Content of Human Factors Information in Medical Device Marketing Submissions, Final Guidance
July 22, 2026

Moderator: CAPT Kim Piermatteo
Presenters: Andrea Fiala and Anthony Maiorana PhD

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CAPT Kim Piermatteo: Hello everyone and welcome to this CDRH town hall event. This is CAPT Kim Piermatteo of the United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within FDA's Center for Devices and Radiological Health. I'll be the moderator for today's event.

Today we will be discussing the final guidance titled, Content of Human Factors Information in Medical Device Marketing Submissions, which issued on May 29, 2026. This guidance provides a risk-based approach to human factors assessment and guide manufacturers and FDA staff on the human factors information that should be included in a marketing submission to CDRH to facilitate the efficiency of the FDA review process.

I'd now like to introduce our presenters who are from CDRH's Office of Product Evaluation and Quality, specifically the Human Factors Team and they are, Andrea Fiala, General Engineer, and Dr. Anthony Maiorana, Acting Team Lead.

After today's presentations we will have a question and answer segment, where we provide responses to questions regarding the final guidance that were previously submitted in advance of this town hall event.

Before I turn it over to Andrea, I'd like to remind everyone, the intended audience for this event is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom.

Thank you all again for joining. I'll now turn it over to Andrea.

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Andrea Fiala: Thank you Kim. Welcome everyone, and thanks for joining us today.

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Andrea Fiala: Today's topic will be about the recent FDA Guidance titled Content of Human Factors Information in Medical Device Marketing Submissions. We will refer to this guidance for the remainder of the presentation as the Human Factors Content Guidance. Please note, that this guidance was finalized on May 29, 2026 with a 60-day transition period, so this new guidance will be implemented on August 1, 2026.

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Andrea Fiala: In today's town hall our primary learning objectives are: an overview of FDA's two human factors guidance documents; a description of the risk-based approach to help submitters determine what human factors information they should include in a marketing submission; an overview of human factors related submission content and the associated Human Factors Submission Categories; and using the logic and flowchart to identify a Human Factor Submission category (1, 2 or 3). Additionally, we want to emphasize that the Human Factors Content Guidance does not replace the existing Human Factors Guidance and does not eliminate the requirement for conducting risk management activities, but rather provides guidance on how to communicate human factors information and use-related risk management activities to FDA. Finally, we provide an overview of corresponding updates to eStar.

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Andrea Fiala: So let's start with an overview of the human factors guidances.

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Andrea Fiala: The Human Factors Guidance provides FDA's recommendations to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that the new medical device will be safe and effective for the intended users, uses and use environments.

The Human Factors Content Guidance provides a risk-based approach for determining what human factors information to provide in marketing submissions including Premarket Notifications or 510(k)s, De Novos, Premarket Approval Applications or PMAs, and Humanitarian Device Exemptions or HDEs. This guidance is complementary to the Human Factors Guidance.

The new Human Factors Content Guidance focuses on the level of documentation provided in marketing submissions while the Human Factors Guidance focuses on the application of human factors principles during the device development process.

The Human Factors Content Guidance does not replace nor eliminate the requirement for conducting risk management activities, but provides guidance on how to determine what documentation of human factors processes should be included in a marketing submission provided to FDA.

The Human Factors Content Guidance aims to improve efficiency for both FDA and sponsors by establishing clear expectations through the implementation of a risk based approach to human factors submission categories. The recommended structure for reporting human factors information is intended to reduce requests for additional information and provide consistency in determining when additional information is needed.

Upon the implementation date of the Human Factors Content Guidance, we intend to update the Human Factors Guidance with minor updates to ensure consistency between these two human factors guidance documents.

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Andrea Fiala: So let's now further discuss the risk-based approach to human factors information in marketing submissions and an overview of the human factors submission categories.

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Andrea Fiala: The new Human Factors Content Guidance recommends utilization of a use-related risk analysis or URRA to systematically identify use-related hazards and to estimate the use-related risk. An example of the URRA in the format recommended in Table 2 from the Human Factors Content Guidance

is shown here on the slide for original or new devices. The URRA incorporating risk analysis approaches such as Failure Mode & Effect Analysis, analysis of known use problems, and formative evaluations should be referenced for Human Factors Submission Category 3. The URRA should include all user tasks and identify those considered to be critical tasks.

A URRA is intended to be living in that it is updated as new risks and hazards are discovered during the device design process.

Table 3 from the Human Factors Content Guidance is similar, but is intended to identify change in risk for modified devices through a comparative analysis. These changes may be critical or important during device design and development activities and can be used to support human factors categorization in a marketing submission, in particular those for Human Factors Submission Category 3.

For completeness of definitions, please refer to the device Human Factors guidances.

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Andrea Fiala: As described in the Human Factors Content Guidance, there are three human factors submission categories. The guidance uses a flowchart, appendices, tables, and examples to guide submitters through a risk-based approach to help submitters determine what human factors information to include in their marketing submission. After walking through the flowchart logic, we will apply it to some examples.

Category 1 is for modified devices where there is no impact to the overall use of the device, and therefore such changes do not affect the human factors assessment. Category 1 may also be appropriate when the new device has the same or similar user interface as one of a sponsor's own legally marketed devices and they are leveraging human factors information from their marketed device for the new device. Therefore, only a human factors conclusion and high-level summary are recommended for the marketing submission.

Category 2 could encompass many different situations, but is mainly focused on scenarios where there is a change that affects the human factors assessment, but for reasons further described in the upcoming slides, we recommend submission of a detailed rationale for why human factors validation should not be submitted based on analysis of critical tasks, user interface, and existing risk control measures.

Category 3 is for when human factors validation testing needs to be submitted to and reviewed by FDA. Before we dive into the flowchart logic to determine the appropriate human factors Submission category, it's important to note that a manufacturer's internal documentation of risk management, human factors engineering, and design optimization processes can help provide evidence, where appropriate, that the needs of the intended users were considered in the design and that the device is safe and effective for the intended users, uses, and use environments.

The Quality Management System Regulation requires that manufacturers of certain finished devices verify and validate device design, review and approve changes to device design, and document changes and approvals in the design and development files. We recommend that human factors information be maintained by the manufacturer regardless of whether it is submitted to FDA. Manufacturers must keep records to the extent required, including the Quality Management System Regulations.

The next few slides describe decision making for the human factors information that may be appropriate for submission to FDA in a marketing submission. The amount and type of information in the submission is considered within the context of the device history, risk profile, and reason for the submission.

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Andrea Fiala: Next I'm going to discuss the decision-making flowchart and human factors submission categorization.

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Andrea Fiala: The initial flowchart question asks if the submission is for a modification to an existing FDA-authorized medical device. The response to this question could also be yes when the new device has the same or similar user interface as one of your own legally marketed devices and you are leveraging human factors information from this legally marketed device for the new device, if yes, move to Decision Point B.

If this is a completely new device without prior FDA authorization, or there is no legally marketed device of their own with a similar interface to leverage human factors information, then the answer to decision point A is no and the sponsor should move to Decision Point C.

Decision Point A does not provide a categorization yet.

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Andrea Fiala: Decision Point B, is there a change to any of the following: user interface, intended device users, intended device uses, intended use environments, training, or labeling.

If none of these aspects are impacted by the changes, you answer no to Decision Point B and fall within Human Factors Submission Category 1, for which we recommend a conclusion and high level summary only. The submission should include a statement justifying that the device modifications do not affect the human factors considerations of the modified device. If previous human factors engineering or usability engineering evaluations are being leveraged, these should be described as part of the conclusion and high-level summary.

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Andrea Fiala: For Decision Point C, we are considering risk analysis and critical tasks.

For a new device, based on the use-related risk analysis of the user tasks associated with the device, are any considered to be critical tasks?

For modified devices, are there new critical tasks introduced, or are there impacts to existing critical tasks?

If you answer no to Decision Point C, you fall within Human Factors Submission Category 2 and should provide a rationale that clearly describes the basis of this decision that there are no critical tasks for a new device, or no new critical tasks introduced and no impacted critical tasks for a modified device.

If you answer yes to Decision Point C, move to Decision Point D.

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Andrea Fiala: Decision Point D, given considerations related to the history of the user interface for the intended use/users and environments, the complexity of the device user interface, and the adequacy of existing risk control measures, should new human factors validation testing be submitted to FDA?

If the answer is no to Decision Point D, the submitter should submit a rationale that clearly describes the basis of their decision to not submit human factors validation in the marketing submission, including a

discussion of the identified considerations impacting the decision. If the answer is yes to Decision Point D, a full Human Factors Engineering or Usability Engineering Report with validation testing would be recommended. This is appropriate for Human Factors Submission Category 3.

This decision point is where there is the most discretion. Some manufacturers may choose to submit a URRA to support their decision, while others may find it unnecessary. Section 6 of the Content Guidance provides a number of examples that illustrate the different factors that could go into the decision making at this point.

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Andrea Fiala: Now let's discuss what to provide for each human factors submission category and how to provide the documentation in CDRH's electronic Submission Template and Resource or eSTAR.

Slide 17

Andrea Fiala: Once a sponsor or manufacturer has determined their human factors submission category, the Human Factors Content Guidance in Section V provides a comprehensive discussion on what FDA expects in a premarket submission for each submission category. This slide summarizes that information at a high level. In the guidance, there are also summaries provided in Appendices A, B, and C for each Human Factors Submission Category. Notice that the level of evidence to provide for each human factors submission category builds upon the lower categories as part of the risk-based approach identified in the Content Guidance.

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Andrea Fiala: To support the implementation of the Human Factors Content Guidance a new version of eSTAR has been released reflecting the guidance recommendations. The Human Factors section of eSTAR has an option for sponsors to choose "guide me" and eSTAR will walk them through the previously described decision points for categorization.

eSTAR also allows sponsors and manufacturers to make their own categorizations immediately if they already know their category based on their own analysis.

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Andrea Fiala: In this example, the sponsor has determined they are Category 2 and eSTAR then prompts them to provide their documentation for how they are supporting this decision. The sponsor should provide a report containing each piece of information or identify the location of the recommended human factors information as identified in report sections 1 through 4, elsewhere within the submission.

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Andrea Fiala: For Human Factors Submission Category 3, we anticipate that the sponsor or manufacturer will provide a full Human Factors Engineering or Usability Engineering report. For completeness we are looking for the information provided for Human Factors Submission Category 2 as well as the following a summary of preliminary Human Factors Engineering or Usability Engineering analyses and evaluations; a use-related risk analysis or URRA; an analysis of hazards and risks; an identification and description of critical tasks; and details of the human factors validation testing of final design.

A Human Factors Engineering report might contain all of the above in a single document, but some of this information may also be spread across other sections or areas and their location should be documented in eSTAR to facilitate FDA's review.

I'll now turn it over to Tony to discuss some examples from the guidance.

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Dr. Anthony Maiorana: Thanks Andrea.

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Dr. Anthony Maiorana: Now that we have covered the thought logic or risk-based approach and eSTAR overview, we can cover some practical examples, which are included in the HF Content Guidance, Section VI.

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Dr. Anthony Maiorana: A sponsor has a 510(k) cleared gastrointestinal lesion software detection system and the submission is for a modification to the device's detection algorithm's ability to detect a lesion but does not change aspects of the user interface.

This is an HF Category 1 example where a sponsor submitted a 510(k) for an algorithm improvement. This is a modification of an existing device with no impact to the user, user interface, uses, use environment, or labeling. The sponsor should provide a statement justifying that the device modifications do not affect the human factors considerations of the modified device and the conclusion and a high-level summary of HF evaluation, as prompted in the eSTAR. The next slide provides an example of how simple this explanation could be for this type of change.

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Dr. Anthony Maiorana: As shown by this example, the first paragraph describes the conclusion, while the second provides a high-level summary of their HF evaluation.

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Dr. Anthony Maiorana: An implantable infusion pump with a physician programmer was approved through a PMA. A supplement is submitted for an expansion of the volume of the pump reservoir.

This is a modification to an existing device with changes to labeling and software to reflect the new reservoir volume. There is no change to the medication concentration, dosing calculations, or programming of the pump by the physician. Therefore, at Decision Point C, there are no new critical tasks introduced or impacted by the device change. This type of change would be appropriate for HF Category 2. Within eSTAR the sponsor would document how they are supporting this categorization using the prompts to identify where the recommended information is located within the submission.

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Dr. Anthony Maiorana: Next, a 510(k) for a new blood lancet intended for a single use to puncture the skin to obtain a drop of capillary blood. The device design includes an integral sharps injury prevention feature in the form of a spring-loaded auto-retracting blade, which allows the device to be used once and then renders it inoperable of further use.

The submitter compares their device with the predicate device and demonstrates that the indications for use, use environment, and users are the same between the two devices. Moving through decision points, this is a new device and there are critical tasks present, but the sponsor does not need to submit HF validation test data because the subject device design incorporates user interface components that are of low complexity and similar to existing legally marketed devices with the same intended use. There are no

major differences in the technology compared to the predicate and the labeling is comparable to the predicate. Therefore, we arrive at HF Category 2.

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Dr. Anthony Maiorana: This example relates to the implantable infusion pump previously discussed on Slide 25, Example B.1. However, instead of changing the reservoir, they are changing the programming interface, moving from a monochrome screen to a mini tablet computer with a touchscreen, full color, and new menu icons.

Going through our decision point list, this is a modified device that changes the user interface, as well as making updates to the relevant training and labeling, and impacts critical tasks for a device with a complex user interface and a history of known use errors.

Therefore, this is HF Category 3 and we would expect a full HFE report including a Use-Related Risk Analysis, HF validation protocol, and test results and analysis from a new HF validation study. Similar to the other categories, the information could be compiled into a single report and attached within eSTAR, or the location of the elements within the submission could be documented in eSTAR.

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Dr. Anthony Maiorana: The HF Content Guidance published on May 29, 2026 where we identified an implementation period of at least 60 days after final guidance publication. The new version of eSTAR is available as of June 1, 2026 for sponsors to start using to prepare future submissions.

The guidance will be implemented on August 1, 2026. For submissions received before August 1, sponsors are not expected to include the newly recommended information outlined in the guidance in their submission and are not expected to use the new version of eSTAR. However, we do intend to review newly recommended information if it is submitted to us at any time.

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Dr. Anthony Maiorana: There are now two Human Factors Guidance documents that complement each other to be used for medical devices, but not for combination products.

The use-related risk analysis and comparative use-related analysis are described in Tables 2 and 3 of the Human Factors Content Guidance and are recommended for inclusion in submissions to support Human Factors Submission Categories 3. However, they are generally important to systematically identify use-related hazards and to estimate the use-related risk.

The flowchart and associated text in the HF Content Guidance provides a logic to guide industry and FDA on how to categorize the HF information to provide in marketing submissions. There are also examples and appendices which provide helpful information.

Finally, there are updates to eSTAR that will either guide sponsors through how to choose appropriate HF submission categorization, and once determined, walk through the content to provide in their marketing submission.

Thank you for your time and attention, we are now going to move to our Q&A segment.

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CAPT Kim Piermatteo: Thank you Tony and Andrea for your presentations. As Tony mentioned, we will now transition to the previously submitted questions segment of today's event.

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CAPT Kim Piermatteo: For this town hall, I'll read a previously submitted question regarding today's topic and then ask Tony or Andrea to provide a response.

So for our first question, I'll be directing that to Tony and Tony the question is, how does the new guidance document on Content of Human Factors Information in Medical Device Marketing Submissions affect design validation requirements identified in ISO 13485:2016, Clause 7.3.7. incorporated by reference into the QMSR, therefore, does accomplishing the recommendations in the new guidance fulfill the requirements in the ISO quality management standard?

Dr. Anthony Maiorana: Thanks for the question, Kim. The HF Content Guidance provides recommendations on what human factors information to include in marketing submissions to CDRH. However, fulfilling the requirements for the quality management system regulation, which incorporates the 2016 edition of ISO 13485 by reference, is not within the scope of this guidance. A manufacturer's internal documentation of risk management, human factors engineering, and design optimization processes can help support the development of the human factors information described in the Human Factors Content Guidance.

CAPT Kim Piermatteo: Thanks Tony. Alright, Andrea, the next question I'm going to come to you and that one is, is it correct to say that Human Factors Submission Categories do not affect test design? That is to say, a device in Human Factors Submission Category 1 would be subject to the same standard of validation testing as a similar device in Human Factors Submission Category 3?

Andrea Fiala: Yep, that's right. So to reiterate, the scope of the Human Factors Content Guidance is limited to recommendations on what human factors information to include in a marketing submission to CDRH. The specific level of human factors documentation recommended in your submission is what the human factors submission category determines, not what human factors processes should be applied.

For recommendations on the application of human factors and usability engineering processes, which are applicable to the development of all medical devices, you should refer to the final guidance titled Applying Human Factors and Usability Engineering to Medical Devices.

We would like to also emphasize that human factors should be considered and integrated into design and development and risk management activities, regardless of whether human factors validation test data are submitted to FDA. Device manufacturers subject to the design and development requirements in ISO 13485, Subclause 7.3.3, which is design and development inputs, must comply with the regulation and should follow their internal processes and procedures to determine when to conduct human factors validation testing.

CAPT Kim Piermatteo: Thank you Andrea. Tony, the next question I have you for is, are all three criteria in Decision Point D equally important or is there a hierarchy?

Dr. Anthony Maiorana: Thanks Kim. That's a great question. So the considerations listed in Decision Point D of the flowchart are really intended to be part of a holistic, totality-of evidence assessment in which submitters examine multiple considerations, you know, including but not limited to the three factors that we have listed, which is the, which are the user interface, the history of use and you know history of use for the intended use, the users and use environments, you know, device user complexity, and the adequacy of the existing risk control measures alongside you know others such as intended user characteristics, technological features, user familiarity, clinical impact of use and the use environment.

So there's examples in Section VI of the guidance illustrate that those examples illustrate some of these different considerations that carry, you know, essentially variable weights depending on the specific device context.

So for example, for instance, in Example A.4, the interface complexity and the introduction of a different control mechanism are the dominant drivers of the Decision Point D outcome. In Example A.5, the history of known use errors related to reprocessing is a primary factor. So hope that answers the question.

CAPT Kim Piermatteo: Thanks Tony. The next question I'll direct to Andrea and this one has two parts. So the first part is, are there any medical devices that are per definition exempt from human factors and usability engineering processes? The second part is, are there any medical devices per definition that do require human factors and usability engineering processes?

Andrea Fiala: Thanks Kim. So we do not per definition exempt or require human factors processes for any specific medical devices. Again, the 2016 edition of ISO 13485 requires that design and development inputs include usability requirements according to the intended use, so device manufacturers subject to these design and development requirements must comply with the regulation and should follow their internal processes and procedures to determine when to conduct human factors validation testing.

And separately, the risk-based approach conveyed in the Human Factors Content Guidance is designed to streamline the amount of human factors information submitted in medical device marketing submissions and that is regardless of what human factors processes have been performed during your device development. And again, FDA recommends that human factors information be maintained by device manufacturers, regardless of whether it is submitted to FDA. Thanks.

CAPT Kim Piermatteo: Thanks Andrea. Tony, next question, what is the definition of a complex device user interface?

Dr. Anthony Maiorana: Thanks Kim. Yeah, this is a bit of a nuanced response. But I think that defining a complex device for human factors purposes is challenging because complexity is multidimensional and context dependent, and it's, you know, essentially it's resistant to binary categorization of, this is simple or this is complex.

Complexity can be driven by the context of use including the users, use environment, and intended uses. You know, for example, the use environment can introduce complexities, where you know a device may be, you know, has the same device, you know, maybe, you know, maybe different at a hospital versus a home setting.

Additionally, as devices incorporate features like software, interoperability, artificial intelligence, and adaptive algorithms, this technological, you know, evolution is continuously shifting and it also shifts what complex means.

So this makes it really difficult to establish an explicit definition with regulatory criteria and so for these reasons, the guidance takes a risk-based approach rather than attempting to formally define device complexity as a fixed category.

CAPT Kim Piermatteo: Thanks Tony. That was very helpful. Alright Andrea, the next question is, should the Human Factors Content Guidance be interpreted to mean that new human factors or usability data for changes to a currently marketed device must be submitted as a Traditional 510(k)?

Andrea Fiala: Thanks, this is a good question. The Human Factors Content Guidance is not intended to identify what type of marketing submission is appropriate for a specific device or device modification.

Instead, submitters should refer to the relevant 510(k) guidance documents for information about the types of device modifications considered appropriate for the different premarket notification pathways.

CAPT Kim Piermatteo: Thanks Andrea. Tony, here is the last question we have for today's town hall, in the URRA table there is a column for "validation method for effectiveness of risk control measure." Not every task in a URRA is included in a human factors validation. Does the FDA expect that column to be left blank for tasks that are not included in the validation study?

Dr. Anthony Maiorana: Yeah, I think this is a great question. And, you know, essentially the Use-Related Risk Analysis or URRA should be a comprehensive living document that assesses all user tasks for both critical and non-critical tasks. The column for validation method for effectiveness of risk control measures should be updated with, you know, appropriate information as intended to support traceability to the final validation testing.

So we would expect, you know, traceability for validation testing data, but some tasks may not be classified as critical in the Use-Related Risk Analysis under that critical task column. So the HF validation testing data should include all necessary tasks and should be organized in a logical order to represent a natural workflow. This is actually discussed in Section 8.1.2 of our, of the FDA's Guidance for Applying Human Factors and Usability Engineering to Medical Devices, which is complementary to the HF Content Guidance.

CAPT Kim Piermatteo: Thanks Tony. Alright, that will wrap up this segment on previously submitted questions for today's town hall. Thank you to all of you who submitted questions in advance and thank you to Tony and Andrea for providing the responses.

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CAPT Kim Piermatteo: I'll now turn it back over to Tony to provide a few closing remarks. Tony…

Dr. Anthony Maiorana: Thanks. Yeah, so in closing, I just want to bring up that within the HF Content Guidance, there is a dedicated e-mail at the top, you know, at the top of that guidance. And that's really only for questions related to the HF Content Guidance. If you have questions related to a future premarket submission, or about a specific medical device, the Pre-Submission pathway would probably be the most, you know, with the appropriate office, is probably the most appropriate way to ask those questions.

And Kim, please take it away from here.

CAPT Kim Piermatteo: Thanks again Tony.

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CAPT Kim Piermatteo: And thank you Andrea. From my end, I wanted to remind everyone a recording of today's town hall, a copy of the slides and a transcript will be posted in the next few weeks to the town hall event page, as well as to CDRH Learn under the section titled Specialty Technical Topics and the subsection Human Factors. A screenshot of CDRH Learn, with those headers, and where you can find those materials is provided on this slide.

If you have any additional general questions regarding today's town hall, please feel free to reach out to us in DICE at dice@fda.hhs.gov.

And lastly, we hope you're able to join us for a future CDRH event. And a listing of all of our upcoming CDRH events, including future webinars and town halls, is available via the link provided on the bottom of this slide.

Thank you all again for joining us. We hope you've found the education provided today informative and helpful. This concludes our town hall.

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