NWX-FDA OC

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. After the presentation, we will conduct a question and answer session. If you would like to ask a question, you may press star 1.

Today's conference is being recorded. If you have any objections, you may disconnect at this time. Your host for today's conference is Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education. On December 9, 2015, the U.S. Food and Drug Administration issued the final version of the guidance document, Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.

This guidance clarifies and describes the premarket regulatory requirements for gowns regulated under 21 CFR 878.4040, and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings.

The focus of today's Webinar is to review the document and help manufacturers and other interested stakeholders understand information provided in the final guidance. Your presenters are Terrell Cunningham and Lauren Lilly, both scientific reviewers from the Office of Device Evaluation.

Following the presentation, we will open the lines for your questions related to topics in the guidance only. Additionally, there are other Centers' subject matter experts available to assist with the Q&A portion of our Webinar. Now, I give you Terrell.

Terrell Cunningham: Good afternoon. I would also like to also add my thank you to all of those who have joined us for today's discussion. I am Terrell Cunningham, team lead for personal protective equipment in the Infection Control Branch.

Today we're going to discuss the recently published guidance document, Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care, and FDA's regulations of surgical gowns.

Different types of gowns are used in various health care settings to prevent the transmission of infection and illness. This guidance clarifies the premarket regulatory requirements and performance testing needed to support liquid barrier claims for these gowns.

For the purpose of today's discussion, the term surgical gown will be used to refer to the gowns that are intended for use in health care. Today's discussion will start with a review of the scope of the guidance document and device clarification.

Next up, Lauren Lilly will provide an overview of FDA's premarket review of gowns and the recommended performance testing, labeling requirements, and we will conclude with the FDA's expectations of gown manufacturers.

It is important to ensure health care workers and patients are adequately protected and informed about their protective equipment. Hopefully, this information presented today, will reinforce current knowledge that you have about FDA review of surgical gowns.

The scope of this document is limited to gowns making liquid barrier protection claims and intended for use in health care settings. For the purpose of this guidance, the term "minimal" or "low barrier protection" refers to ANSI Level 1 and Level 2 protection or equivalent levels of protection.

The terms "moderate" or "high barrier protection" refers to PB70 Level 3 and Level 4 protection. Please note that this guidance does not address the data needed to support gowns making claims of provided protection against specific organisms, chemical agents, chemotherapy drugs, or those gowns that are labeled to provide specific disease prevention claims such as “protects against Ebola”.

Manufacturers desiring to make and to market their gowns with these types of claims or design features are encouraged to utilize the pre- submission process to obtain guidance from the Agency prior to submission of a 510(k).

Surgical gowns are classified under the surgical apparel regulation. Surgical apparel by definition are intended to be worn to protect both the patient and the health care worker from transfer of microorganisms, body fluids, and particulate matter.

Surgical apparel includes surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, isolation masks, and isolation gowns. The primary function of a surgical gown is to act as a barrier.

All surgical gowns are Class 2 devices, subject to special control, and require 510(k) clearance by FDA. Surgical apparel other than surgical gowns and surgical masks are Class 1. Class 1 devices are subject to general controls, and are exempt from premarket notification procedures.

In determining whether a gown is intended for use as a surgical gown under the surgical apparel regulation, FDA considers the terminology used, the level of barrier protection claimed, and the device's technological characteristics.

A gown is a Class 1 exempt and not a “surgical gown” if all of the following factors apply: It is labeled as a gown other than a surgical gown, for example, an isolation gown. It is not described in its labeling as a surgical gown, and it has a statement relating to barrier protection, such as claims of minimal, low, or no barrier protection.

If all of the above factors apply, the gown is considered Class 1 exempt from premarket notification, or, simply put; no 510(k) is required. The device is a Class 1 exempt because general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device.

For purposes of determining classification of a gown under the surgical apparel regulation of gowns falling within this regulation, is a surgical gown if any of the following apply: It is labeled as such, using terminology such as surgical gowns or surgical isolation gowns. It is described as such in its labeling. "This gown is suitable as a surgical gown."

It has the statement related to moderate or high level barrier protection, PB70 Level 3 or 4 barrier claims, or claims of impervious, prevents strikethrough, bullet proof, or impermeable. And, it has a statement, that it is intended for use during sterile procedures. That it also includes sterile isolation gowns or gowns distributed in sterile packages.

FDA considers gowns that claim moderate to high level barrier protection to be a higher risk than those that claim minimum or low level of barrier protection. All gowns with Level 3 and Level 4 barrier claims are considered Class 2 devices, under the surgical apparel regulation and are subject to premarket review.

All Class 2 gowns are subject to premarket review. This includes surgical gowns and surgical isolation gowns. Isolation gowns are Class 1. However, they become Class 2 if additional claims are made, such as moderate or high barrier functions, or claims associated with PB70 Level 3 or Level 4.

These gowns are defined as surgical isolation gowns, and should be reviewed by FDA. Isolation gowns with barrier function claims are defined, again, as surgical isolation gowns.

Lauren Lilly: Hello. My name is Lauren Lilly, and I'd like to give an overview of what information FDA expects or recommends be provided when submitting a 510(k) for surgical gowns.

Most of the information I will mention today can be found in our two guidance documents relating to gowns, the 1993 guidance document for Premarket Notification Submissions for Surgical Gowns and Drapes, as well as the guidance document published most recently, which is a supplement to the 1993 guidance.

We also recommend that sponsors look at guidance documents relating to the 510(k) process, and what general information is recommended when submitting a 510(k).

Most of the guidance documents referenced in this talk will be included at the end of this presentation.

When it comes to review of gowns with moderate or high barrier claims, information regarding performance and safety testing conducted should be submitted. For liquid barrier testing, FDA recommends the use of FDA recognized standard, ANSI/AAMI PB70. Depending on the level of barrier protection claimed, water impact penetration, hydrostatic pressure resistance, and resistance to viral penetration are testing methods recommended by the standard.

In addition to barrier integrity testing, safety is also an important aspect and sponsors are expected to provide data demonstrating that the device is safe for use. We will look more closely at FDA expectations and recommendations regarding premarket notifications in the upcoming slides.

Representative engineering drawings should be included with your submission with the critical and non-critical zones identified. Any special features should also be depicted.

Sample labeling should also be submitted. The provided labeling should clearly identify the level of liquid barrier protection claimed. Prior to the existence of ANSI/AAMI PB70, moderate or high barrier protection claims included, but were not limited to, wording such as prevents strikethrough;

high fluid protection; impervious; fluid-proof; fluid-resistant; highest level of protection; and impermeable.

Because of the lack of specificity with respect to performance characteristics and test methods, FDA now discourages the use of such language, and no longer clears products with such labeling claims.

Instead, manufacturers are encouraged to specify the level of liquid barrier protection as per ANSI/AAMI PB70 on all labeling. Labeling should also include the directions for use, the indications for use and, if applicable, validated reprocessing instructions.

For gowns making moderate to high barrier claims, sponsors are expected to provide data to support claims when sending a premarket notification. Therefore, sponsors should provide evidence that the gown complies with the claimed level of liquid barrier protection as according to ANSI/AAMI PB70 or an equivalent test method.

Copies of performance testing should be provided for FDA review. This information is necessary to support barrier performance claims. FDA recommends that adequate, statistically significant sample size is used. Generally, we recommend a sample size of approximately 32 gowns. Liquid barrier testing should be done on all critical zones and non-critical zones, including the back of the gown.

FDA also recommends that performance at the seams of the gown should also be tested. Please note that for surgical isolation gowns, that is, isolation gowns with moderate to high liquid barrier level claims, the critical zone encompasses the entire gown.

For surgical gowns intended for use in the operating room, the critical zone is defined as the front mid-chest area to the upper knees, as well as the lower arms. The non-critical zones of surgical gowns can have any protection level from 1 to 4. Additionally, the back of the surgical gown may be non-protected, according to PB70, but must be specifically labeled as such.

In addition to providing performance data, a clear description of the device design, including all models, dimensions and manufacturing specifications and tolerances, should be stated for each device design.

Additionally, all materials including adhesives and dyes should be specified. Representative engineering drawings should be included with your submission, and the critical/non-critical zones as well as the seams should be identified.

Additionally, sample labeling should clearly identify the level of the liquid barrier protection as per ANSI/AAMI PB70. As mentioned previously, claims such as prevents strikethrough, highest fluid protection; impervious; fluid-proof; fluid resistant; highest level protection; and impermeable are no longer cleared by FDA.

Please be sure to include sample labeling that also includes the directions for use and indications for use. When submitting a 510(k), all components for the device should be listed and the use life for each component of the device should be identified. Therefore, manufacturers are expected to state if the gown or any part of the gown is intended for single use, single patient use, or multiple patient use.

Under the 510(k) program, substantial equivalence is evaluated. Therefore, a comparison table between the subject and predicate device is expected. The

comparison table should include a comparison of the indications for use, the materials used in constructing the devices, sterilizations methods, and importantly, the PB70 level of the subject and predicate device.

Additionally, sterilization according to the K90 guidance document issued by FDA should also be included; particularly the sterilization method, validation method and packaging information should be included. If the device is also intended to be sterilized by re-packagers, sterilization instructions according to the referenced sterilization method should be included.

While a shelf life claim is not required at this time for gowns, single use and reusable gowns with shelf life claims should be supported by testing performance at the end of shelf life.

To support a shelf life claim, it is FDA's expectation that performance testing at the end of shelf life demonstrates that aging does not adversely affect the performance of the gown. FDA recommends that at minimum, sponsors should assess the liquid barrier performance of the device at the end of the claimed shelf life.

If the device or gown is intended to be reusable, in addition to demonstrating the barrier performance at the end of shelf life, the performance of the gown at the end of the maximum reprocessing cycles should also be demonstrated.

The reprocessing protocol used to assess the liquid barrier performance at the end of the labeled use life, should be similar to the reprocessing instructions included in the labeling. The maximum number of reprocessing cycles should also be stated on the labeling.

Presented on this slide are the four performance levels according to ANSI/AAMI PB70. The level of gown obtained is determined by its ability to resist fluid penetration under the conditions described in the table presented on this page.

Level 1 and Level 2 liquid barrier performance claims are considered minimal or low levels of performance. Conversely, Level 3 and Level 4 are considered to provide moderate or high levels of protection.

To reiterate, isolation gowns making moderate or high level liquid barrier claims are defined as surgical isolation gowns, and should be reviewed by FDA. For Level 3 gowns, please note that according to PB70, both AATCC 42 impact penetration testing and AATCC 127 hydrostatic water pressure testing should be performed.

We also advise that the sampling plan recommend by ANSI/AAMI PB70, that is an AQL of 4% with an alpha of .05 and an RQL of 20% with a beta of .1, is followed.

In addition to barrier performance testing, it is recommended that sponsors also assess the physical and mechanical properties of gowns. It is FDA's expectation that gowns should have the physical strength to resist tears and punctures. Secondly, the gowns should be comfortable to wear. As such, we would recommend that non-barrier property testing, such as grab tensile strength, snag resistance, linting, heat loss and water vapor transmission, be performed.

Data from flammability testing according to 16 CFR Part 1610, should also be documented within the submission. If the device is a surgical gown, and

therefore required to be sterile, the sterilization method and validation should be stated.

Again, if the device is labeled reusable, either as a single patient reusable or multiple patient reusable, laundry instructions should be described. The maximum number of uses, as well as the method used in order to track the number of uses, should be stated and presented in the labeling.

Lastly, in addition to physical and mechanical related testing, the device should be demonstrated to be safe for use. Biocompatibility is an important safety aspect for gowns, and therefore needs to be assessed. FDA recommends the use of ISO 10993 Part 10 for skin contacting devices and that skin irritation and sensitization should be assessed.

Terrell Cunningham: Hello. I'm Terrell Cunningham again, and I will conclude today's discussion with FDA expectations on what we expect from manufacturers. Manufacturers intending to market or those currently marketing Class 2 gowns as described in this guidance, should accomplish the following.

One, submit a 510(k) for the gown to the agency within 60 days of the publication of the final guidance. The due date for this will be February the 7th, 2016. Number 2: Have a 510(k) submission for the gown accepted by the agency for review within 75 days of the publication of the final guidance. The due date for the 75 day publication is February 26, 2016. Thirdly, obtain a 510(k) clearance for the gown within 180 days from the publication of the final guidance. This will be due June 6, 2016. FDA intends to work interactively with manufacturers as appropriate during the review process.

If a manufacturer has completed steps one and two above but has not received clearance of this device within the 180 days because the submission remains

under active review, the manufacturer should contact FDA to discuss whether the agency intends to continue to defer enforcement under these circumstances.

FDA recommends that surgical gowns cleared for marketing need the minimal performance specifications provided in the guidances that are listed on the slide above. These documents may be found at the Web sites that are listed.

Other relevant FDA guidances are listed on the next two slides. FDA recognized consistent standards facilitate the premarket review process. FDA recognized standards for surgical gowns are listed on the next two slides.

The use of these standards produce voluntary consensus among industry, health care device users and FDA. The standards provide defined qualification criteria for the device quality assurance. Consensus standards are updated as technology and experiences advance. This concludes our portion of the presentation, and we're now ready to accept questions.

Coordinator: Thank you. At this time, we will now be the question and answer session. To ask a question, please press star 1. You will be prompted to record your first and last name.

To withdraw your request, press star 2. Once again, press star 1 to ask a question. Please stand by for our first question. Our first question comes from (Mark Craymars). Your line is now open.

(Mark Craymars): Thank you and we appreciate the opportunity to get some clarification. I just wanted to find out, if I label my gown for sterile use in compounding pharmacies, does the surgical guidance apply to this?

Terrell Cunningham: (Mark), this is Terrell Cunningham. If I understand your question correct, would there be any patient contact? What is the intended use of that use of that function?

(Mark Craymars): No patient contact whatsoever. It's for mixing solutions in a compounding pharmacy.

Terrell Cunningham: My initial response is that that may fall more of an occupational use, and not necessarily a health care function, which was the intent of our guidance document. But to just be on the safe side, I would recommend that you would email that question or this would afford us an opportunity research it, and we will give you formal feedback via email. And thank you for the question.

(Mark Craymars): Could I get that email address, or is that just fda.gov?

Terrell Cunningham: It will be the email address that's posted on the slide.

(Mark Craymars): Excellent. Okay, I appreciate the initial reply, and we'll put it in writing for further guidance.

Terrell Cunningham: Thank you.

(Mark Craymars): Thank you.

Coordinator: Our next question comes from (Daniel Gluxom). You may ask your question.

(Daniel Gluxom): Hi, and thank you for taking the question. You mentioned, Mr. Cunningham, you mentioned some dates like February 7. Is that the expected date of the publication of the final guidance?

Terrell Cunningham: The actual guidance document that we are discussing today was published on December the 9th, 2015.

(Daniel Gluxom): Okay.

Terrell Cunningham: Based on that guidance document, there were several dates that were crucial. There was the 60 date, 75 and 180. And if you look at that slide, it will actually clarify on which date, what was expected.

(Daniel Gluxom): All right. Thanks.

Coordinator: Our next question comes from (Mike Shola). You may ask your question.

(Mike Shola): Hello Terrell. It's (Mike). How are you?

Terrell Cunningham: Doing well, (Mike). How are you?

(Mike Shola): Good. I have a question for you. So the guidance document says "or equivalent" to AAMI PB70. But AAMI PB70 also not only describes barrier performance, it also describes an AQL Level. So, I want to make sure that I understand that, if you make a claim to barrier resistance without an AQL Level, it's not equivalent, right?

Terrell Cunningham: Restate your question again, please.

(Mike Shola): So, AAMI PB70 describes four levels of protection. It also describes an AQL Level. If you make claims in your, in the guidance document, the document that was published in December, it says, "or equivalent". So, I'm asking the question, if you make the claims of meeting ASTM 1671, but no claims around an AQL, is that equivalent?

Terrell Cunningham: I would not interpret that as being equivalent, because you have failed to provide evidence that your product meets the pass/fail criteria as stated within the standard. When we use the term...

(Mike Shola): No, no. I want to make sure. This is a very pertinent point. In AAMI PB70 describes a quality level and people describe a compliance with standards, without AQL, and I want to make sure that I understand the fact that, if you don't describe an AQL, it's not equivalent. Because your guidance document says, all over the place, equivalent.

(Erin Keith): Hi. My name is (Erin Keith). I'm the division director that houses, for the division that houses INCB. What I wanted to make clear to you is about, in the language that you're talking about is, the ANCM standard is a voluntary standard. And we do not require voluntary standards as law.

But what we say is that you can provide alternative testing, at times in general circumstances, and the guidance is trying to leave open the window for circumstances where someone would provide equivalent methodology to that standard, but not yet meet that specific standard.

So, as Terrell was saying, we would, because the standard itself addresses the AQL Level, we would expect the equivalent alternative testing that was, that's been submitted or suggested is equivalent to redress those issues and explain why they are equivalent.

(Mike Shola): Okay, so I have one more question. What differentiates a gown from a coverall?

Terrell Cunningham: This is Terrell. I will attempt to provide a response. When you look at the actual title of our guidance document, it's focused on gowns intended for use in health care settings. While we definitely use the term gown, the actual publication is concerned that there are other products.

And we've talked about the terminologies that have been used in describing some of the other products, as being cover gowns, procedure gowns. And whereas the actual name that you call that product is not as important as what is the intended use of the product. What is the function? What are the claims?

So, when we look at our guidance document, I think we have to really read the guidance document and seek to understand what the agency's concerns are. The concerns are that you have a product that's being promoted for use in the health care setting that hasn't been proven or cleared by the agency.

And we're concerned with the uses and the functions of that product. So that's a question I think that we could entertain offline. It's a very direct question and it's an important question.

But I believe we stated - and I don't know if you recall that at some of the PB70 meetings that we can continue that discussion that when you have a coverall and you're actually making disease prevention claims, you have tripped the exemption of that device and you've brought it into medical device land.

(Mike Shola): All right. Thank you very much.

Coordinator: Our next question comes from (Hannah Shohan). Your line is now open.

(Winging): Hello. This is (Winging) from Medtronic. Thank you so much for the overview and the guidance document. So my question is in regards to Page 8 of the guidance.

For what is in scope of a Class 2 surgical gowns? So there are four bullet points that are listed. And my interpretation of that, and I want confirmation, is if any one of those applies, not all four. Is that correct?

Terrell Cunningham: It's - it would just so happen I don't have Page 8. But I do recall our discussion. And it - for the purpose of determining classification if - all of those apply.

(Winging): Okay. And I think this goes to the previous questions that were asked so it's almost like I'm...

Terrell Cunningham: No. It's just - if you could let me just clarify that. It's not all, it's any of those or. (Lawrence), are you going to speak to it? There's an "or. If labeled as such, if it's described.

And it's labeled as such, if it has a statement relating to moderate or high levels barrier protection. Or, if there is a statement that is intended for use during sterile procedure. So if any of those apply it would be considered a Class 2 gown.

(Winging): Okay. Thank you for that clarification. I have a follow up question to that. So the third bullet says if it has a statement relating to moderate or high level barrier protection.

And in the last question that you answered, you talked about this guidance documents being applicable to the health care setting. So, if there were, kind

of, a nonsurgical application for a specific gown that was used in the health care setting for let's say, mixing personal protective equipment for mixing caustic drugs.

Or other types of chemicals, but it was still in the health care setting, is that, would that put those products within the scope of Class 2 surgical gowns if it had the statement of moderate to high level barrier protection?

Terrell Cunningham: Yes, it would. And if you recall there was one of the slides, I don't have the number, that actually addressed some of the intended uses that went beyond the scope that we recommend that you use the pre-submission process to obtain greater or more information.

We are concerned with gowns that are labeled to provide protection against chemical agents or chemo therapy agents. There is an expectation that you have actual performance test data that demonstrate that performance and that that product be labeled accordingly. So I would encourage you to use an avenue for follow up discussion as it relates to that.

(Winging): Great. Thank you very much.

Coordinator: Our next question comes from (Earla Clark). Your line is now open.

(Earla Clark): Yes. Thank you so much for your presentation today. My question has to do with understanding whether you have guidance available for hospital equipment vendors.

On the correct gowns or coveralls for engineering where when servicing equipment in the hospital oncology compounding area. I've read a number of

comments that the most defective and protective gowns are the ones that are the hottest.

They don't dissipate heats, moisture. So, it sounds as though that's not what's covered here today, but I'm wondering if you have alternate guidance available somewhere?

Terrell Cunningham: Well, I thank you for the question, but at the point I am not knowledgeable on any such guidance as it relates to that product. But we would encourage you to forward your question to our - the address on the slide and we will give you a follow up response to that.

(Earla Clark): Thank you so much.

Terrell Cunningham: Thank you.

Coordinator: Our next question comes from (Caroline Netelli). You may ask your question.

(Caroline Netelli): Hi. This is (Caroline Netelli) from Cardinal Health. We have a couple questions for you and we appreciate this presentation today. It's been very helpful. The first question that we have is, will the FDA accept submissions for surgical isolation gowns that do not include an AAMI rating assignment to the gowns?

Terrell Cunningham: Repeat that question, please? Just for clarity, let me just repeat it to tell me if I understood it correctly.

(Caroline Netelli): Okay.

Terrell Cunningham: Am I understanding you correct in - your intent is to submit a 510(k) for a gown that would be under the classification of a surgical isolation gown. However, there would be no reference to PB70 classification. Meaning, there would be an expectation of a Level 3 or a Level 4. And you're questioning whether or not we would review that?

(Caroline Netelli): Yes.

Terrell Cunningham: Now, I will simply make this as an initial response. While it's a voluntary standard, you don't have to comply. However, given the fact that it is a medical device, the agency expects you to have evidence that that product will perform as a barrier as expected.

Whether or not you make a choice to put it in your labeling that it's a Level 3 or a Level 4, I believe that could actually be at the discretion of management. Your product line manager.

However, I'll question whether or not that product would be as competitive on the market as those other products that would be clearly labeled with that level of effectiveness.

But however, to answer your question, there is no requirement that it be labeled as such. However, you would have to have testing data to support that function and that is claimed. I wouldn't say claim, but that it performs at that level.

(Caroline Netelli): Okay. Thank you. And then my second question is, the AAMI standard PB70 described only isolation gowns with backs. But there are many products on the market marketed as isolation gowns that don't have backs. So, would FDA

consider a garment used for high fluid protection in medical settings without a back to be considered an isolation gown?

Terrell Cunningham: I have my thoughts. But rather than I tell you what I think, I think it would be best that we actually discuss that question within the agency and give your firm a response.

So again, if you would email that question to us and we will get back with you. Because when you look at our understanding of an isolation gown, that gown should provide you full coverage front and back.

That would be FDA's expectation of such a product. That is how surgical gowns and isolation gowns differ in terms of full coverage as well as the level of various protection.

(Caroline Netelli): Okay. The reason that we ask this question, it kind of goes back to the first question about includes the AAMI rating with the gown. But we'll submit it to you in writing.

Terrell Cunningham: I can understand that - yes. Thank you very much.

Coordinator: The next question is from Mr. (Sole). You may ask your question.

(Sole): Hi. Good afternoon. Thank you for your presentation. With related to the isolation gowns that would be considered now a Class 2 medical device, if you had an existing product which you were calling a fluid resistant gown which would be under the original classification, does that now fall under the Class 2 classification and require a 510(k)?

Terrell Cunningham: It is my understanding that it would. It would be - what, the term you referenced would be equivalent to a Level 3 Classification if I'm understanding your terminology correct.

(Sole): Yes. So, it would be a fluid resistant would be considered moderate to high and record the 510(k)?

Terrell Cunningham: And it should. That is what we would expect that it would be a Level 3. And any moderate or Level 3 or higher would be subject to 510(k) review.

(Sole): Okay. If you have products, you know, that you had in infantry, is there a period time given to slash those out before the 510(k) comes in product with 510(k) which would be classified with the, you know, Class 2?

Terrell Cunningham: We do have the office of compliance in the room if you would be so kind as to repeat the question, please.

(Sole): Okay. If you have products which, you know, have the fluid resistant claim which are isolation gowns which would have been, you know, previously considered Class 1 are now considered Class 2, is there a period of time to flush those out of infantry before, you know, the gowns with the 510(k) is Class 2 come in.

(Erin Keith): Yes. This would be a good conversation to have more offline since we would have to really get into some discussions in terms of timing to rework your product.

And having an understanding that you have in fact submitted a 510(k) and have a clear understanding of where things are with the application to market.

But yes, we would be happy to actually work with you on the phase out, if you would, or how to relabel or, you know, reconfigure your product.

(Sole): Right.

(Erin Keith): So that you wouldn't necessarily lose inventory.

(Sole): Okay. And there's no, sort of, sunrise date where those have to be completely, you know, out of the system?

Terrell Cunningham: Well, I refer you to Page 9 of the guidance document. And that is where we clearly communicate what our expectations are.

(Erin Keith): Right.

(Sole): Right. That would be the June - having to have everything in place by June the 6th?

(Erin Keith): That's about right. Yes.

(Sole): Yes. Okay. And these particular products, you know, would be tested. In manufacture we would have to, if asked, provide evidence that we're doing, you know, 32 tests, you know, to the PB70 with an AQL of 4%.

Terrell Cunningham: You appear to have gone into great detail. So, if you would have a follow up question that you would want a response, I would exercise the option of emailing the question and we will get back to you.

(Sole): Okay.

Terrell Cunningham: Thank you.

(Sole): All right. And that's to DICE at fda.hhs.gov?

Terrell Cunningham: Yes.

(Sole): Okay. All right. Well, thank you.

Terrell Cunningham: You're welcome.

Coordinator: Our next question comes from (Josh Uller). You may ask your question.

(Josh Uller): Hi. Thank you for the session today. We have a couple of questions to clarify just because it seemed a little ambiguous. So, for a single use product there is no shelf life claim required? I just want to confirm that that's the case.

Terrell Cunningham: That is true.

(Josh Uller): Okay. With that in mind, for the 510(k) submission, are you expecting us to submit aging data as well?

Terrell Cunningham: When you look at - A, is it - what are you referencing? A sterile? Nonsterile?

(Josh Uller): Nonsterile.

Terrell Cunningham: What are your claims? If in fact, you're looking at a nonsterile surgical isolation gown, then that's your question, there's no requirement for sterility, nor is there aging requirement.

Because there - the concerns about aging is related to products that would be sterile or products that would have other types of claims. Products that would be reprocessed. That's when we start looking at our concerns of aging. And - on top of...

(Josh Uller): You know what? Appreciate it. My next question is, can you recommend a predicate device to look at? We're looking specifically at a nonsterile AAMI 3 gown, isolation gown. And because these haven't been approved in the past we've been having some difficulty finding predicates.

Terrell Cunningham: That is totally beyond the scope of today's presentation. What I would recommend you, is look at the 510(k) summaries that are present on the Web.

(Josh Uller): Okay.

Terrell Cunningham: The some senior type of product.

(Josh Uller): Okay. Now that - so you've clarified too that isolation...

(Erin Keith): Hi. Hi.

(Josh Uller): Oh, go ahead.

(Erin Keith): Hi. I'm sorry. This is (Erin Keith) again. I wanted to say that you could also, for some of these more product specific questions, there is also a pre-submission process that has its own guidance document on the FDA website.

That describes the process where you can ask us more directive and specific questions about your product and what sort of testing requirements would be necessary for the design features and the claims that you want to make.

(Josh Uller): Okay. I just have one last question that you may defer to that as well, but I should probably ask while I'm here. For a gown made with a material that meets any three requirements, but does not meet the seam requirements and know any three claim is made, is that considered a Class 2 device? So it's made at any close with that detail.

Terrell Cunningham: That is Terrell again. What you're posing is a very product specific type of question. I think that would be best handled via our pre-submission process as a worst case scenario, or by direct contact with me in the office and we can just - we can actually look at your question.

(Josh Uller): Perfect. Thank you very much. I think there's one other person who might maybe - oh, no. Never mind. Thank you very much for your time. Appreciate it.

Coordinator: Our next question comes from (John Salt). You may ask your question.

(John Salt): Good afternoon. This is (John Salt) here at Precept. And my question is similar to Cardinal's question. And right now, roughly based on market data for non-surgical gowns used, whatever they're called in a hospital, let's say approximately 40% of those gowns used, nearly half are where nurses are using an isolation gown called something other than a surgical gown.

They're using an isolation gown, and for comfort they have an open back. For protection it varies. According to your guidance, if somebody seeks moderate or high protection, they can't have a product. Are you proposing to eliminate that 40% of the market and have it change?

Or is this some confusion factor given its public knowledge that right now the F23 ASTM Committee is now trying to figure out a new isolation gown standard. So, in that sense, I'm saying the 510(k) is being issued at the same time that the F23 Committee is trying to grapple with, you know, issues.

Terrell Cunningham: Well...

(John Salt): And maybe this relates to, on your 510(k) guidance on Page 9 under .3, it's a representative drawings et cetera, et cetera, and include the mentions and location of the critical and noncritical zones.

So, for an isolation gown, the way the standard was developed, you know, 12 or 14 years ago, the whole gown is, you know, considered to be a critical zone, but as anybody would know looking at the back of the gown, all of those gowns will fail the PB70 test because it's open in the back no matter how you cut it.

Terrell Cunningham: Well, again, this is a question that goes beyond the scope or the expectation of today's presentation. Because what we are actually discussing is a product that has newly evolved and it is...

(John Salt): This product's been around forever. This product's been around for 20 years. These types of products. Open back, over the head gowns have been around for a long time.

Terrell Cunningham: Well, just to my knowledge, having been here at FDA for 20 years, I am totally unaccustomed to having reviewed, and we're talking about 20 years of review, I'm not accustomed to having reviewed an isolation gown with an open back because the device design would have been confirmed.

(John Salt): And I think that's because until these guides came out they were not subject to review. I think that's what the buy is in...

Terrell Cunningham: Well, I think...

(John Salt): In that sense, whether I'm right or wrong, I feel like my question, kind of, fits with Cardinal's question.

Terrell Cunningham: Well, I think your question...

(John Salt): It may be - if I could be, you know, a precept could be included in that, that may help us. We're just trying to understand what the agency's intent here is with, based on GHX, kind of, information.

I may be off. It could be 30% or just 1/3. There's a huge amount of gowns being used with an open back called isolation gowns, and the clinical workers do care about the protection level as well.

Terrell Cunningham: Well I, again, I recommend that you forward that question to DICE using the slide that's posted. And also that we can openly address this question in F23.

(John Salt): Okay. And our representative (Shane) will be there to talk with you Terrell. Thank you.

Terrell Cunningham: Because I think that would - and it's not so much talk with me, it's something that we need to speak to as a committee, because that's...

(John Salt): Okay. I do believe that the - this is something that the committee should be able to clarify, or that if they have a role to play, they should have already clarified this by now and actually I would think.

Terrell Cunningham: And I think...

(John Salt): But the half of it's been out many years in a committee, so and the name of the lady is - the state too. I guess, well, (Shane) will speak to you Terrell, or whoever else he needs to. We cannot see our slides today, so that's why I'm not sure how to spell the name AAMI. Thank you.

Terrell Cunningham: You're welcome.

Coordinator: Our next question comes from Donna Swenson. You may ask your question.

Donna Swenson: Hi. This is Donna Swenson. I'm the coach here at PB70. And I have a question on where do the decontamination gowns that are used in sterile processing departments fall in this new guidance?

Are - they're definitely protective attire, and my personal opinion is they should be Level 3, or Level 4 protective attire. So, but they typically are not isolation gowns in that they're not total protection back and front. So, do you need - are these considered isolation gowns? Are they considered surgical gowns where you have critical zone? Not clear where these really fall then.

Terrell Cunningham: Donna, you pose a very good question, and neither am I at this time because in their absence of a clear indication for use, in the absence of product labeling.

Those are all issues that we would have to look at to make a determination. So, for formal review and to address it, again, what you would forward that question and concern for DICE at fdahhs.gov and we will get back to you.

Donna Swenson: Okay. Thank you.

Terrell Cunningham: Our next question comes from (Josh Uller). You may ask your question.

(Josh Uller): One of my coworkers just had a quick question to get some clarification.

Man: Hello. My question falls very in line with (Precepts) and Cardinal's around our group trying to understand the applicability of gowns sold into the markets. So, based on our knowledge, about 48% of what we would call gowns used in health care setting have - are marketed either as fluid resistant, impervious, impermeable, any of those descriptors that you used before.

Out of those 48%, less than 2% are AAMI compliant. So you would only have 2% of the gowns that would actually meet AAMI 3 or AAMI 4 based on the standards due to either the product not passing it to seams due to the fact that a lot of fluid resistant gowns have sewn seams.

Or, due to the fact that the largest gown style in the market have an open back. So we're really grappling with half of the gowns that are currently sold into health care, how we would fit those into your guidance.

So that's the first question. The second one would be all of these questions, we're just hoping we can also get the feedback if Cardinal or Precept or anyone has asked that question that's applicable to get the industry knowledge to understand that feedback because, you know, we are struggling with how to classify these gowns.

Terrell Cunningham: Well, from a regulatory perspective, if I'm hearing you correct, you'll have gowns that are labeled as fluid proof, fluid resistant. However, you question whether or not they would pass PB70? And it's in fact, that is the clarity that is the question that I have a concern about accuracy promotional product in the market.

Man: I think that the concern would be that the material used would be referred to as a test so that fluid resistant would be a term that's used for a product that's, say it's a film.

But either has an open back or the technology to close the seams is a sewn technology. So, I would agree that ANSI is looking at adjusting their standards to more reflect what's happening in the market.

But it is a challenge for us when the gown coming into the market is marketed as fluid proof, and more - half of the gowns today are, but that doesn't necessarily correlate to the AAMI standards.

It might correlate to a cap within the standard for the material, but the gown itself, the whole gown; the whole critical zone doesn't meet it. So we're trying to understand if we need to take fluid resistant off our labeling. It's a challenge for us to really understand how to react. And specifically on a very tight timeline.

(Erin Keith): Hi. This is (Erin Keith). So, I would say at a high level in answering your question, this is the sort of situation where the part of the guidance document talks about or equivalent tests to the PB70 test.

That the standard has its scope and it deals with what it defines. And when you have a product that falls within the scope of that, then it's easy to meet the requirements, the test requirements of the standard to be able to have it match up with your claims and, sort of, develop the data that you need to support your marketing applications.

It's harder when you have a design variation what the standard is covering. And this is where talking with INCV during the pre-submission process about the types of information to submit in order to substantiate the claims you want to make for your specific device would be the best place to have this conversation.

Because it would require the technical people in the branch to have a little bit better understanding about the device and that's going to involve some trade secret confident information I'm quite certain you don't necessarily want to discuss in this webinar.

And so I think that the pre-submission process for an offline phone call with the Infection Control Devices branch would be the best way to get some of that information to you.

Man: Okay. Perfect. I think just, our main concern is that a macro level half the gown is going into the market have a fluid claim. And we just don't understand. This is not specifically just for our company or, you know, it's consistent across the entire market.

So our concern is with the timelines, if it's a gown that comes in the market on June the 6th or even exists in the market no longer are allowed to be sold, there could be a big disruption to what's going on right now in the health care marketing that day.

(Erin Keith): Okay. That's a fair point. And so, what I would suggest that you then do is that you have a conversation also with the Office of Compliance about the logistics and the implications of me being the currently established grace periods that are in the guidance document to see how the office feels about an extension of those.

Man: Okay. Well, hope - yes. We appreciate your time, and hopefully through the direct emails we can get more direct clarity on how to proceed.

Coordinator: Our next question comes from (Mike Shola). You may ask your question.

(Mike Shola): Hello. I'm sorry to interrupt again. Protective apparel to protect against biological agents is used outside of health care. And as such, it migrates into health care.

For instance, in a crime scene or accident situation where somebody has to pull dead bodies out of a car, people wear protective apparel, and it needs to be impervious, or AAMI Level 3 or 4.

And I just want to make sure that I understand that the agency is not trying to regulate those garments that are used outside of health care. Because, you know, if you were a sewage worker in Philadelphia and a sewage line broke, you would probably want the same protection that a health care worker would.

(Erin Keith): Hi. This is...

(Mike Shola): To go in that sewage line and repair it.

(Erin Keith): This is (Erin Keith). We - the guidance document only applies to things that are medical devices that meets the specific scope of what the guidance document is dealing with.

If you have questions about other applications or other products, there are different mechanisms in which to receive feedback on that. One of them would be the 513G process where you could submit for clarity on the standing of other products.

(Mike Shola): I'm sorry. What was that process again?

(Erin Keith): It's referred to as the 513G submission process. And you can send a question related to that to the DICE email address and we can get you linkages to information about how to go about doing that.

(Mike Shola): Okay. Thank you.

Irene Aihie: I believe that was our last question. Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Thursday January 28.

If you have additional questions about the final guidance document, please use the contact information provided at the end of this slide presentation. As always, we appreciate your feedback. Again, thank you for participating. This concludes today's webinar.

Coordinator: Thank you. This concludes today's conference. Participants, you may disconnect at this time.

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