted.

A practical suggestion is that the category framework is most useful when software and human-factors teams share one traceability record, so that a UI ticket automatically triggers the Decision Point B and C screen. That is an operating suggestion, not an FDA position.

Frequently Asked Questions (FAQs)

What human factors information does a 510(k) need? The guidance recommends content scaled to the category: a conclusion and summary (Category 1), a rationale with report sections 1 to 4 (Category 2), or a full HFE/UE report with validation (Category 3). These are recommendations.

Does the guidance apply to De Novo and PMA? Yes, and to HDE. eSTAR is mandatory for De Novo and voluntary for PMA.

When is human factors validation data required? The guidance is nonbinding, but FDA recommends submitting validation data when critical tasks are present or impacted and Decision Point D leads to yes. FDA may still request data in specific cases.

Is "summative evaluation" the same as validation testing? FDA notes "summative testing" is sometimes used for validation testing but can be defined differently.

Is there an HFE report template? Appendices A, B and C give sample outlines for the three categories.

What happened to submissions received before August 1? FDA did not generally expect the new information but would review it if submitted.

How are combination products handled? They are outside the guidance.

Conclusion

The May 29 guidance and June 1 eSTAR update give regulatory and human-factors teams a usable structure: one category per submission, four decision points, report sections 1 to 8 scaled by category, and an eSTAR flow that either guides the choice or accepts it directly. An existing usability-engineering file is submission-ready when it can answer the Decision Point B and C screens against the finished device, supports any Category 2 rationale with objective evidence, and, for Category 3, contains a URRA, critical task list and validation report mapped to *Table 2*.

Limitations of this report: the eSTAR template itself and its on-screen field names were not read; the QMSR design-validation provisions incorporated from ISO 13485 were not read directly; no FDA statistic on HF deficiencies or eSTAR adoption was found; and the planning calculator rests on stated assumptions. Treat the crosswalk as a starting point and confirm device-specific decisions with FDA through a Pre-Submission and with qualified regulatory counsel.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/media/163694/download
2. https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program
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