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

Moderator: Ivory Howard
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Coordinator: Welcome and thank you all for standing by. At this time all participants will be in a listen-only mode until the question-and-answer portion of today's conference. During the question-and-answer portion if you do have a question you may use Star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference over to Ivory Howard. Thank you. You may begin.

Ivory Howard: Hello and welcome to today's FDA Webinar. I'm Ivory Howard of CDHR's Office of Communication and Education. Welcome to the ninth CDRH Webinar in a Respirator Webinar series. The FDA along with the Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, NIOSH and the Occupational Safety and Health Administration OSHA will be available to answer your questions related to respirators and other PPE for healthcare personnel use during the COVID-19 pandemic.

Following a few opening remarks we will open the line for your questions related to information provided during today's discussion. I now give you Dr.

Binita Ashar the Director of CDRH's Office of Surgical and Infection Control Devices and the Office of Product Evaluation and Quality.

Dr. Binita Ashar: Great thank you and welcome everyone. As (Ivory) mentioned this is the ninth session in our biweekly Webinar series on Personal Protective Equipment or PPE. At our prior Webinars we have spent the first part of the session discussing policies and scientific considerations related to filtering face piece respirators, facemasks, gowns and other apparel and then taking live question and answers for the remainder of the session.

The format of today's Webinar is more of a town hall where the entire session will be devoted to answering your questions related to PPE. As (Ivory) already mentioned we have on the line with us FDA representatives and our federal partners and colleagues from CDC, NIOSH and OSHA. To get started I have some frequently asked questions that I would like to run through first before turning it over to the question and answer session.

So the first question is, "Can I reuse a cloth gown?" And the answer is yes cloth gowns that will not be used in a sterile field such as surgery can be reused if they are laundered in enzymatic detergent or per the hospital standard operating procedures.

Okay second frequently asked question, "Are surgical masks required to be NIOSH certified?" No surgical masks are Class II medical devices subject to 510(k) review. During the COVID-19 public health emergency surgical masks may also be marketed under the FDA enforcement policy guidance and/or the emergency use authorization for surgical masks. NIOSH certification is not applicable to surgical masks.

Third question, “Can a surgical mask or a facemask claim conformance with NIOSH filtration efficiency standards?” No. Masks cannot make any claims to meet a NIOSH filtration efficiency standard. Such claims can only be made for a respirator when the respirator meets the specified filtration efficiency.

Next question, “What masks can be decontaminated and with which decontamination system?” The answer according to CDC’s recommendations decontaminated respirators should only be used when unused - with new FDA cleared N95 respirators, NIOSH approved N95 respirators or other FDA authorized respirators are not available.

The decontamination systems authorized for emergency use by FDA are only authorized to decontaminate non-cellulose compatible N95 respirators. As such healthcare personnel should not reuse a respirator that is incompatible with an authorized decontamination system but has nonetheless been decontaminated using such a system. Users of any respirator whether or not it has been decontaminated should always assess for proper fit after placement. Respirators with poor fit, visible soiling or damage should not be used.

Additionally please check the scope session of the letter of authorization in the fact sheet for each individual decontamination system. If you are not sure please contact the manufacturer of the decontamination system. Note that for vaporized hydrogen peroxide based decontamination systems cellulose-based respirators cannot be decontaminated. Please note that FDA has not authorized any decontamination system for decontaminating surgical masks or facemasks.

And the last frequently asked question, “I would like to import masks for COVID-19 what do I need to do?” The answer to avoid delays of legitimate shipments we urge importers to review the importing supplies for COVID-19

and instructions to importers for important information about importing product including facemask and surgical masks to ensure the proper documentation is submitted at the time of entry.

The FDA is ready and available to engage with importers to minimize disruptions during the importing process. If you have questions related to the general importation process you may email covid-19fdaimporting inquiries all one word at covid-19fdaimporting inquiries@fda.hhs.gov. If you have questions regarding an active entry please contact the FDA office covering your port of entry by visiting the FDA Import Offices and Port of Entry page.

With that we are going to switch over to our live question and answers. Operator can we have our first question please?

Coordinator: Thank you. We would now like to open the phone lines for any questions. If anyone does have a question please unmute your phone, hit Star 1 and record your name when prompted. Again that's Star 1 to ask a question and Star 2 to withdraw your question. One moment while we wait for the first question. And it looks like we have one queuing up, one moment. And our first question is from Mr. (Glenn Fey). Your line is open.

(Glenn Fey): Yes this question relates to power air purifying respirators specifically for biological for COVID-19 issues? And basically we were - it's very unclear does the EUA cover that or do we have to go through NIOSH and get that - go through the standard application procedure? And then the other question I have is if we do the standard application procedure how long would that take for testing?

Dr. Binita Ashar: This is Binita Ashar. Thank you Mr. (Fey) for your question. I'm going to direct your question to Dr. Cynthia Chang and Afton Ross. Can one of you address it please?

Dr. Cynthia Chang: Hi. Yes this is Cynthia Chang. Thank you for the question. I can start. So we do have an EUA that allows for the use of NIOSH approved powered air purifying respirators which would be authorized under our EUA for use in healthcare settings. That is for NIOSH approved power air purifying respirators.

So if you have NIOSH approval then you are authorized under the FDA EUA. If you are not authorized then you should seek NIOSH approval (unintelligible) NIOSH. And I'll…

Dr. Binita Ashar: And then…

Dr. Cynthia Chang: Go ahead.

(Jeff): Cynthia this is (Jeff)…

Dr. Binita Ashar: Please (Jeff) go ahead.

(Jeff): So I'll go ahead and chime in. So, you know, as Cynthia said if you're interested in NIOSH approval of a powered air purifying respirator that offers particulate protections in accordance with our regulation there's several factors that play into the time considerations with approval of a device like that. So we do have a prioritization policy on our Web site. And you'll note that, you know, folks that do all of their manufacturing, quality assurance and design and development activities domestically certainly are getting priority.

So I - the second thing I want to reinforce is that the NIOSH approval is much more than just a testing scheme. So we are also interested that you meet all the minimum quality assurance requirements within the standard. So that's typically where the most - that's typically the most challenging aspect of achieving approval. So certainly if you have additional questions after, you know, this Webinar you can reach out to myself and I can provide you some more details about the process.

(Glenn Fey): Okay thank you.

Coordinator: Thank you. And again that is Star 1 if you have a question on the phone. And next we have (Maher Diudi). Your line is open.

(Mayor Diudi): Yes hi. Can you hear me? Hello.

Dr. Binita Ashar: Yes we can hear you.

(Maher Diudi): All right great. So a question for you guys so the CDC and NIOSH had a new rulemaking of the PAPR of 100 on April but they're still talking about using the HEPA filter NERVH17. Now the crew we are working with and we've got basically a PAPR system that is literally 3000 times better than what's kind of out utilizing a more advanced filtration system. The problem is the NIOSH rules basically are stated that you have to have an LPM range that you have to stay within but we need to be over 170 LPMs in order for this to work. But this is 99 like 99.99999% it captures COVID so that's one.

And then two we've created an open source (unintelligible) self-oxygen concentrator anybody could build utilizing common parts around you including, you know, at Home Depot and online. There's several people who kind of our building these. Proven it works great. It filled the oxygen gap. So

it is a DIY open source model we'd like to see how we can get, you know, more of this out there. This has been actually like - people from the World Health Organization and there's some really big - we've got like 200 very strong readers chief medical directors backing this as well.

Our chief medical director is the chief residency director for Kaiser. And so but everyone is like this is what's needed right? So it's - I guess we've got awesome products here we'd like to push through before the second wave obviously. But how do we – we need some help to navigate through the regulations to get these out. And of course adjust - I mean that one rule would you guys adjust that rule of the 170 LPM to allow it just allow an increase in LPM for the PAPR to work?

Dr. Binita Ashar: This is Binita Ashar. I think you have several questions embedded in there but perhaps I'll turn it to my CDC colleague Dr. (D'Alessandro) to perhaps talk generally about the rule and common considerations related to filtration systems. And perhaps part of the question may need to be taken off-line to discuss your particular circumstances but let me turn it to Dr. (D'Alessandro).

Dr. Maryann D'Alessandro: Binita, Jeff is going to take this one thanks.

Dr. Binita Ashar: Okay wonderful. Thank you.

(Jeff): So hi. I'm Jeff again. So, you know, essentially I think one of your concerns was, you know, the minimum airflow rate correct?

(Maher Diudi): It's actually the maximum airflow rate is at 170. It needs to be more than - we need more than that.

(Jeff): Actually a misinterpretation. So the minimum airflow rates for a tight fitting powered air purifying respirator are 115 and for a loose fitting system 170. So if you're maximums are a bit higher that's fine as long as you would continue to stay in the realm of not creating too much noise within the hood if the hood goes over the ears. That's one of the concerns along with, you know, drying out eyes and such.

So, you know, what I think I, you know, from based on what you said if you're greater than 170 we should be good and we can take this discussion, you know, off-line to discuss specific details. In terms of, you know, the open sourcing question that's not the way that a NIOSH approval is set up to work. So whoever the approval holder is owns the design, controls the design and controls the manufacturing. So in terms of open sourcing product that's not possible to achieve under a NIOSH approval it would need to be controlled by the approval holder.

(Maher Diudi): Okay. So how - when you're saying take it off-line how can I get in touch with you and (unintelligible) and have a kind of designer engineers on there as well?

(Jeff): So I can certainly give you my email address. Binita is it better to do that in some other manner or can we say it out loud here?

Dr. Binita Ashar: I think what we might have this individual do is make sure that the operator has your contact information and so that we can circle back with you.

((Crosstalk))

(Maher Diudi): And if you want can I just give you the - my email address. It's very simple Maher M-A-H-E-R@shieldmission.com. Does that help?

(Jeff): Sure thank you.

Dr. Binita Ashar: Great thank you

(Maher Diudi): You're welcome.

Dr. Binita Ashar: I think we're ready for the next question.

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

(David): Hi there. Thanks for making the time this afternoon. I had a quick question to confirm whether the reusable quarter face piece elastomeric respirators would be considered to be within the product code MSH and if not which would be appropriate product code for the thinner product.

Dr. Binita Ashar: I think I'm going to first turn to my FDA colleagues to see if somebody from OHD4 knows the answer to that question. Dr. Chang, would you know the product code?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. Maybe I can try to address the question. So for elastomeric respirators they do not fall under MSH. That is for filtering face piece respirators such as N95s that are surgical respirators. At this time there is not a specific product code for elastomeric respirators however they are covered by the umbrella EUA for NIOSH approved air purifying respirators. So if you have an elastomeric respirator that is approved by NIOSH then your elastomeric respirator would be covered or it would be authorized for use by healthcare personnel for the duration of the public health emergency.

(David): Perfect. And then a quick follow-up, what would be the most prudent thing to pursue in preparation for the emergency period being lifted provided we would have NIOSH approval?

Dr. Cynthia Chang: Yes I would recommend that you contact our Office of Surgical and Infection Control Devices for specifics about the marketing of their specific device.

(David): Perfect. Thank you.

Coordinator: Thank you. Our next question is from (Jose Chavez). Your line is open. Mr. (Chavez) your line is open.

(Jose Chavez): Hello. Good morning.

Dr. Binita Ashar: Good morning.

(Jose Chavez): Good morning everybody. I was overhearing the conversation regarding prioritizing domestic firms specifically for the, you know, the appropriate approval processes for pursuing NIOSH approval for face piece respirators. I'm unsure whether that same type of policy is being applied for the non-NIOSH approved respirators under the EUA Appendix 1. I have been noticing a tremendous influx of approvals for respirators that are specifically from one jurisdiction. In fact there was one jurisdiction a whole standard created for one jurisdiction.

Now for the KN95 type of respirators but for the Appendix 1 which is the - which was release I believe or updated in June 6 of 2020 that lifted EUAs or our approvals have not really changed. Actually as of August 21 there has not been any recent updates to any approved manufacturers or establishments that

have submitted products for review under that EUA. And I'm starting the question - the prioritization here because for example our firm submitted an EUA under Appendix 1 for respirators back in August 10 and it's now September 29 and we have not gotten a response that would quantify either an approval or a rejection.

Dr. Binita Ashar: Hi. This is Binita Ashar. I can start and then I might turn it over to my colleague at FDA Dr. Ross to chime in. So, you know, it's very difficult to be able to tell a particular - any company the exact duration of time it's going to take to review an EUA application simply because companies may have a different amount of preparedness if you will with their application. So they're, you know, sometimes applications are set and ready to go all of the information is present and it's a matter of processing in other cases the teams and several individuals are involved in the review and there's a lot of back and forth discussion. I think as we said at prior Webinars we are however very committed to making sure that we have good communication with the applicant so that you know the status of your file.

Now with respect to prioritization specifically for non-NIOSH approved respirators I'm not aware of any particular prioritization related to domestic versus outside of the US but I'll have Dr. Ross may be comment on that.

Afton Ross: Thank you Dr. Ashar. So just to make sure that everyone is clear. I think the caller might understand this but I think that the way it might have been posed might be a little confusing for others. So I just want to make sure that everyone understands that the EUA that's being referenced is for imported respirators. So these are from countries other than China. So we're not talking about domestic manufacturers here. I just want to make sure that that point is clear.

And certainly as Dr. Ashar said we have staff that are working on these submissions. We are getting a good number of submissions and it takes time to work through those. We will try to be as communicative as we can. And certainly if we have questions or need additional information as we review your submission we will reach out with regard to that. But certainly, you know, we are recognizing the importance of these products but as Dr. Ashar said it does take some time and we are receiving a good volume of submissions.

(Jose Chavez): If I may ask, you know, we – despite the fact that the full - the manufacturer it is foreign us our company is here in California is the design holder. And we have begun communication was Dr. Attwood to pursue the appropriate CDC NIOSH approval which encompasses the quality management system as well as the product approvals. But just it's a little bit - we haven't had - we haven't received a straight answer yet from anybody from the FDA on this.

(Jeff): Okay.

(Jose Chavez): And we followed the - we followed the guidance document that was provided and updated on August 21 verbatim. And so that's why I'm - it's a little bit disheartening and trying to understand what is it that we're, you know, we did not provide that is postponing aside from understanding the workload that both, you know, the Center for Disease Control and the Food and Drug Administration are undertaken during this pandemic. So I – it's a degree of communication yes. But it's also in reference to I have not – have made it as straightforward as possible so that reeling our package would be user-friendly for lack of a better word.

Dr. Binita Ashar: Right so this is Binita Ashar. I think we're talking about two different things there. So I just want to make sure that we're very clear so the authorization

process involving these respirators that is something that you would come to FDA for. Now what it sounds like is it sounds like you're looking for actual approval of your respirator. And that would be a CDC led effort. And so I will turn to my CDC colleagues and see if they have any additional advice or feedback regarding the approval process?

(Jeff): So this is (Jeff). So Mr. (Chavez), you know, we can - if you could contact me off-line that would be great. We can talk about the details. You know, certainly I think we are providing every effort to correspond with everybody who makes a request and share with where they may be deficient in their request. For what it sounds like you're trying to achieve is approval of some type of respirator and you're trying to get your manufacturing code in order to pursue that.

So, you know, there is a process for that. The questionnaires need to be completely, you know, filled out. And typically what happens if there is a deficiency identified that is communicated. So, you know, if, you know, there again I think this is a better conversation to have off-line to talk about the details but certainly we can see where you're at if you contact me and try to provide some clear guidance if that's the case the needs to happen.

(Jose Chavez): My apologies I think I may have misplaced my question. I guess I didn't explain myself properly. We've submitted a request to be added to Exhibit 1 of the authorizing import non-NIOSH disposable face respirators. And that was updated on August 21. So we have a very short list of companies that are on that list so establishments excuse me manufacturers.

We are in parallel coordinating or actually we already initiated the questionnaire process with Dr. Attwood. So my - and we understand the priority of those domestic versus nondomestic manufacturers, establishments

design holders of face piece respirators especially in this context N95s. My concern -- and what's probably coming out as a little bit of frustration -- is the really the lack of appropriate response or review on the FDA side on reviewing our applications within the confines of the FDA not the CDC.

Dr. Binita Ashar: Okay well I think what I would encourage you to do is to circle back with your point of contact at FDA because like I said before we are committed to letting you know what the status is of your application. You know, I know that, you know, it is frustrating. We have a lot of work that we're trying to plow through and, you know, it's never as fast as we all wanted to be. But our staff are working around the clock and are committed to their jobs and to being responsive. So I think I would, you know, do whatever necessary to communicate to the team the urgency around your request and solicit any feedback from them regarding what might be necessary to move your application forward.

(Jose Chavez): I appreciate that. Thank you.

Coordinator: Thank you. Next we have (Michelle Lott). Your line is open.

(Michelle Lott): Hi. I have been working on several different types of submissions between EUAs and actual 510(k) submission. And I'm getting a wide variety of feedback about the ASTM 2119. And the FDA's interpretation of the AQL sample size as well as the interpretation of three nonconsecutive lots. And I've worked in masks a long time before health crisis and this is the first time that we're getting feedback like this. I know that ASTM is subject to be rewritten October 20 but can the FDA speak to these changing requirements that might be happening behind the scenes right now internally and then how you're going to consistently implement them, you know, moving forward?

Dr. Binita Ashar: Thank you for that question. This is Binita Ashar. I'm going to turn it to my colleagues in OHT4. Dr. Jiping Chen, can you comment on this?

Dr. Jiping Chen: Yes sure. This is Jiping Chen. Thank you for the question. So your question is about our, you know, the sampling size and the large media to demonstrate the performance of the surgical mask.

So this request is consistent to the way ASTM (unintelligible). For the broader penetration testing we request three - two samples per lot for the testing which is based on the ASTM (unintelligible) which would extend the referenced in the (unintelligible) 100 applicant is also FDA recognized standard. So the sample size - so there's two samples per lot for the test.

Then for the left the performance testing including the particulate (unintelligible) testing and the bacteria filtration testing (unintelligible) testing et cetera. And based on the ASTM (unintelligible) 2019 version. And for each of the performance testing and you need to (unintelligible) 4% based on the then the sample size should be selected based on the product and lot size and (unintelligible).

And then ASTM can be 100 also reference the site here two standard for the examples of acceptable sampling plan is this to standards size here in the ASTM 100 are also FDA recognized. So what we request is based on the FDA recognized standards on the ASTM 100.

And also when we do the 510(k) review we will also consider the - your claim. For example if your claim ASTM can be one Level I. And if you can claim the conformance standards to expect here all the testing should be conducted in accordance to the standard new (unintelligible) new claim conformance. So this is – and look regarding the lot size, you know, it is our

general recommendation you need to demonstrate a loss to market perform to demonstrate your mask can perform as intended consistently across the different production lots.

So this is the basis the scientific basis and the regulatory basis for our request. We people are asking if we are raising the acceptance bar for the surgical masks under review we are not and all the requests in consistent with the industry consensus standards and also consistent with our regulatory history too. Our regulatory history is based on, you know, the (unintelligible) identify and also and the claim you try to made. And to demonstrate your device is safe and effective and the performance well or better than the private device identified.

Woman: Thank you for that. And just to bring it to the agency's attention I know that it's always desirable to be able to count for lot variation between test methods or test sample sizes. However particularly for masks most of this raw material comes off of rolls and a single shipment of raw materials might not capture the lot variation that the agency may be anticipating and would be a significant investment for industry to give the quantity of raw materials to capture this type of variation.

Dr. Jiping Chen: And this is Jiping Chen again. Thank you for your comment. But just for FYI our 510(k) (unintelligible) for the substantial equivalents is based on the final finished device. So our review is not based on the raw materials will use and/or each of the raw materials you use.

So all the performance testing should be based on the final finished device because the final finished device after going through all the manufacturing processes including sterilization if we're (unintelligible) and the main change here the (unintelligible) of the raw materials. So all the performance testing is

expected to be conducted based on the final finish of device - product you intended to put on the market.

Dr. Binita Ashar: This is Binita Ashar. I just wanted to, you know, thank you for the feedback regarding the, you know, the testing may appear burdensome. But I do want to point out just one thing is that we have several we - during the pandemic now we have developed several pathways by which these important devices are able to be marketed.

If you want to look at it this way the lowest bar would be adherence to our enforcement policies. So those exist for surgical masks. And then there is the umbrella EUA for surgical masks. And those requirements are a little bit more than what is required in the enforcement policy.

And then finally is there the 510(k) requirements which allow your masks to be marketed beyond the public health emergency. And the 510(k) requirements have been the same requirements that we had even before the pandemic. So I think that, you know, you're doing the right thing. You're already marketing your device either under our enforcement policy or under the EUA and you're moving to meet the requirements of the 510(k).

But these have been very standard requests for our 510(k) review practices. And while we encourage manufacturers to submit 510(k)s we are not changing our requirements for the purposes of the pandemic because we already have done so with respect to the enforcement policy and the umbrella EUA. But we do appreciate your feedback and thank you for the question.

(Michelle Lott): Thank you. You bet.

Coordinator: Thank you. Next question comes from (Russ Olmsted). Your line is open.

(Russ Olmsted): Yes good afternoon everybody. Thanks for providing this forum and really appreciate the convergence of OSHA, NIOSH, CDC and FDA on this. I think it's very helpful. I have two questions. The first one is have the agencies looked at or worked with professional organizations around other types of respiratory protection in the surgery suite specifically PAPRs or elastomeric respirators in those settings? I know there's theoretical concern about contamination of the surgical site when those are worn but I - there is some preliminary evidence that that probably is not a major issue certainly for people that are not directly involved in the procedure like the surgeon and first assist but just curious on that one.

Dr. Binita Ashar: I think it's a great question. Thank you for asking it. I'm going to turn to my OSHA and CDC colleagues to see if they wanted to address that question?

Andy Levinson: So this is Andy Levinson from OSHA. And from OSHA's perspective our authority and jurisdiction is only for the workers in the surgical suite. And from a worker safety and health perspective there's no concern. I think the infection control issues you're raising are more going to wind up being FDA and/or NIOSH issues.

(Russ Olmsted): Great.

Dr. Maryann D'Alessandro: This is Maryann from NIOSH. We do have some preliminary data that is saying that it is not an issue to use these devices in the surgical suite. But currently the CDC guidance is that if you are using them you're using elastomeric respirator you should have a surgical mask over the respirator a surgical mask with ties so it does not compromise fit. And if you're using a PAPR then you should have one underneath the PAPR.

So again we do have some preliminary data. We do believe in the future they guidance will be updated but at this point in time those of the CDC recommendations. Thank you.

(Russ Olmsted): Great very helpful. That sounds good. And then part two is - we from our supply chain leaders within our health system have - are aware of some pending or concerns about a shortage of raw materials related to the development or production of gowns and other materials such as - that involve spunbonds for example. Are FDA and CDC kind of revisiting their contingency in crisis strategies if we do end up with for example on the surgical site or surgical suite where we may not have foot covers or gowns available, you know, traditional materials but just curious if there's any awareness or discussion on those?

Dr. Binita Ashar: This is Binita Ashar from FDA. I think, you know, our CDRH team is always monitoring and, you know, for potential shortage issues. Now whether or not they're familiar with this one this specific item I am uncertain. I don't know if Dr. Ross you have anything to add around this potential shortage issue?

Afton Ross: Thanks Dr. Ashar. So as Dr. Ashar said we continue to engage with various public health stakeholders to understand where there might be supply chain or product availability concerns as well as what might be some of the root causes of that. Very early on in the pandemic FDA had communicated about alternatives for consideration when you have short supply of various types of PPE certainly linking to CDC guidance as appropriate for regard to that.

We continually look at that information to see whether it makes sense based on new information that may come in to make any updates. So we haven't at this time but certainly please know that we are monitoring the situation that we can evaluate the mitigations that have been put forward to see whether

there might be other options depending on where we are in the pandemic scenario.

(Russ Olmsted): Great very helpful. Appreciate it. Thanks so much.

Coordinator: Thank you. Our next question is from (Ricardo Romero). Your line is open.

(Ricardo Romero): Well good afternoon. So my question is (unintelligible) the 510(k) while we know right now in the pandemic and the universe for these the 510(k) but we're actually searching through the forest fires in this process to export from our manufacturing company per the US. And we would like to know how much time do you think it actually takes? We've been told around from six to, six months to eight months but we want to hear it from.

Dr. Binita Ashar: And thank you. I think your question was is how long is the review time for a 510(k) submission on a Personal Protective Equipment device. Maybe I'll have Dr. Chang would you like to address that question?

Dr. Cynthia Chang: Yes hi. This is Cynthia Chang. So for 510(k) the – during the public health emergency we were recognizing the importance of prioritizing these submissions. And so we are doing that. We are, you know, putting a high priority on PPE 510(k)s.

The typical review time for a 510(k) is 90 days for FDA's review. If there is the need for additional information to be requested or any additional testing then we might place the file on hold to stop our 90 day review clock to allow the company to, you know, get that additional information and respond back. So at this time as I mentioned we are actually prioritizing PPE submissions.

The, you know, the time that it takes for a particular submission really depends on the completeness of the submission when it comes in. So if you, you know, have most of the testing done and most of the information or all of the information and all of the testing available at the time of submission then the review process is going much faster than the typical 90 day review clock.

However, you know, if it's not complete then it might actually take longer as, you know, we have to work with the companies to bring them, you know, to the point it may be cleared. We are working interactively with (unintelligible) to get them across the finish line as much as possible because we do recognize the intensive need for these PPE devices. Thank you.

(Ricardo Romero): Thank you.

Coordinator: Next we have – go ahead.

(Ricardo Romero): Yes (unintelligible) thankyou much. So I was wondering if you already got all that you need for our submissions speaking ASTM testing and all the paperwork. I just want to know like the approximate time to the really didn't hear it's (unintelligible)…

Dr. Binita Ashar: Okay this is Binita Ashar. I think what you're asking is the specific status of your file related to some of the testing that you've provided. So what I would do is I would reach out to the lead reviewer that's been assigned to your file and ask them if they have all the information that they need. As Dr. Chang pointed out we are looking to be interactive with the submitter so that if there is a question that we will pick up the phone, give you a call, ask you to provide the information on the order of days so that we can continue to move forward and progress the application.

(Ricardo Romero): All right that sounds perfect. Thank you.

Dr. Binita Ashar: Thank you.

Coordinator: Thank you. Next we have (Janel Bentz). Your line is now open.

(Janel Bentz): Hi. Thank you. My question is related to the sampling plan question. ASTM F2100 references 16 CFR Part 1610 for the flammability testing. That standard very specifically talks about how many samples to test for the testing. And it's up to 14 but it usually ends up being nine. With the request for 32 samples from the FDA is there a proposal from them about how to modify the standard to accommodate that?

Dr. Binita Ashar: This is Binita Ashar. I'm going to ask my colleague Captain (Claberle) if she could answer this. I know that she's aware of some of the work that's being done by the standards organization.

(Claberle): Hi. Thank you so much for the question. And I'm going to just so I can make certain that I respond to you correctly would you please remind repeating the question for me please?

(Janel Bentz): I would love to. With the questions about sampling size ASTM F2100 references 16 CFR Part 1610 for flammability testing. That CFR speak specifically to the number of samples to be tested. Usually ends up being for four preliminary testing and then five samples and there's potential for there to be five more for a total of 14. But just wondering if the FDA has a recommendation for accommodating either, you know, going back to that requirement for the CFR without that AQL or modifying that CFR to allow for AQL testing?

(Claberle): Okay very, very good question. So right now we are actually working with the standards organization. We are looking at the standard of to see whether or not – we're looking at the standard right now because as you know ASTM is thinking about making some changes to the standard. And we hope to be able to come out with better guidance in the very near future but as of right now we're continuing to follow the standard that's current. And I'm going to ask Dr. Chen if she has any more visibility on anything in addition to what I said from the standards organization?

Afton Ross: Sorry if I could just clarify before Dr. Chen there are two standards here F2100 talks about an AQL of 4% but the CFR that's referenced gives a specific number to test. So it's confusing to know which standard to follow when the testing standard gives a number to test but we're being asked to test a different number.

(Claberle): Dr. Chen…

Dr. Jiping Chen: Yes thank you for the question. So actually this is related to the question. This is something of the standard that show that, you know, will make more collaboration in the next division. So regarding the flammability testing the standard efficacy 100 the referenced for the CFR 1610 for the standard method. So yes for the standard method (unintelligible) we also agree and they should follow the method of the 16 - CFR 1610.

But the CFR 1610 standard itself is not recognized by the FDA yet. So regarding the sampling plan the efficacy 100 says it's 4% says the sampling size should be collected based on the production lot size and also the standard (unintelligible) in the two standard (unintelligible) in the efficacy 100 for the sampling plan.

So my recommendation is if you believe your sample size is adequate then you provide certification during the 510(k) to follow 510(k) submission. But right now and we, you know, think that the ASTM efficacy 100 is your - the ASTM is the most current and we should be recognized and generally we will go with the efficacy 100 until it is realized and recognized by the FDA.

But always while the standard if you reference the ASTM efficacy 100 and claim the performance to the standard (unintelligible) if you do the testing based on your conformance to the standard. I mean always you can provide the originals for any (unintelligible) made from the standard we will review your scientific (unintelligible) and also the (unintelligible) to see if it's acceptable.

(Janel Bentz): Thank you.

((Crosstalk))

Dr. Binita Ashar: Hi. Binita Ashar I just wanted to with that last question wrap up from my end and then turn it over to (Ivory). We, you know, again want to thank all of the subject matter experts who joined us today. Our next session will take place in two weeks on Tuesday, October 13 at noon Eastern.

The announcement of topics will be forthcoming. And we encourage you to share with us those that might be of interest to you. I'd like to know turn the session over back to (Ivory) who will close it out.

Ivory Howard: All right thank you. This is Ivory Howard. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be available on the CDRH Learn Web site at www.fda.gov/training/cdrhlearn by Wednesday, October 7. If you have additional questions about today's

presentation please use the contact information provided on the slide. As always we appreciate your feedback.

Following the conclusion of this Webinar please complete a short survey about your Webinar experience. The survey can be found on www.fda.gov.cdrhwebinar immediately following the conclusion of this Webinar. Again thank you for participating. This concludes today's Webinar.

Coordinator: Thank you for participating in today's conference. You may disconnect your line and enjoy the rest of your day.

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