Medical Device Sterilization Town Hall: Sterilization Method Selection for New and Existing Devices
May 23, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello, everyone. Thanks for joining us. Welcome to our seventh Medical Device Sterilization Town Hall in this series. This is Commander 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 in CDRH's Office of Communication and Education. I'll be today's Town Hall moderator.

The FDA is committed to reducing reliance on ethylene oxide sterilization use while ensuring the integrity of the supply chain so that patients and providers have continued access to the sterile devices they need. To meet this goal, FDA continues to take a multi-pronged approach, including regulatory flexibilities, supply chain analysis and mitigation, collaboration, innovation, and communication, including this series of Town Halls.

For today's Town Hall, we will have some detailed panel discussions. We still want to have time for our live Q&A segment following these panel discussions; therefore, we have extended our Town Hall today to 75 minutes.

As always, I'd like to share a few administrative items before we get started. First, printable slides of today's presentation are currently available on CDRH Learn. To obtain these slides, you can go to cdrhlearn@fda-- or sorry-- www.fda.gov/training/cdrhlearn and select the section titled Specialty Technical Topics, and then scroll down to the subsection titled Sterility. There you will find the Medical Device Sterilization Town Hall section and a link to the printable slides for today's Town Hall, as well as materials from past Town Halls.

Next, please make sure you've joined us through the Zoom app and not through a web browser to avoid technical issues. And trade press reporters are encouraged to consult with the CDRH Trade Press team at cdrhtradepress@fda.hhs.gov. Members of national media may consult with FDA's Office of Media Affairs at fdaoma@fda.hhs.gov.

I now have the pleasure of introducing today's Town Hall panelists. Tamara-- sorry, Commander Tamara Rosbury, Health Scientist and EtO Incident Response team member in the Division of All Hazards Preparedness and Response in the Office of Readiness and Response within CDRH's Office of Strategic Partnerships and Technology Innovation, or OST; Christopher Dugard, Assistant Director in the Office of Health Technology number 4 in the Office of Product Evaluation and Quality, or OPEQ; Dr. Nadia Kadry, Biologist in OPEQ's Office of Health Technology number 3; Stephen Anisko, Team Lead in OPEQ's Office of Health Technology number 4.

Also joining us is Dr. Jon Weeks, Acting Assistant Director of the Division of Biology, Chemistry, and Materials Science in the Office of Science and Engineering Laboratories in CDRH; Dr. Paulo Laranjeira, Senior Staff Fellow in OPEQ's Office of Health Technology number 4; and Dr. Aftin Ross, Deputy Director of the Office of Readiness and Response in OST.

Welcome all of you, and thank you for serving as a panelist for today's Town Hall. I'd now like to turn it over to Tamara to start today's discussions. Tamara?

CDR Tamara Rosbury: Thank you, Kim. Thank you for joining us for our seventh Sterilization Town Hall. Before we get started with our discussion today, we'd like to take the opportunity to discuss poll results from our last Town Hall.

During our last Town Hall on April 29, we shared some suggestions we received about potential Town Hall topics going forward. Our panel, made up of staff from offices across the center, discussed the potential topic opportunities and expanded formats for the town hall series as we continue through 2024. We also gathered real-time feedback with live polling questions, and we'd like to share some high-level results now.

The first polling question asked for the level of interest for eight potential town hall topics. 219 of our attendees responded and scored each as very interested, interested, slightly interested, or not interested. For six of the topics, attendees selected the top response or very interested more than any other response. For these six, if we tally the percentage of very interested and interested responses, the results are as follows; risk-based approaches to sterilization validation, 93%; alternate sterilization methods modalities, 89%; sterility consensus standards, 85%; additional regulatory considerations for changes, 85%; material compatibility discussions, 81%; and international regulatory harmonization, 79%. I can also note that the not interested rate for the topics I just shared was between 0% and 3%.

The other two topics, using master file pilot programs and additional policy incentives, structures, regulatory flexibilities were the top second choices, both with combined very interested and interested rates at 54% and 64%, respectively. Today's discussion will touch on a few of these topics and have plans to include each topic in future events.

The second polling question asks for the level of interest for six current and potential town hall formats using the same four-point scale. 180 of our attendees responded and overwhelmingly showed support for all the potential new formats. Though selecting very interested or interested came in at a total of 95% for case studies, 88% for interactive panels, and 83% for mock Pre-Submissions, 79% of the attendees are very interested or interested in our live Q&A. 78% expressed that level of interest in CDRH activities and information sharing like we've done in previous events. And 64% were for the what we heard from you last time segment where we shared questions from our mailbox.

Being that we see high rates of interest in all the formats, we're pleased to share that we plan to include all instances of the new formats in the series going forward. Thanks again for participating in our live polling, and if you have additional feedback or suggestions, please reach out to our mailbox. We've already received a request for a topic not listed above, and we do have potential opportunities to include other topics. Next slide.

We've shared this timeline previously. During our last town hall on April 29, we announced a pivot in our topics and formats. And today, we're hosting the first new topic in Part 2 of our Sterilization Town Hall series. Next slide.

In today's Town Hall on medical device sterilization, we're implementing our pivot to a more interactive format in our town hall series by hosting the first panel discussion with our sterilization experts. Panelists will discuss considerations during modality selection with the expected outcome that

manufacturers will feel more confident approaching a sterilization modality shift, know where to start, and gain insight on what FDA reviewers look for during the review process.

Please note that assessments of adequacy are outside the scope of this Town Hall. Today, our panel will focus on the four topics shown here. These are technical considerations when selecting or changing a sterilization modality; maintaining sterility throughout the product life cycle; challenges and considerations during new product design and development and transitioning to an alternate modality; collaboration opportunities and additional information for decision making. I will pass it to Christopher Dugard, our moderator, for the first topic.

Christopher Dugard: Thank you very much. Some previous town halls, we tried to give you a high-level look at how we regulate sterilization. So we're hoping with this Town Hall that through our panel discussion, we can provide you with a bit more nuance that will guide your thinking as you approach sterilization for your product. So I'll begin the discussion for our first topic, what aspects of your device need to be considered when you choose a modality? And what technical considerations might you be thinking about to understand or justify the change?

So when choosing a sterilization modality, there are some considerations around device design and your validation that are independent of the chosen modality. In other words, things you would need to consider regardless of the modality chosen. And then there are modality-dependent considerations, which are those considerations that are specific to the chosen modality.

So the first question I have is related to modality-independent considerations. Nadia and Jon, do you have any thoughts on what aspects to think about that might be sterilization modality-independent?

Nadia Kadry: Yeah. Thanks, Chris, for the great question. I can kick off this discussion. So I think one of the largest considerations for any device manufacturer would have to be-- regardless of sterilization modality is whether the materials of your device are actually going to be compatible with the chosen method. If you're looking to use a sterilization modality that's heat-dependent like steam, you want to make sure that your device can actually withstand those temperature and moisture conditions without significant melting or warping.

Similarly, in that same vein, not every material is going to have the same compatibility with a certain modality. So thinking about something like radiation where certain polymers and resins aren't going to be able to withstand the same amounts of radiation. And a lot of that has to do with thinking about how-- the actual mechanism of action for a particular modality. Radiation interacts with polymers differently, and that can actually impact the strength and integrity of your device, and ultimately device performance.

And you know, if there is going to be a potential change to the performance of your device or to the potential safety or effectiveness due to a change in sterilization modality or a change in design, it's important to know that new marketing application might be required.

For example, if a device is going to be sterilized with ethylene oxide, your residuals could become a safety concern to think about. FDA has a really great guidance on deciding when to submit a new 510(k) for a change to an existing device that discusses these changes and how to evaluate them in more detail.

I also think more broadly related to whether you need a new marketing application, it's going to be important to think about whether changing sterilization modalities actually makes sense for you. You know, it's important to consider both the industrial and administrative burden of changing a sterilization modality for your device. Throughout the entire process for any modality, you really need to be sure that design controls are being implemented correctly. Jon, what are your thoughts?

Christopher Dugard: So we may be having a couple technical difficulties. Jon, are you able to unmute?

Jon Weeks: Sorry, I apologize. I was talking to mute there. Nadia, you bring up a good point about the logistics. I think that one of the challenges for a sterilization change can also be related to the sterilization modality itself. You know, if you have something like ethylene oxide, those chambers can be pretty large and can accommodate many pallets of devices.

And if you're switching to an alternative gaseous sterilization modality, those are going to have much smaller-- can have much smaller chamber sizes. And so converting to an alternative sterilization modality could pose some logistical challenges. You know, you may need to switch to using inline sterilizers instead of using pallets. And also with that, the size of the chamber itself can have some issues where if the chamber itself is on the smaller side, you may have to consider the size of the device inside of its packaging or sterile barrier system and whether or not that can fit into the capacity of the chamber.

Going back to what you said earlier about materials compatibility, Nadia, I think there are some materials-adjacent things that can influence compatibility as well. For example, sometimes materials may be compatible with a sterilant when exposed to a lower concentration or a shorter time. In that regard, things like quality and bioburden control of the incoming materials and manufacturing process can influence the final bioburden on the product or the load.

Additionally, understanding the raw materials will allow you to understand whether certain additives like plasticizers and antioxidants will be compatible with the sterilization modality. All of these things can influence the validation method that you select. If you understand the incoming bioburden, you can potentially choose something like a BI/bioburden-based approach or some other method instead of relying on the overkill method. Thanks, Chris, for this great question.

Christopher Dugard: Thank you, Nadia and Jon. Great points. So let me pass to the other panelists to discuss modality-dependent considerations. Paulo and Steve, do you have any advice around this topic?

Paulo Laranjeira: Yes, Chris, thank you. My initial consideration is regarding standards. And even though citing recognized standards is voluntary, FDA really encourages manufacturers to use them in their device submission.

When an FDA-recognized standard is cited in their Declaration of Conformity, DOC, less information and less documentation may be needed. This reduces the burden for both device manufacturers who are compiling the submission and also for the FDA staff who is reviewing it.

Finally, remember that at its core, the DOC is a communication to the FDA, and communications are always welcome. In this case, a DOC makes it easy for us to understand how you use the standards to support your device claims or meet a regulatory requirement.

There will be situations where a modality-specific standard is not available. And in this case-- for instance, in sterilization-- we recommend referencing ISO 14937, which is the sterilization of health care products, general requirements for characterization of sterilizing agent and development validation and routine control of sterilization process for medical devices.

This standard, ISO 14937, is the main reference document for all current sterilization standards and AAMI new work item proposal. Steve, in cases where we have two standardization methods, what are your thoughts?

Stephen Anisko: Well, thank you, Paulo. I agree that these standards are very helpful as firms look to develop alternate product sterilization methods, modalities. You know, however, as you noted, there can be situations which require adoption of alternate methods for which there is no dedicated standard or for which a firm is required to adopt multiple methods.

In these more complex cases, the path forward may not always be as straightforward as it would be if, say, they selected an established method such as steam. It's very well understood and the material compatibility issues are understood.

You know, for example, where there is a need for two sterilization methods, we encourage firms to closely look at the existing standards and to ensure that they have addressed the requirements for supporting all proposed methods. For traditional methods, as I mentioned earlier, such as radiation or steam, utilizing the applicable standards can be a great place to start and very helpful as firms develop their validation and how they address the changes being introduced, especially in terms of product and process definitions. When you get into cases where more novel sterilization methods are being considered, we recommend you reference ISO 14937.

To further expand on this, if you look toward adoption of alternate sterilization modalities, one thing that's very critical is for firms to fully assess the impact that the new sterilization method will have on your product and existing procedures and processes. So once you've identified a potential new method, you're really in a good position at that point to look at that specific impact to your proposed method, to your product, and the existing procedures.

We've heard earlier some excellent discussion points around the general considerations, such as material compatibility, logistical aspects, validation, and ultimately product functionality. These are certainly things that should be considered at this point.

However, once you've identified the specific sterilization modality, the new method, you can start looking in a more focused way. So specific questions such as, are you changing third-party providers? Are you bringing processing in-house? Because these will introduce additional considerations, and it's important that you've evaluated these impacts and also considered the appropriate levels of validation that will be needed to support the change.

And it varies. You know, if you're impacting-- are there impacts on transportation logistics? You have in-house laboratory capabilities if you're bringing testing in-house. Do you need new lab equipment? Do you need new personnel? Are you identifying a new lab? Items such as that would be very specific.

In all cases, it's important to remember that some level of validation should be expected. And as always, there is a time and cost associated with this activity. The amount will vary based on the specific impact to your product. What do you think, Paulo? Are there any additional elements important for firms to consider?

Paulo Laranjeira: Great point, Steve. I would also look into additional production steps that might be required. An example is sterilization used in an alternate modality may not allow the sterilization of a complete shipping carton like we see in ethylene oxide, for instance, requiring that device might need to be sterilized in their sterile packaging only. And then the IFU and final carton may happen in a different-- after that phase. Should we also address anything else, Steve?

Stephen Anisko: No, that's a good point, Paulo. And one thing I neglected to mention earlier is the evaluation of the impact on the product's packaging system. As we've discussed earlier, I mean, we do expect that the different sterilization methods will impact packaging materials in different ways. So once you've identified potential new methods, you can look at these modality-specific impacts.

So in many cases, it will impact critical aspects of your packaging system. So it could impact items such as your shelf-life, your shipping validation, your transportation requirements. You know, in some cases even require development of a new packaging system, which is better suited for the proposed method. Thank you, Paulo. I'll pass it back to you. And any additional thoughts?

Paulo Laranjeira: Yeah, I would take a closer look on also the residual assessment, the sterilant residual assessment, because we might not have a specific standard residuals. And then biocompatibility studies with residuals in mind might be one way of addressing this. Chris, I'll pass it back to you.

Christopher Dugard: Thank you all. Yeah, that was a great discussion. Thank you, panelists. So as I was listening, I did want to note that given the nature of this Town Hall and assuming the audience is coming up with potential questions for the Q&A, it may be hard for us to address questions around specific situations without detailed information in front of us.

So if you're coming up with a very specific question or a specific scenario, I do highly recommend that you consider reaching out in a different form, such as a Pre-Submission. But we will move on to the next topic. I will turn it over to Nadia Kadry, who will be the moderator for our next discussion topic.

Nadia Kadry: Thank you, Chris. So we'd now like to talk about topic 2, which covers how we can maintain sterility throughout a product's life cycle. You know, although each device and each manufacturer might have specific needs that we may not be able to address in today's discussion, we can talk about general principles that are important to consider when thinking about how to maintain device stability. I'll pass the discussion to the panelists and we can hear your thoughts. Chris, would you like to start us off?

Christopher Dugard: Thank you. So package validation and manufacturing process controls are critical to maintaining product sterility throughout the product life cycle. Inadequate sterile barrier can result in patient injury or infection. And even if no adverse events are tied to a faulty package, evidence of widespread issues can result in the potential for an expensive recall.

There are a lot of great resources out there, so I wanted to focus a bit on advice that is perhaps not widely known. The first is considering accelerated versus real-time aging. We accept accelerated aging to support maintenance of sterility as long as you confirm concurrent real-time aging is ongoing. You should also consider whether the product you are sterilizing is suitable for accelerated aging. And if it's not, it may be more worth your time to stick with real-time aging alone.

Reviewers will be looking to ensure you have addressed both performance of the device and maintenance of sterility in your shelf-life information. If you provide two sets of studies supporting differing lengths of time, we will typically accept the shorter of the two.

While we include it in our guidance, we often see simulated transport being missed. Please ensure that you address transport and consider the various environments your device will be transported to or stored in when determining exposure conditions. Regarding what FDA needs for review, this was mentioned a bit in a previous town hall, but just to emphasize, summary-level information is adequate in a 510(k), but full reports may be needed for other submission types like PMAs.

You should be considering packaging throughout product development. Package specifications should be considered at the earliest possible stage of development. If your product changes, you may need to also change the packaging, so being flexible is key here.

You should consider multiple packaging types. There's a huge variety out there, so having multiple options ensures flexibility. In some situations, you may also be able to take care of some preliminary tests prior to finalizing the design of your device. While the agency expects testing on the final finished device, you may be able to eliminate options that won't work for you through that testing or what will work.

In addition, you should be geared up for this sort of change, as having an adequate quality system is key to ensuring smooth development. Steve, I was wondering if you have any thoughts about this.

Stephen Anisko: Sure. Thank you, Chris. Those are some good points on product packaging and some of the impacts that could come off failures of those. I just wanted to build off a little more on those points you just discussed.

You know, the importance of establishing an adequate quality systems program really is so important to support any potential change, including adoption of an alternate sterilization modality. Firms with a robust quality system in place are oftentimes better suited to leverage programs such as change control management, and also risk management activities that can support the ongoing evaluation of any pending changes.

Additionally, these programs also support your overall product knowledge. And by that, it should help you identify any potential impact the changes might have on your product that go unnoticed or unevaluated during your initial assessment. These are also-- these activities are also great tools to help support and identify the level of validation that's appropriate to mitigate the changes in any potential impact that you may identify.

And ultimately, Chris alluded to some postmarket activities. These activities may also potentially help you ensure more stability in your product supply. Jon, I'm going to pass it back to you. In addition to

change control and risk management, are there any other quality system elements that you think firms should consider in support of these changes?

Jon Weeks: Thanks Steve. You know, as part of your quality program, you may wish to consider things like bioburden monitoring if you're not already monitoring this for a specific requirement of your QMS. ISO 11737, sterilization of health care products, microbiological methods, provides key information, specific requirements, and guidance for enumeration and characterization of bioburden.

This can help to inform your bioburden monitoring plan. And it's important to remember that bioburden monitoring plans should include an account for things like seasonal variation, warning limits and/or action limits for bioburden. And even if you're not using radiation for terminal sterilization, bioburden monitoring can allow for alternative sterilization validation methods such as a BI/bioburden-based approach in lieu of reliance on the overkill approach. Paulo, do you have any considerations?

Paulo Laranjeira: Yes, Jon. Yes. I would also would like to point out that when making changes to a device like updating a design or new materials or even a different supplier, you should consider the impact to the microbial quality, microbiological quality and control, as well as an impact to the sterilization process and impact on product functionality. Back to you, Nadia.

Nadia Kadry: Thank you, Paulo. And thank you, everyone, for the really great discussion. I think you each raised really important considerations that everyone on this call can take away from and use. I'll turn it over to Steve Anisko and Jon Weeks, who will be our moderators for the next discussion topic.

Stephen Anisko: Thank you, Nadia. So now we're going to move on to topic 3. We're going to discuss some of the considerations that may be important for evaluation during the design and development of new products.

Incorporation of these elements into your early phase activities may be important to support the product throughout its future intended life cycle. For this topic, I am also accompanied today by my co-panelist, Jon Weeks.

The first subtopic we would like to discuss is related to material compatibility and other device design characteristics, which may be important considerations. To start us off, I'm going to turn it to Paulo and Chris. Do you guys have any thoughts on what material compatibility and/or design aspects would be important for consideration to support new sterilization methods and new products?

Christopher Dugard: Thank you, Steve. So I'll go ahead and get this one started. So not all modalities are conducive to all materials and design features. For this reason, it's wise to begin considering sterilization early on in the development of your product so any issues with compatibility can be addressed up front.

Your first stop for material compatibility should be AAMI TIR17, compatibility of materials subject to sterilization. It provides guidance on the qualification of polymeric materials, ceramics, and metals for products intended to use radiation, ethylene oxide, steam, dry heat, hydrogen peroxide, nitrogen dioxide, peracetic acid vapor, liquid peracetic acid, and hydrogen peroxide with ozone. Of course, if you are using materials that you may have questions about, we encourage you to reach out to the Agency as well.

Some design features to take into account are designing the device to allow for maximum sterile penetration. So this is where early consideration of sterilization and device design comes in. Can you use a heat-based method, or are you locked into a chemical-based method? Steam penetration and penetration of whatever chemical sterilant you're using can be quite different. Should the device be packaged not fully assembled? You may have some human factors considerations there, but that may work better to ensure you're hitting the appropriate sterility assurance level.

The mass of the device should be considered, if it's going to be reusable, especially as many health care sterilizer systems have weight limits. Even local climate should be considered, as this has been known to impact the efficacy of chemical-based modalities. Of course, these are just a small amount of the things you could consider, but I think this helps get you thinking about the various aspects that you should consider when designing your device.

Other things to consider like user specifications such as material aspects, device geometry, device packaging, contract sterilizer limitations, logistical limitations, and potential regulatory pathway should be considered. Sometimes you may even need to get creative with your strategies. I think Steve mentioned earlier, we've seen submissions with multiple modalities. We've seen submissions where some components are sterile and some are not. For example, they may be aseptically processed. You may find that no sterilization modality seems to work for you, in which case aseptic processing may be the best path.

Device manufacturers should not feel locked into one particular modality or strategy. And again, I really want to emphasize open communication with the Agency to figure out what works best for you. Paulo, do you have any additional thoughts on this?

Paulo Laranjeira: Yeah. Thank you, Chris. Yes, I would also look into tracking any design features that limits the use of certain modalities. For example, like our colleague Nadia mentioned during topic 1, there might be a material that is heat-sensitive, and heat cannot be used due to the material choices. Or for instance, we have a sterilant that might degrade due to the presence of certain material types. So it is important to incorporate this design consideration throughout the development of the final device form to allow greater flexibility and sterilization options. Jon, any thoughts on that?

Jon Weeks: Thanks, Paulo. No thoughts on that. But the next sub-topic area that I thought we should touch on is related to ensuring that a product's usability over its intended use and shelf-life. Nadia, do you have any things that you would consider for reusable devices?

Nadia Kadry: Yeah, definitely. Great question, Jon. You know, if a device is meant to be used as a multi-use device that's going to be reprocessed, it becomes really important to ensure that your device design allows for your device to be compatible with cleaning, disinfection, and sterilization agents. You know, all things that that device would be exposed to during reprocessing.

And this has been a theme that we've been talking about during all of these discussions, but different materials used in your device from the body to adhesives inside of a device can all interact differently with the chemicals that reusable devices are exposed to during reprocessing and sterilization. And that can really impact whether your device can actually withstand reprocessing cycles.

With reprocessed devices in particular, it's also going to be important to think about how harsh reprocessing can be as a process. You know, if a device needs to undergo cleaning and a soak and a sterilant as part of its reprocessing, you really want to make sure you're designing a device that can actually be brushed adequately and that can be submerged without losing its functionality. You know, Chris touched on this idea earlier, that it's really important to be thinking about designing a device with the reprocessing and sterilization needs in mind early on in the design process rather than trying to identify a strategy that will work for you after the fact.

And with both single-use and reprocessed devices, it's going to be important to demonstrate that your final finished device will remain functional over its entire intended use life. You know, with single-use devices, we're thinking about whether the device remains functional over its labeled shelf-life. But with reusable devices, it's going to be important to demonstrate that your device remains safe and effective after multiple reprocessing cycles.

Jon Weeks: I think a great—

Nadia Kadry: Yeah, go ahead.

Jon Weeks: No, you make some really good points there, Nadia. Do you have more thoughts?

Nadia Kadry: I just want to emphasize that reprocessing is a very harsh process. And if your device is not designed with that in mind, you really could see degradation due to chemical breakdown or physical breakdown over time, just, again, from that repeated exposure to harsh sterilants, harsh detergents.

So you should not only be thinking about whether your device can withstand that single terminal sterilization cycle like you would for single use. You really want to consider whether your device can withstand a reasonable reuse life, and that makes sense for your device. What are your thoughts, Jon?

Jon Weeks: Yeah, and going to that, I think one of the things that we brought up over and over again is considering chemistries and their interaction with the materials. And that's important not just for the single-use devices, but also for those reusable ones.

And in the single-use space, if you are looking at different compatibilities of the materials with chemistries, you may be able to look into multiple types of sterilization. So having multiple modalities that could be used could potentially increase your suitability if there are supply chain issues.

And you may also want to consider for a single modality if you have multiple sites. That might be important for things like PMA devices that could help mitigate the supply chain. Thank you all for this great discussion. I'll now turn things over to Paulo, who will be our moderator for the last discussion topic.

Paulo Laranjeira: Thank you, Jon. So on this topic, we would like to bring additional points to help with the decision making discussed in the previous topics. One topic that Chris mentioned in the previous one is related to material compatibility information. And FDA recognized AAMI TIR17, so it is a good start, like Chris mentioned.

But I also like to emphasize that we do not recognize TIRs as often as we do consensus standards because TIRs are not the same as consensus standards with respect to making a DOC. However, the recognition of this TIR emphasizes that we are exploring every option and opportunity to be creative in how we are supporting the development of alternatives to ethylene oxide within our regulatory purview.

This TIR has general information about the compatibility of materials subject to different stabilization methods and includes material compatibility tables that are helpful for understanding how a specific modality might impact device materials. We understand that this generalized information and that there would still need to be device-specific assessments of material compatibility made to select and validate a stabilization process for a specific device.

The TIR also supports this with considerations for material testing and functionality testing. This is ongoing work on this TIR, and within-- it's ongoing work TIR within the AAMI working group that is developing it. The working group is working on expanding the material compatibility information, including materials beyond the most common use, ethylene oxide and radiation. Jon, what are your thoughts on this?

Jon Weeks: Paulo, you make some great points there. And AAMI TIR does provide-- or TIR17 does provide a lot of great, consolidated informational materials compatibility. And I think it's a great starting point for a medical device manufacturer.

And think it's also really good for the modalities themselves. As we expand to having more alternative methods, peer-reviewed publications in the scientific general information can be really a suitable tool for developing more sterilization modalities. And with that, we would kind of need to understand with new novel methods that are being developed or are developed, having information on the microbicidal robustness such as the most resistant organism, how well different organisms are killed, what the mechanism of action is, those will be imperative.

And in addition to understanding the modality's ability to kill, understanding materials compatibilities and incompatibilities of the sterilization modality will provide key information. And first, getting it into the peer-reviewed publication space will allow that information to be disseminated broadly into the medical device ecosystem to have a greater understanding of technology, and hopefully will be able to be incorporated long term into future revisions to things like AAMI TIR17. Nadia, do you have some thoughts?

Nadia Kadry: Yeah. I mean, to both of your points, Jon and Paulo, as we learn more about a specific modality, consensus standards can become really important and useful guidelines for understanding how to implement a modality and how to understand considerations for a medical device. You know, for sterilization modalities for which there is an FDA-recognized consensus standard-- so an established A method-- there's a significant history of safe and effective use and really clear guidance for development, validation, and routine control. Steve, what are your thoughts?

Stephen Anisko: Thank you, Nadia. No, exactly, I agree. You know, modality-specific consensus standards are a great tool for some of the more established methods. So as you mentioned, these have a longer, more comprehensive regulatory history. You know, they're better known, better understood.

You know, however, for some of these newly developed alternative sterilization methods, referred to as novel, there's generally more limited regulatory history in place with the Agency and no consensus standards that have been established that are out there for firms to utilize and for us to utilize during the review process. Adoption of these novel modalities can therefore introduce some unique challenges as firms look to adopt these.

You know, this is why when we do see reviews and we do see documentation related to these new methods, we really do recommend that firms focus on narrowing down their sterilization-- the intended sterilization process in terms of critical process parameters and how the parameters are to be controlled and monitored during a cycle.

Additionally, definition of sterilants and its delivery are very important considerations to understand. In general, I would point firms to the ISO 14937 standard again for additional information to support the development of their validation activity.

And finally, one thing that's probably useful to point out, it's very likely that the Agency will request additional full test reports as part of the marketing submission for modalities that are considered novel. Chris, I'm going to pass it to you. Do you have any additional thoughts on this topic?

Christopher Dugard: Thanks, Steve. I think you all covered a lot of really useful points, so I'm not sure I have anything additional on that topic at the moment. But I did want to take this time to mention our collaborative efforts with industry.

So I'll mention up front collaborative community. So we're aware of significant interest in establishing a sterilization collaborative community. But I did want to note that this is an endeavor that FDA cannot lead or run. But if others were to get it running, then the Agency would gladly participate in that group. And as has been clear from the discussion here, one of the ways that we engage internationally is through voluntary consensus standards. We regularly communicate and collaborate with the broader international community, and we have initiated conversations to understand those challenges and explore where opportunities might exist, especially in areas where significant increases in regulatory requirements might be anticipated.

So we've heard from you that even if FDA was to offer certain flexibilities, there still might be challenges for those companies that have an international presence, unless some sort of harmonization or alliance effort is in place. So we welcome having conversations around this, and also recognize that different jurisdictions may require the use of different technical standards.

So this is the reason we emphasize open communication with us. If you have an idea, a standard, a proposal, we would like to discuss it with you. Internally, we have the Pre-Submission process. We have the Breakthrough Devices Program, Safer Technologies or STeP Program. If you're unsure of the best route of communication, reach out to the office that regulates your product or to any of the SMEs that have been presenting in these town halls, and we will direct you to the right place. Let me pass this back to Paulo. Thank you.

Paulo Laranjeira: Thank you, panelists, for the thoughtful discussion. That concludes our panel discussion on each of the four discussion topics today. So now I will turn it over to you, Tamara. Thank you.

CDR Tamara Rosbury: Thank you, Paulo. Next slide. The next two slides include the resources mentioned earlier in the presentation, along with the full URLs that you can access after the presentation. Next slide.

To summarize today's discussion, the panel discussed four topics, including technical considerations when selecting or changing a sterilization modality; maintaining sterility throughout the product life cycle; challenges and considerations during new product design and development and transitioning to an alternate modality; and collaboration opportunities and additional information for decision-making. Next slide.

Before we open the discussion, I am excited to announce our next town hall on June 12 where our panel will engage in interactive discussion and live Q&A on topics identified by the audience and topics provided prior to the event via our medical device sterilization mailbox. Information about the town hall series can be found at the link here. Now I will turn it back over to Kim.

CDR Kim Piermatteo: Thanks, Tamara. And thank you to all of our panelists. We hope you enjoyed the discussions our panelists provided today. We will now transition to our interactive segment for today. I'd like to go over how we will manage this segment, and of course, a few reminders before we begin.

So to ask a question or to provide a comment, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted in Zoom, please select the blue button to unmute your line, identify yourself and your organization, and then ask your question or provide your comment. If you have a question, please remember to limit yourself to asking one question only and try to keep it as short as possible.

After you ask your question or provide your comment, please lower your hand in Zoom. And if you have another question or comment, please raise your hand again to get back into the queue, and I'll call on you as time permits.

As we wait to receive some of your questions and comments today, I'd like to ask our panelists a few questions. So I'd first like to start us off with a few questions we received in our mailbox that ask about CDRH's messaging related to EtO and what appears to be a push to move away from EtO sterilization.

One emailer shared challenges with other modalities and asked whether it was realistic for manufacturers to be able to find alternatives while another emailer states they felt like they were receiving some signals that FDA reviewers are discouraging manufacturers to use EtO as a sterilization modality for new products. And the third emailer asked if FDA intends to pursue a similar reduction on the reliance of radiation sterilization. I'd like to ask Aftin. Aftin, would you like to provide some comments in response to these emails we've received?

Aftin Ross: Thank you, Kim. In response to these questions, I'd like to share that before most sterile medical devices are on the market, the FDA reviews premarket submissions to determine if the sterility information provided demonstrates that the device is sterile, irrespective of the sterilization method you choose.

In addition, with its high material compatibility, effectiveness with complex geometries, and high scalability, there will always be a need for EtO sterilization, as other methods of sterilization cannot replace the use of EtO for some devices. FDA continues to support innovation in medical device sterilization by encouraging the development of new sterilization methods and the development of approaches that reduce ethylene oxide emissions. Back to you, Kim.

CDR Kim Piermatteo: Thanks, Aftin. Next, Chris, I'd like to come to you with a question, and you can provide a response. That question is, we are a contract sterilization firm that also offers consulting services to our customers. In that capacity, we are often asked for initial guidance from manufacturers in what approaches can be taken to reduce EtO in a manner that is most agreeable to the FDA.

Does the FDA have a hierarchy of EtO reduction approaches and the respective validation methods for each approach? For example, in consultation with a manufacturer, if we sought to reduce EtO gas concentration from 600 milligrams per liter to 400 milligrams per liter, would it be acceptable to use a BIER vessel or one-pallet chamber to compare relative resistance at the two gas concentrations, or would the agency want a full revalidation in our production chambers? Chris, I'm going to turn that one over to you.

Christopher Dugard: Thanks. So yeah, so we advise following the principles described in ISO 11135, which is a consensus standard fully recognized by the Agency. We do not prescribe how to comply to this standard, and do not necessarily have a hierarchy for validation or reduction methods. We recommend using the approach that best suits your device or situation.

One area to start, however, is clause 7.1.6 where it states it shall be demonstrated that the specified sterilization process is effective in sterilizing the most difficult-to-sterilize location within the product or within the product family. So as the standard states, this can be achieved by performing process definition and validation of a new product-- in this case, a new cycle in the production sterilization vessel-- or through the demonstration of equivalence to a previously validated product or internal Process Challenge Device, or internal PCD, used to qualify the product SAL when exposed to the specified sterilization process.

Therefore, one means of demonstrating suitability might be determining the resistance to sterilization for the portion of a subject device considered most difficult to sterilize and the proposed cycle, and comparing it to the results achieved in the existing cycle. To speak to the specific situation referenced in the question, studies performed in a BIER vessel or small-scale sterilizer used for that purpose should result in comparative devalues for the most difficult-to-sterilize product location that can be used to calculate the minimum requirements for the new cycle.

That can be confirmed by running a half cycle with the new cycle specification in the production chamber using suitable process challenge devices. Thank you. Hope that helped.

CDR Kim Piermatteo: Thanks, Chris. I see a few hands raised, but I would like to ask two more questions to our panelists.

So now Nadia, I'm going to come to you. And the question I'd like to ask you is, if alternative modalities are not feasible for my product and EtO is my only viable option, would changes made to the sterilization cycle, such as reducing the concentration of EtO or adding additional or deeper vacuums, or

changing the validation method from half cycle overkill to fraction negative warrant a new 510(k) submission to the agency? If a new 510(k) is warranted, what information would need to be supplied with the submission, providing it is an established category A method of sterilization? Nadia, would you like to provide a response?

Nadia Kadry: Yeah. Thanks, Kim. I think that's a really great question. So in that kind of case, the firm would be expected to perform appropriate validations based on the changes to the sterilization cycle or sterilization method. The need for a new submission is based on whether the change could significantly impact the safety or effectiveness of the device. We've talked about this a few times during today's panel discussion, but we recommend you reference FDA's guidance document deciding when to submit a 510(k) for a change to an existing device to help determine if a new 510(k) submission would be required.

We also recommend you have a look at the supporting documentation for Town Hall 4, which can be found on the CDRH Learn website, where we discuss decision making using the mods guidance, including a change in sterilization modality. It's also important to note that changing critical parameters while trying to reduce the EtO concentration may impact product and packaging shelf-life. Thanks, Kim.

CDR Kim Piermatteo: Thanks, Nadia. Alright, one last quick question. I'd like to take this question to Chris. Chris, the question we received was, my product can be sterilized using various modalities. Do my packaging shelf-life studies need to address all modalities?

Christopher Dugard: Thanks, Kim. Good question. And the answer is yes. Since different modalities can impact packaging materials in different ways, your packaging performance, maintenance of sterility, and shelf-life testing should be completed for all modalities the device may be exposed to for your intended device labeling and instructions. Thanks.

CDR Kim Piermatteo: Great. Yeah. Thanks, Chris. Alright, we will now hear from our first live audience member, Vanessa. Vanessa, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Vanessa Rivel: Thank you. Yes, thank you so much for holding this series of webinars. I think they are very helpful. My question is, will FDA provide an update on the challenges and successes you have seen in reducing EtO emissions by moving to other modalities since the FDA started this initiative on January 2024, sharing some figures to see what the state of the use of EtO in the medical device industry has decreased?

CDR Kim Piermatteo: Thanks, Vanessa. I'm going to look to our panelists. Does anyone want to provide a comment or response to what Vanessa has said?

Aftin Ross: I can start, Kim. This is Aftin. With regard to our challenges, we certainly do keep our web pages up to date with regard to that. We have also included some updates in some of the different statements that we have made with regard to medical device sterilization.

In general, we have shared that we have seen from the participants in the challenge who have been looking at reductions that they have seen reductions in terms of some of the emissions by trying to reduce their cycles. We have also seen for those who are looking at alternative modalities that they

have started to partner in some cases, depending on the method, with other sterilizers or other providers, manufacturer and sterilizer collaborations in order to better explore these options.

And so it is something that we continue to pay attention to. Certainly interested in hearing from industry any success stories you might have that you could share or insights based on your experiences as well. Thank you for the question.

CDR Kim Piermatteo: Thanks, Aftin. And thanks, Vanessa. Our next question is coming from Lucie. Lucie, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Lucie: Yes, thank you. The sterilization site is one of the information that's suggested in the 510(k) sterility guidance for a 510(k) submission. I'd like to know, as manufacturers are adding more sites to ensure supply chain or are moving sites, what's the best or most appropriate way to update the files or to document that and report it to the FDA?

CDR Kim Piermatteo: Thanks, Lucie. So again, I look to the panelists. I don't know. Chris, did you want to start with providing a response, and then anyone else can chime in?

Christopher Dugard: Yeah, sure. I'll start. Thank you for the question. So as far as the qualification you'll need to be doing on your own, typically site changes will require a complete revalidation as, you know, we tend to look at it per chamber.

As far as what you need to submit to us, I would encourage you, again, to use the mods guidance, which are the modifications which describes what to consider when you're modifying a 510(k) cleared device. We also have a version of that for PMAs as well. We discussed this in some past town halls. If you have any more questions about how to use that guidance, I recommend reaching out, but that does have some information about site changes there.

Lucie: Thanks.

CDR Kim Piermatteo: Thanks, Chris.

Aftin Ross: This is Aftin. I also wanted to add on to the previous-- Chris reminded me when he mentioned that we had some previous town halls on the question he got asked. We also had a previous town hall-- I believe was Town Hall number 2-- that talked through some of the learnings and things that we had gotten from our innovation challenges, as well as our Master File Pilot Programs. And so I would also direct-- I believe it was Vanessa who was the caller-- to take a look at our Town Hall 2 materials as well.

CDR Kim Piermatteo: Thanks, Aftin. Alright, our next attendee I'm going to call on is Markus. Markus, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Markus Heerlein: Hello. I have a quick question in regards to topic number 2 when it was talked about stability for sterile barrier packaging. And it was commented there that transit testing and environmental conditioning should be part of it. What was not really clear to me is should that be also part of it for accelerated aged or real-time samples? Because the standard-- more or less, the guidance says that stability and performance testing should be separated.

CDR Kim Piermatteo: Thanks, Markus, for your question.

Christopher Dugard: Hi. Yeah, this is Chris. I can-- so really-- yeah. I mean, it's a consideration, but I apologize if I caused any confusion by taking you away from the standard. Certainly defer to the standard and follow those methods, especially when you're considering accelerated aging. But when-- but the environmental conditioning more I was referring to was around the chosen sterilization modality and storage conditions in general when you're thinking about your overall shelf-life.

Because even beyond the standard, it's entirely possible that a product could be stored in an extreme climate, and you may want to label against that or consider it in your testing. But yes, please do follow the standards.

Markus Heerlein: Thank you.

CDR Kim Piermatteo: Thanks, Markus, for your question. And thanks, Chris, for your response. Next, Vanessa, your hand is raised again. I'm going to unmute your line. Did you have another question or comment?

Vanessa Rivel: Yes, thank you. I just wanted to ask, since the BHB was adopted by FDA as a Category 1 method, have you seen an increase in the submissions of 510(k)s or PMAs using this modality? That was my second question. Thank you.

CDR Kim Piermatteo: Thanks, Vanessa. Chris, I'm going to come to you first. But if any other panelists want to provide a comment, please feel free to chime in as well.

Christopher Dugard: OK. Thank you. Yeah. So I can speak from the perspective of the Sterility Devices team, but then I welcome it to other panelists from other OHTs as they have more visibility to the device-specific issues that we're seeing.

So for the Sterility Devices team, I would say we've seen more interest. I wouldn't necessarily say the volume of submissions has increased, but there is more interest. And I see-- yeah, we do have a slight increase, but it's nothing-- it's not a huge increase at the moment, but I have seen a lot more interest in the topic.

Aftin Ross: And I'll also just add that we just recently had that guidance update back at the beginning of the year. And we also do usually see a lag between a policy change and where we might start to see a lot of changes in submissions, so I think time will tell with regard to that.

The other thing that I would like to say is that we do have a resilient supply chain program and they continue to track potential supply chain challenges related to EtO, as well as looking at shifts to other modalities. As we have had presentations previously in these town halls regarding our Tiger Team, we're going to continue to explore how the activities that we are engaging in are reflected in any ways and any shifts in modalities going forward or other reductions.

Paulo Laranjeira: And I would like also to add on the hydrogen peroxide on the standard side at AAMI, we are seeing a lot of work and discussions. And we have other proposals and revisions, and you know,

we are working on biological indicators. So there is a lot of work that is being done towards expanding the use of hydrogen peroxide.

Nadia Kadry: Yeah, and I can chime in as well just from the perspective of GI devices. I have very similar sentiments as Chris where we are seeing more interest from device manufacturers. But since the recognition was relatively recent, we have not seen a ton of submissions yet, but we do expect to see more of them in the future.

CDR Kim Piermatteo: Thanks, Nadia. And thank you to Paulo, Aftin, and Chris also. Thank you for all of your responses to Vanessa's question. Our next question is coming from Brent. Brent, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Brent Huberty: Thank you and thank you for having this series. It's extremely helpful. As you guys are seeing manufacturers successfully move away from ethylene oxide, are you also seeing them wanting to maintain their ability to sterilize with ethylene oxide as part of their own supply chain resilience and potentially use the new method as their primary and have ethylene oxide as a backup? And if so, what are some of the regulatory hurdles or roadblocks you see in having a dual sterilization strategy like that? Thank you.

CDR Kim Piermatteo: Thanks, Brent. I'm going to turn it to Aftin. Would you like to start?

Aftin Ross: Thanks, Kim. I can start. So certainly, one approach to supply chain resiliency is looking at alternate modalities. One of the others that our panelists talked about today is also looking at alternate sites for sterilization. With those approaches, there are certainly considerations that you need to be thinking about, many of which our panelists-- with regard to some of the material compatibility and geometries and process items our panelists talked about today.

And then we also have talked about in the past as well as today considerations if you need to undertake site changes. Those are certainly things that we find are considerations as manufacturers are trying to understand what options might exist for them in terms of building additional resiliency through those two approaches. We definitely also understand that facilities themselves, sterilizers themselves, are continuing to try to get better with regard to their EtO emissions. And that also helps with overall reduction efforts.

CDR Kim Piermatteo: Thanks, Aftin. Do any of the other panelists want to chime in and provide any additional comments?

Christopher Dugard: This is Chris. I'll say one thing and then pass to any others that may want to say something. If we're thinking of just the technical issues, the technical roadblocks you might see, I think the biggest concern or the biggest issue I've noticed that trips people up is not realizing that you've still got to do all the performance testing that you do for one modality with the other modality, as different modalities can impact devices and materials in different ways. So that's definitely a consideration.

And there are definitely certain-- there's certain bits of information you can leverage from the previous modality. But if you're faced with this kind of situation, this is the perfect kind of situation where I recommend reaching out to us through a Pre-Submission and discussing it with us directly.

CDR Kim Piermatteo: Thanks, Chris. OK. Brent, thank you very much for your question. We're going to move on now to Indah. Indah, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Indah Kusumawardhani: Hello. I have quick questions with regards to the accelerated aging. So we have the accelerated aging data and then the real-time data is still ongoing. Would it be possible to submit the supplement, or like for example, 30-day notice or 180-day supplement with the accelerated aging data and then the real-time data will catch up later? Thank you.

Christopher Dugard: And I can take this one again. This is Chris. So the answer is you do not have to have your real-time aging study completed. As long as you've got the accelerated data supporting the time point that you're after and you confirm to us that your real-time aging is ongoing, there's nothing additional that we would need around that.

CDR Kim Piermatteo: Thanks, Chris. And thanks, Indah, for your question. Our next question is coming from-- I don't believe this is a person. It's V-- I'm guessing it's a conference room. So V Conference, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Vconf1/Sean: Hi, this is Sean with [Emutrex] Just a quick question to follow up on the email that we sent as far as, does the FDA have any interest in moving away from radiation sterilization as it is doing with EtO?

CDR Kim Piermatteo: Thanks, Sean, for your question. I'm going to look to the panelists. Does anyone want to start or to address Sean's question?

Christopher Dugard: Well, I could speak from the device evaluation side of things. No, I do not-- I am not aware of any particular push to move away from radiation. And you know, I hope I'm not going too far as to say, in fact, we're encouraging folks to look at it as an alternative to ethylene oxide. So no, we have not seen-- we are not encouraging people to move away from radiation at this time.

Jon Weeks: And I'll add to that, I know that the Agency has been interested in other types of radiation sterilization such as E-beam and X-ray, as well as gamma radiation, as gamma radiation uses a ionizing radiation source. We are interested in things like X-ray and E-beam, which are machine-generated radiation.

CDR Kim Piermatteo: Thank you, Jon, and thank you, Chris. Thank you, Sean, for that question. Our next question is coming from Jiayi. Jiayi, I've unmuted your line. Please unmute yourself and ask your question or provide your comment.

Jiayi Li: Hello. First of all, thank you for hosting this Town Hall. I think it's very helpful for members of the community to be able to speak directly with FDA. So my question is, I think a lot of companies do want to move away from EO and look at other alternative modalities.

But one hurdle is that with the low-temperature modalities and also X-ray, it's difficult to make that an in-house process, and there's also a lack of vendors providing that as a contract service. So is FDA trying to work with current contract sterilizers to provide alternative modalities?

CDR Kim Piermatteo: Thank you for that question. Again, I'm going to look to Chris or any of the other panelists. Feel free to provide a response.

Christopher Dugard: Yeah, this is Chris. So as far as recommending specific modalities to you, that's not something we would necessarily do. We really try not to take a hand in anything that might be considered design of the product or anything that would normally be the device manufacturer's responsibility.

What we can do is discuss with you proposed modalities. So if you do a little homework and you find some modalities that you think might work for you, and then you submit a Pre-Submission to us asking us specific questions around that modality, we certainly could give you feedback there. But as far as recommending a certain modality to you, we kind of stay away from that.

Jiayi Li: Sorry. I don't think that was my question. I don't know if you can still hear me.

Christopher Dugard: I apologize if I misunderstood. Can you repeat it?

Jiayi Li: Yeah. I think the question was, so one hurdle is we want to use alternate modalities, but we don't have the capability of bringing that sterilization in-house. There's a lack of contract sterilizers that provide X-ray sterilization, VHP for example. So we're unable to source a sterilizer that provides the service. And is FDA working to make those services more available?

Christopher Dugard: I see. No. We don't participate in that either because we don't want to look like we're favoring any particular contract sterilizer or manufacturer.

Jiayi Li: OK. I mean, could there be some kind of encouragement for contract sterilizers to provide those services?

Christopher Dugard: Let me pass this to another panelist. Is there anyone else that might be able to chime in a little bit more here?

Paulo Laranjeira: Yes, Chris, this is Paulo. I can mention that there are a lot of activities going on, especially related to standards. So for us to have new modalities, you also need to have new guidance. And at AAMI, we have a new work proposal to reactivate Working Group 11 to start writing TIRs related to the new sterilization modalities. So there are a lot of work being done. It's a new technology, so it is going to be-- as we move forward with these new challenges and new documents, we will see more of ability-- the availability of these technologies in the market.

Jiayi Li: Thank you.

CDR Kim Piermatteo: Thank you, Paulo, and thank you, Chris. And thank you for your question. That will wrap up our question-and-answer segment today. Thank you all for your participation. I'd now like to turn it back over to Tamara to provide her final thoughts for today's Town Hall.

CDR Tamara Rosbury: Thanks, Kim. Thank you for joining us today for today's Town Hall and our panelist discussion about selection of sterilization methods, and for sharing your questions via email and during the live Q&A. We had a very robust discussion and questions related to challenges and successes,

moving to other sterilization modalities, adding sites or moving sites, shelf-life storage conditions, whether we've received any increases in VHP submissions, dual sterilization strategies, supply chain resiliency, real-time and accelerated aging studies, radiation sterilization, and challenges faced when switching to other sterilization modalities.

We are very much committed to continuing the dialogue on these critical medical device sterilization topics to try to make sure that patients and providers have the medical devices that they need. Thanks again for attending, and now I'll turn it back over to Kim.

CDR Kim Piermatteo: Thanks, Tamara. A few closing remarks from me. As I mentioned earlier, printable slides of today's presentations are currently available on CDRH Learn at the link provided on this slide on CDRH Learn under the section titled Specialty Technical Topics and then the subsection titled Sterility.

A recording of today's Town Hall and a transcript will be posted to CDRH Learn under the same section and subsection in the next few weeks. And a screenshot of where you can find these materials on CDRH Learn is provided on the right-hand side of the slide.

Also mentioned earlier, if you have any additional questions or comments about today's topic or presentation, as well as if you have a comment or question for a future town hall, you may email the emails provided on the slide as well, but it's medicaldevicesterilization@fda.hhs.gov. And if you have any general questions about today's Town Hall, feel free to reach out to DICE at dice@fda.hhs.gov.

You can find a listing of all of our upcoming town halls and other CDRH events via the link provided on the bottom of the slide at www.fda.gov/cdrhevents.

And then of course, lastly we hope you're able to join us for our next Medical Device Sterilization Town Hall, which Tamara mentioned earlier, that is scheduled on Wednesday, June 12, from 2:00 to 3:00 PM Eastern time.

This concludes our Town Hall for today. Thanks again for joining us. Have a nice day.

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