

FDA Webinar Series - Respirators and Other Personal Protective Equipment (PPE) for Health Care Personnel Use During the COVID-19 Pandemic

**Moderator: Irene Aihie
October 27, 2020
12:00 pm ET**

Coordinator: Good afternoon and thank you all for standing by. For the duration of today's conference all participants' lines are on a listen-only mode until the question-and-answer session. At that time if you would like to ask a question press star 1. Today's call is being recorded. If you have any objections, you may disconnect at this time. It is my pleasure to introduce Ms. Irene Aihie. Thank you, ma'am. You may begin.

Irene Aihie: Thank you. Hello. And welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the 11th CDRH webinar in our TPE webinar series.

The FDA will share information on recommendations for surgical mask premarket notifications or 5-10(k)s as part of the series on respirators and other personal protective equipment also known as PPE, for healthcare personnel use during the COVID-19 pandemic. Representatives from the FDA and CDC's NIOSH, will be available to answer your questions.

Following a few opening remarks, we will open the lines for your questions related to information provided during today's discussion. Now I give you Dr. Cynthia Chang from CDRH's Office of Surgical and Infection Control Devices.

Dr. Cynthia Chang: Good afternoon, everyone and welcome. As Irene mentioned, this is the 11th session in our webinar series on personal protective equipment or PPE. In prior webinars we have discussed the regulation of surgical masks during the COVID-19 pandemic, including a discussion of our enforcement policy for surgical masks on August 4 and a presentation on the surgical mask umbrella EUA on August 18.

Today Dr. Jessica Mavadia-Shukla, a biomedical engineer in our Office of Surgical and Infection Control Devices, will provide an overview of recommendations for premarket notifications, or 510(k)s, for surgical masks. After her presentation we will turn to our operator for live Q&A. With that, I am pleased to introduce Dr. Mavadia-Shukla.

Dr. Jessica Mavadia-Shukla: Thank you, Dr. Chang. Good afternoon. In this presentation we will provide additional information on the review of 510(k) premarket notifications for surgical masks. Before I start, I want to emphasize that surgical masks are different from respirators and facemasks.

Both surgical masks and facemasks are loose-fitting products in contrast with respirators, which have a tight fit to the face and provide respiratory protection. Facemasks are not personal protective equipment for protecting the wearer, however they do serve as source control.

Surgical masks are personal protective equipment, serve as source control and as barrier devices that provide full protection. Remember, that because of the

loose fit, surgical masks do not reliably block very small particles in the air that may be transmitted by cough, sneezes or certain medical procedures.

Surgical masks are not recommended for the use in aerosol generating procedures and any clinical conditions where there is a significant risk of infection through inhalation exposure.

Under those conditions, a filtering face piece respirator, such as a N95 respirator with a tight fit to provide respiratory protection, is recommended. As mentioned, thus far we have had two previous webinars on surgical masks. The first, on August 4, was our webinar on the regulation on facemasks and surgical masks during the COVID-19 pandemic.

The second webinar held on August 18 on FDA's surgical - was on FDA's surgical mask umbrella EUA. In these previous webinars, we discussed the ways in which surgical masks are regulated during the public health emergency.

Firstly, under FDA's enforcement policy, surgical masks intended to provide liquid barrier of protection may be marketed without prior FDA review and risk discussion for certain other FDA requirements for the duration of this national emergency.

Secondly, surgical masks can be marketed once authorized, under the umbrella emergency use authorization. Under this pathway, once information has been submitted to the FDA and the surgical mask is authorized, the mask can be added to Appendix A.

Third, a surgical mask can be marketed under the 510(k) premarket notification program. Even after the national emergency is declared over a

surgical mask that has been cleared under a 510(k) premarket notification can continue to be marketed.

In this presentation, we will focus specifically on providing you additional information on the regulation of surgical masks under 21 CFR 878.4040 and product code FXX under the 510(k) premarket notification pathway. As I described earlier, surgical masks are medical devices and are intended to provide liquid barrier of protection.

In the agency's guidance on surgical masks, we have stated a surgical mask covers the user's nose and mouth and provides a physical barrier to fluids and particulate material. The surgical masks referenced in the guidance document, includes masks that are labeled as surgical, laser, isolation, dental or medical procedure masks, with or without a face shield.

Before moving forward, I would like to say that products for a pediatric user population or products that contain any drugs, biologics, antimicrobial or antiviral agents, nanoparticles or nanotechnology, any novel materials and technology incorporated into the device, are beyond the scope of this presentation.

This talk also does not cover EUAs or the enforcement policy for surgical masks as the requirements and recommendations for those pathways are different than 510(k)s for surgical masks. This webinar will focus on premarket review of surgical masks and will not discuss any post-market questions.

Now that I have discussed the definition of a surgical mask, I want to go over the general contents of a surgical mask 510(k) premarket notification. The

510(k) premarket notification pathway for a surgical mask is no different than the 510(k) pathway for other medical devices.

For your reference, the resources slide at the end of this presentation also includes helpful links to the agency's guidance document on the 510(k) program and evaluating substantial equivalents. While the content and format of any 510(k) submission is the same, this presentation is intended to provide you with helpful information on the content to include in a 510(k) submission specific to a surgical mask.

The general information to provide any 510(k) submission for a surgical mask, should be a device description, comparison of the subject and predicate device, labeling and sterility or shelf-life information if applicable. In the next few minutes I want to spend some time on each of these items.

In your submission it is important to provide a detailed device description with all attributes of the mask including the style of mask and physical dimensions of ear loops, ear ties and the nose clip. The device description should also include a list or table of the material composition of each component of the mask, such as mask layers, ear loops, ear ties, nose clips, as well as any other colorant that results in a colored mask.

Next, you should provide the same information in your substantial equivalent discussion and comparison of the subject and predicate devices. In addition to the comparison of technological characteristics, you should ensure that the substantial equivalence discussions also include the comparison of the performance between the subject and predicate device.

Commonly, when reviewing 510(k) submissions deficiencies are issued for incomplete device descriptions or technological comparisons. For example, if

any of the physical dimensions of the subject device are missing or the colorant is not clearly stated.

It is important to ensure that you provide a complete description and comparison of the subject and predicate device, in order to facilitate a determination of substantial equivalence. The next item I want to discuss is the labeling.

The labeling for surgical masks can include package labels, box labeling, or inserts. And you should ensure that you submit all box labeling. The agency recommends that you also include draft box labeling. The labeling should clearly state the indications for use, device name, prescription statement if applicable, and indicate that the device is for single-use only.

In addition, please state the sterility status or method if applicable. In terms of labeling there are two commonly issued deficiencies. First, deficiencies are issued for labeling claims that have not been supported with performance data. Secondly, deficiencies are issued when labeling does not include appropriate information, such as the indications for use or single-use only symbol or text.

In order to streamline the review of draft labeling, ensure that the language is clear, concise, and that you have not included any claims for which you have not provided supporting performance data. In addition, ensure that labeling is complete and includes an indication for use statement, single-use only statement as well as any other applicable text as previously mentioned.

The last point on this slide that I will discuss is information regarding sterility and shelf-life if you are labeling your device as sterile or specifying a shelf-life. For sterility and shelf-life information, we would like to convey that this

information is optional. A surgical mask does not need to be provided sterile and a shelf-life does not need to be claimed.

If you would like to submit a sterile surgical mask safety and performance testing should be provided on the sterile surgical mask. In addition, you should provide sterilization information as recommended in the FDA's guidance, submission and review of sterility information in premarket notification 510(k) submissions for devices labeled as sterile.

If you are also claiming a shelf-life, please ensure that the performance testing is performed on the final finished device at the end of its proposed shelf-life. Along with the safety and performance testing on the subject device, the submission should include a summary of methods used to establish that the device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life.

In the next two slides I will discuss the safety and performance testing that should be submitted to demonstrate substantially equipment performance to the predicate device. The biocompatibility assessment is the information that needs to be provided to demonstrate biological safety of the subject device.

In your biocompatibility assessment it is important to include the context classification of each of the components of the device. Please note, that the surgical mask guidance states that surgical masks are considered prolonged surface contacting devices due to the extended wear of the device.

For a surgical mask comprised of commonly used mask textiles or materials without any novel technology or agent, biocompatibility endpoints include biotoxicity, irritation or intracutaneous reactivity and sensitization. The standard test methods are also listed next to each biocompatibility endpoint

and additional information can be found in the agency's guidance on biocompatibility and the resource slides at the end of this presentation.

In the review of biocompatibility assessments there are several deficiencies that have been commonly issued for the following reasons - firstly, if we identify that the biocompatibility testing was not performed on the final finished device. Please note, the agency recommends that all biocompatibility assessments are conducted on the final finished device as intended to be marketed.

Secondly, deficiencies are issued when testing is not performed on the entire mask including the nose clip, which is considered an indirect patient contacting component. Please note, that biocompatibility testing should be conducted on the entire mask including all mask layers and components.

Thirdly, testing may not be performed on all representative final finished devices within a submission that includes several models. It is important to ensure that if there are multiple models in the submission, all final finished devices that have different material properties due to style or color for example, are tested.

Fourth, oftentimes, the biocompatibility reports do not contain all the details regarding the test system within the report. Therefore, please ensure that the biocompatibility information you submit contains complete test support. It is important to ensure that your biocompatibility assessment is complete in order to ensure a streamlined review.

In this last slide, I would like to discuss the performance testing expectations for surgical masks. The agency recognizes the voluntary consensus standard, ASTM F2100 standard specification for performance of materials used in

medical facemasks. This standard covers the testing requirements for materials used in the construction of medical facemasks that are used in providing healthcare services such as surgery and patient care.

The standard also references test methods for fluid resistance, filtration efficiency including bacterial filtration efficiency, and particulate filtration efficiency, differential pressure and flammability, to evaluate the performance of mask materials.

During the pandemic, in order to streamline our review processes, we will only accept submissions with complete safety and performance data to streamline our review processes. Therefore, if you claim conformance to ASTM F2100 for a surgical mask 510(k) submission, it is important to understand and adhere to the standard.

One of the most common reasons for an RTA-1 is an inadequate performance testing. For example, a sampling plan and lot size are not specified for each performance test. Clause 7.2 in ASTM F2100 states that an acceptable quality limit of 4% shall be used for all required testing to establish conformance of medical facemasks to a specific performance class.

Therefore, sample sizes for bacterial filtration efficiency, particulate filtration efficiency, differential pressure, and flammability, are determined based on 4% acceptance quality limits per ASTM F2100, depending upon the production lot size where the lot size could be shipped for interstate commerce.

We have received many questions on the subject of sample size and performance testing. So in your submissions we recommend you address the following item. We recommend that you state the production lot size and

provide the calculation of sample size for bacterial filtration efficiency, particulate filtration efficiency, differential pressure, and flammability based on the reference standard ASTM F2100 and acceptance quality limit of 4%.

Please note that ANSI/ASQ v1.4 and ISO 2859-1 are standards specific for sampling procedures which are FDA recognized. ANSI/ASQ v1.4 and ISO 2859-1 state that people should use a general inspection level II unless a different inspection level is specified.

As ASTM F2100 does not specify the inspection level, we recommend general inspection level to be used for surgical masks. We recommend that you also provide performance testing based upon sample size calculated according to the lot size and general inspection level II.

Specifically for fluid penetration, please ensure that the sample size is at least 32 samples, to be consistent with ASTM F1862. Finally, it is important to ensure that performance specifications are maintained cross production lots. We recommend that performance testing be performed on three non-consecutive lots in order to support that the lot to lot variability in performance is acceptable.

We recommend that you provide testing from three non-consecutive lots for the performance testing for fluid resistance, bacterial filtration efficiency, particulate filtration efficiency, differential pressure, and flammability.

To reiterate, the most commonly issued deficiencies for performance testing, are for an inadequate number of samples on which testing is conducted, making them inconsistent with the 4% acceptance quality limit as stated in ASTM F2100, or the lack of testing on three non-consecutive lots or

justification to demonstrate that lot to lot variability in performance is acceptable.

In addition to the inadequate sampling plan and lack of testing on three non-consecutive lots, for performance testing often times performance testing is only provided for a single model. If there are multiple models or types of masks, it is important to consider how to provide adequate performance testing to cover all the models within the submission.

For example, in the case of two mask models that only differ in the ear ties and ear loops, although the mask layer materials are the same and therefore bacterial filtration efficiency, particulate filtration efficiency, differential pressure and fluid resistance may yield the same results, differences in the ear loop or ear tie materials may necessitate flammability testing to be performed on each model to consider all factors.

In conclusion, when submitting your 510(k) premarket notification for a surgical mask, it is important to ensure that you include a complete submission and sufficient safety and performance testing that takes into consideration all the different models and mask styles that you include in a single submission.

This concludes the presentation portion of this webinar. And the last slide summarizes a list of guidance documents as well as FDA-recognized voluntary consensus standards appropriate for surgical mask 510(k) premarket notification. Thank you for your attention.

Irene Aihie: Thank you, Jessica. We'll now take questions.

Coordinator: Thank you. If you would like to ask a question please make sure your phone is not muted, press star 1, and when prompted, clearly record your first and last name so I may introduce you. We will take one question per caller. Again, to ask a question, press star 1. It may take a few moments for questions to come in. Please standby.

Our first question is from (Mary Majias). You may go ahead.

(Mary Majias): Hi. Thank you so much for this information webinar. I have a question on third party testing. It's very expensive and many labs have increased their prices and lead time during the pandemic. We are in China and we want to make sure the labs we test are accepted by FDA. If the labs have ISO 17025 is this sufficient?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thank you for the question. It appears that you're asking about third party testing and what sort of standards may be acceptable for us to review the testing in your 5-10(k). Let me turn to my colleagues in (OHT4) and see if perhaps Dr. (BiFeng Qian) has any comments on that question.

Dr. (BiFeng Qian): Hey, good afternoon. This is Dr. BiFeng Qian. For our 510(k) review of surgical masks, we do not specifically request which testing laboratory you must send your samples to for testing and the location of the testing laboratory.

However, we do recommend that testing laboratories should follow the FDA-recognized standard to do the testing. So if they use a deviated standard or a different standard or a test method of their own, they need to provide a clear and detailed comparison between the test methods and test criteria they use for testing of their subject surgical mask against the FDA-recognized standards.

They should demonstrate the test methods and the test criteria used are equivalent to the specification requirements and the test methods which are described in the FDA-recognized standards. Remember, this is a 510(k) so you're supposed to demonstrate the subject device is substantially equivalent to the predicate device which is evaluated based on the FDA-recognized standards or equivalent

(Mary Majias): Thank you. I just wanted to make sure that we don't - we've already actually submitted testing and submitted a 5-10(k) and we just responded to an RTA. But we're not aware of this new requirement. Previously, the requirement was like for five pieces for particle BFEDP and flammability. And now you're saying there should be 96 pieces for each (unintelligible) 32? So that's why - that's the least burdensome approach I think.

Dr. Cynthia Chang: This is Cynthia Chang. So we...

(Mary Majias): Yes.

Dr. Cynthia Chang: ...appreciate that you do have a 5-10(k) under review. What we would recommend is that you discuss your specific case directly with your lead reviewer. You know, for the webinar and the purposes of the webinar's public discussion, we'll be focusing on our general recommendations, but we will not be able to get into the specifics of any specific...

(Mary Majias): Okay.

Dr. Cynthia Chang: ...5-10(k).

(Mary Majias): Okay.

Dr. Cynthia Chang: So thank you very much.

(Mary Majias): Okay. Thank you.

Dr. Cynthia Chang: Thank you. We can move on to the next question please.

Coordinator: Our next question is from (Nate Victor). You may go ahead.

(Nate Victor): It was a similar - it's a similar question but it's a little bit different in respect to self-laboratory if you will. Like we use our - we create our own lab here in the US and we're doing our own tests. Is there any additional certification that we need or independent verification outside of our own reports that we'll be printing off from our own lab that you guys would require or be challenged in the future if we do it that way?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thanks for the question about the requirements for - what we might look at from testing labs. In general, we do request that you provide full test reports that describe the test protocol and provide details of how the test was conducted so that we may understand the results. And in terms of any additional recommendations, I will turn it over to my colleague, Dr. (BiFeng Qian) from (OHT4).

Dr. (BiFeng Qian): Yes. Thank you very much for your question. We do accept test reports from a third-party testing laboratory or you do it in house if you have the capacity to do so. However, as I stated before, we do recommend that you conduct the testing based on the test standards, which are recognized by FDA.

Also, you need to validate your test method in your own facilities to demonstrate that you are capable of doing it and the data are valid. We do not

have additional recommendations other than you should demonstrate that testing was validated and you followed the FDA-recognized standards or equivalent. Thank you.

Dr. Cynthia Chang: Thank you. Let's take the next question, please.

Coordinator: Thank you. And our next question is from (Julie Askulian). Your line is open.

(Julie Askulian): Hi there. I just have a question about the biocompatibility. So I apologize if this is - if we're beating a dead horse here, but I just wanted to make sure because I've heard different things from - I actually contacted someone at the FDA two days ago and they said that if the biocompatibility testing is not necessarily required if you can - if like enough is similar - if it's identical to the predicate device.

Is that true or do you have to do biocompatibility testing on your product no matter what?

Dr. Cynthia Chang: This is Cynthia Chang. Thank you for the question on biocompatibility testing and whether there are situations where you might not need to do the actual laboratory testing. I will turn this over to Dr. (BiFeng Qian).

Dr. (BiFeng Qian): Hello again. Thank you for your question. Regarding biocompatibility, if you intend to market your device as a 510(k) cleared surgical mask, the biocompatibility assessment needs to be conducted based on the final finished device that you intend to put on the market.

When we say the biocompatibility assessment, that could be achieved either via testing or rational. You understand the testing. Testing needs to be

conducted based on the final finished mask and the entire mask is considered user contacting. As such, the testing should cover all components of the mask including the inner, middle, and outer layers and the ear loop, the tie on and nose piece, all components contained in the surgical mask.

A rationale is, if you can identify a predicate device of your own that is previously cleared by the FDA, if you use the same materials, processing including sterilization if applicable and have no other chemicals added, you can use the predicate device as a comparison to justify not providing new testing on the subject device.

However, this comparison must be conducted based on the final finished form of the devices including all components as well. That's an example of acceptable rationals. We may accept other rational but it's a case by case. You'll need to provide it for us to review.

Coordinator: And before we go to the next...

(Julie Askulian): Thanks.

Coordinator: ...question, as a reminder we will take one question per caller. Our next question is - comes from (Michelle Lott). You may go ahead.

(Michelle Lott): Hi. Given that it seems like these expectations are coming from a risk-based approach with the agency, what is FDA's plans to do about the 510(k)s that's been over 240 masks cleared since 1976 with 510(k)s that have got these testing way below these current expectations? Is the agency going to take any field action or require people to refile masks to prove that they are safe and effective to these new standards?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. I'll try to address your question. So the recommendations that we're providing today are based on the current guidance and our current recognition of voluntary consensus standards. And so the review process that we go through for 510(k)s is to demonstrate substantial equivalence to a predicate.

Therefore, our decisions are really based on that substantial equivalence standard. The 510(k)s that we have cleared are remaining cleared and are found on our database which may be found at FDA's database. I don't think that we have any additional plans at this time and that, you know, would be outside of the scope of the current webinar. Thank you.

Binita Ashar: And this is Binita Ashar. If I could add, I think your question is a good one and gets at the 510(k) program in general and is not necessarily specific to surgical masks. And you're right, you know, the devices that were available on the market, you know, back in the late 1970s, we've hopefully progressed and are comparing ourselves to the more contemporary predicates.

There have been some discussions about what to do about some of these predicates that have a less favorable, you know, benefit risk, you know, profile. Some ideas include sunseting some devices as predicates.

But that goes beyond the scope of today's discussion and my response is simply to acknowledge that you're raising a good point and it's something that, you know, applies to not just surgical masks but devices in the 510(k) program as a whole. And I think the agency and others are familiar with these issues and are considering them.

Coordinator: And our next question is from (Robert Packard). You may go ahead.

(Robert Packard): Yes. You indicated that another option to providing three non-consecutive lots would be to provide a scientific rationale for lot to lot variability in performance being acceptable. Do you have any guidance on what you would accept as scientific rationale?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thanks for the question on whether we would accept a scientific rationale and what that might look like, regarding sample size. Let me turn to my colleagues in (OHT4). Jessica Mavadia-Shukla, would you like to take that question?

Dr. Jessica Mavadia-Shukla: Yes. Thank you very much for your question. So we believe that it is very important to make sure that there is no lot to lot performance variation. And so the best way to provide this information would be to provide us with three non-consecutive lots.

However, as you identified, we are also providing an option of providing some sort of a justification. And if you are providing a justification your scientific justification should include sufficient detail about, you know, in process sampling, lot verification testing, detection of nonconforming products, and details on how manufacturers ensure that the materials meet material specifications prior to manufacturing.

In essence, we would like to understand how your process is controlled, in order to maintain the lot to lot performance variation. And we will review your rationale on a case by case basis and hopefully we can reach a positive conclusion. Thank you.

Coordinator: And our next question is from (Jessica Chemanski). You may go ahead.

(Jessica Chemanski): Hi. Thank you. Thank you for the webinar. I wanted to ask about the sample size again. I just want to confirm that the requirement is that we test 32 samples from three non-consecutive lots for every single one of the five tests. Is that correct? And I just want to also know where this requirement is stated? Is it in the actual ASTM F2100 or is it somewhere else, because I couldn't find that requirement in any of your guidance documents.

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thanks for the question on sample size and where the recommendations come from. I will turn that over to Dr. Mavadia - Shukla from (OHT4).

Dr. Jessica Mavadia-Shukla: Thank you Dr. Chang and thank you for your question. These recommendations are in line with what is stated in ASTM F2100. The standard identifies that performance testing should be performed according to a 4% acceptance quality limit on the production lot size. So this is how we've come to use this as a standard for our sample size plan.

Now with regards to the second part, I believe that this would be on a case by case basis. It really depends on the production lot size for the devices. And that's how you would calculate, based on the 4% AQL as well as the sampling standards that were highlighted and are provided as resources on the slides.

I believe that should answer your question. Thank you very much.

Coordinator: And our next question is from (Jack Slavik). You may go ahead.

(Jack Slavik): Yes. Thanks for doing this seminar. My question is does the performance testing, can it be done somewhat via the last caller, but can it be done in series or does it have to be done in parallel, because the testing is destructive in nature?

Dr. Cynthia Chang: This is Cynthia Chang. Thanks for the question about whether the testing needs to be done in series or parallel because it's destructive. I will turn it over to Dr. Mavadia-Shukla, to see if she has an answer for that.

Dr. Jessica Mavadia-Shukla: Thank you very much. So I believe that you can perform the testing in whichever way works out for you. I understand it is destructive testing. We're mainly concerned with ensuring that performance of the subject devices. And so as long as you're meeting the appropriate sampling plan based upon ASTM F2100 if you are claiming conformance to the standard you should be able to perform the testing however is most efficient.

Coordinator: And our next question is from (David Shue). Your line is open.

(David Shue): Hello. My question is on this performance testing sampling plan. You mentioned that FDA has a guidance material on it. Can you tell me the name of the guidance material? How can I find it?

Dr. Cynthia Chang: Hello. This is Cynthia Chang. So the question is about where you may find guidance documents related to the topic today. We will have the slides posted on our Web site and you may see on the webinar screen, at this moment, the link where the documents will be posted.

On our slides we have quite a long list of links including to the guidance documents and relevant standards. So hopefully that will help.

(David Shue): Thank you. Thank you.

Dr. Cynthia Chang: Thank you. We can take the next question.

Coordinator: Our next question is from (Ruth Ann Rapp). You may go ahead. And again, (Ruth Ann) your line is open. Perhaps check your mute button.

(Ruth Ann Rapp): I'm sorry about that. I apologize. Thank you for the webinar. My question was specific to the FDA guidance for surgical masks that's currently available on the FDA Web site that's dated from 2004. Do you have plans to update this guidance to include the requirement related to performance testing of three non-sequential lots?

And that performance testing of non-sequential lots, is that requirement applicable to other product codes, not including product code FXX?

Dr. Cynthia Chang: This is Cynthia Chang. I can start to address your question and I'll see if my colleagues have anything to add. At this time the guidance document that we have referenced is the current guidance document and there are no current draft guidances out for the topic.

For COVID-19 we do have a number of enforcement policies for other pathways to market surgical masks during the public health emergency. However, at this time the guidance document that is out from 2004 is the current guidance.

In terms of the recommendations on the sample size and performance testing, those are found in our recognized standards and so that's one way where we provide our recommendations regarding testing. I will turn it over to my colleagues in (OHT4) to see if there's any comments on whether the standards apply to other device types, although that might be outside of the scope of the webinar to some extent. Dr. (Qian)?

Dr. (BiFeng Qian): Yes. Our FDA guidance document does not specifically discuss how many samples you need to test, the sampling plan, the lots to be tested, etc. However, all of this information is clearly described in the FDA-recognized standards. For example, in this case is ASTM F2100. The standard describes how many samples need to be tested for each individual performance testing. For blood penetration testing per ASTM F1862, 32 samples per lot is requested.

For the other performance testing, ASTM F2100 recommends that you should determine the test sample size based on your intended production lot size for interstate commerce and general inspection level 2 to achieve an AQL of 4%. ASTM F2100 references two standards which are also FDA recognized for the sampling procedures.

So all this information are clearly and very much detailed described in the FDA-recognized standards. FDA guidance documents only provide more general recommendations for the testing, what kind of testing will need to be conducted to support the performance including the safety and effectiveness. So this is our current recommendation.

(Ruth Ann Rapp): Thank you very much.

Dr. Cynthia Chang: We should move onto the next question.

Coordinator: Our next question is from (Wilford Chin). Your line is open.

(Wilford Chin): Hi. Hi. Good evening. I just would like to ask - because our factory recently has done a biocompatibility test in a lab in China with SGS actually. And the test was not - or is not GLP compliant. Is that going to be an issue for the 510(k) application?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. I will turn it over to Dr. (Qian).

Dr. (BiFeng Qian): For biocompatibility animal testing we generally recommend that test be conducted in a lab in compliance with GLP regulations. So if it is a non-GLP compliant testing lab you need to provide the justification how the testing data obtained from a testing lab which is not in compliance with GLP regulations is appropriate and acceptable and why the noncompliance would not impact the validity of the study data.

So we need to review your justification or rationale on a case by case basis, to determine if it is acceptable or not.

Dr. Cynthia Chang: Thank you for answering the question, Dr. Qian. I think we could move onto the next question.

Coordinator: And our next question is from (Charles Shen). You may go ahead.

(Charles Shen): Yes. Yes. Hi. I have question about the labeling and you mentioned that in the labeling you'll need to make a shelf-life statement. And I understand that for the sterile products you'll need a shelf-life statement. But if a mask is non-sterilized then do we still need to make a shelf-life statement or it's optional?

Dr. Cynthia Chang: This is Cynthia Chang. So the question is about the need for a shelf-life statement in the labeling. I will turn that over to Dr. Mavadia-Shukla.

Dr. Jessica Mavadia-Shukla: Thank you very much for your question. I believe that there may have been a little bit of misunderstanding but our message is to inform you that you do not need to claim a shelf-life and you also do not need to claim sterility for a surgical facemask.

If you do claim sterility please provide the appropriate information. However, as I mentioned, if your mask is not sterile then you do not need to claim a self-life. Thank you.

Dr. Cynthia Chang: Thank you very much for that question. We can move onto the next question.

Coordinator: And our next question is from (Gene Paraneek). You may go ahead.

(Gene Paraneek): Hi. Thanks for the webinar. This touches on something you addressed earlier but there is a rumor that goes around which is that if your material is the same as other materials that are being used then no, you can skip biocompatibility or do less biocompatibility.

I think those of us who have done this sort of thing recognized that's a pretty high bar. Like if you own both products and you can demonstrate that you're using the exact same material. Can you just address that rumor and express to us what level of similarity do materials have to have to each other? What do I need to know about Material A and Material B to reasonably make a justification that would allow me to forego testing?

Because I think it's a much higher bar than most people recognize, which is promoting that kind of a rumor.

Dr. Cynthia Chang: This is Cynthia Chang. That's a good question about how similar materials need to be to provide a rationale for foregoing biocompatibility testing. I'll turn it over to Dr. (Qian) to address that.

Dr. (BiFeng Qian): Thank you for your question. First of all, I need to modify your question. FDA does not regulate materials. A comparison of the materials used is inadequate. Biocompatibility assessment needs to be conducted based on the final finished device instead of each individual raw material.

It is indicated in FDA biocompatibility guidance document which was just recently revised a little bit, and I think we have this guidance document included in our resources slides.

Based on our guidance document, you can identify a predicate device, a previously cleared predicate device of your own and compare your current device against your predicate device in its final finished form, with respect to the material formulation, processing, sterilization, and have no additional chemicals are added during the manufacturing process.

If you can provide such a material specification statement to us, we will review the information. You may leverage your previous testing to support the biocompatibility of your current device. However, if you have any changes including for example, raw materials or the raw material suppliers, you need to justify how this change is not expected to affect the biocompatibility status of the current device.

Please be mindful, if you change a raw material supplier even if it is the same name of the material, you may change the material specifications. The types, amounts, and levels of residuals in the materials may be different. So that's why we require biocompatibility assessment on the final finished device.

Coordinator: And our next question is from (Jay Bosco). You may go ahead.

(Jay Bosco): Hi. Thanks again for doing this call. My question is to follow up on the sample size that was (unintelligible) by Dr. (Chen). And then the question I have here is in part to the actual lot size. So I understand the 32 is the recommended amount but that is sort of like (unintelligible) lot size for the AQL (unintelligible).

Assuming (unintelligible) small lot size is it a fair statement that we could then justify a smaller sample size (unintelligible)?

Dr. Cynthia Chang: This is Cynthia Chang. So this will be our last question. And I'll turn it over to Dr. Mavadia-Shukla, to address that.

Dr. Jessica Mavadia-Shukla: Hi. Thank you. If I heard you correctly, you are asking if there was a way in which your lot size or based on your lot size, the sampling number would be less. So this is really up to you to determine based on ASTM F2100 and the sampling standards as well as, sampling based on your lot size and general inspection level 2, if it makes sense to have a smaller sample size based on that information and you have done your homework to justify that.

That would likely be acceptable. But again, we're unable to speak to specific numbers or submissions. This is just in general. But you should be looking at the standard as well as calculating your sample size based on the 4% AQL and your production lot size. Thank you for your question.

(Jay Bosco): Yes. Can I just add a quick comment there?

Dr. Cynthia Chang: We do have to wrap up as we are at the top of the hour. So I will again, thank all of the questioners and the speakers. I would like to turn it over to Irene Aihie.

Irene Aihie: Thank you so much, Cynthia. Thank you. This is Irene Aihie and 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 Wednesday, November 4.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Following the conclusion of the webinar, please complete a short 13 question survey about your FDA CDRH webinar experience.

The survey can be found at www.FDA.gov/CDRHWebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

Coordinator: And this concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please standby for post conference.

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