

**FDA Webinar Series - Respirators for Health Care Personnel
Use During the COVID-19 Pandemic**

**Moderator: Irene Aihie
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12:00 pm ET**

Coordinator: Welcome and thank you for standing by. For the duration of today's conference, all parties will be in a listen-only mode until the question-and-answer session of the conference. At that time, you may press star 1 on your phone to ask a question. I would like to inform all parties that 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 Ms. Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I'm Irene Aihie of the CDRH's Office of Communications and Education. Welcome to the fourth CDRH webinar. In our webinar series on the topic of respirators for health care personnel use during COVID 19 pandemic. Today we will be joined by experts from FDA Center for Devices and Radiological Health. And colleagues from Occupational Safety and Health Administration and the Centers for Disease Control.

During this webinar, representatives from the FDA and CDC and OSHA will answer questions from webinars attendees in open questions and answer format. Following a few opening remarks, we will open the line for your

questions related to information provided during today's discussion.
Colleagues from both CDC and OSHA will join us to assist with the Q&A.

Now I give you Doctor Suzanne Schwartz, acting Director of CDRH Office of Strategic Partnerships and Technology Innovation.

Dr. Suzanne Schwartz: Thank you. As Irene mentioned, this is the fourth session in our biweekly webinar series on PPE where we're continuing our discussion on respirators for use by healthcare personnel during the COVID-19 pandemic response.

Thus far we've covered a broad overview of the landscape, a presentation of FDA imports, as well as a briefing on the CDC NIOSH International Respirator Testing program. And most recently, the July 7 session focused on the decontamination of respirators.

Today we're going to change things up a bit. Rather than starting with a formal presentation and then shifting to operator facilitated Q&A, we're going to hold the entire session as a town hall-style. We'll kick things off with frequently asked questions that FDA and CDC NIOSH have accrued over the past months. And then we'll turn to the operator for live Q&A.

I'm pleased that our partners and colleagues from CDC NIOSH and OSHA are on the line as well, and will be fielding questions relevant to their respective agency's work.

We'll start with a few questions that have come into the FDA and to NIOSH and while we go through these questions, Irene - can we display the slide that has the links to resources for all three agencies?

So again, I'm going to start with a few questions that have come into FDA over the past weeks or months that are common. And we'll start with the following: Do the existing EUAs cover non-healthcare uses of decontaminated respirators? And the answer to that is: No. The existing EUAs do not cover non-healthcare uses of respirators. They are specific in covering the scope, which is decontamination of respirators for use by healthcare personnel. To add a use outside of healthcare, an amendment would be necessary to an existing EUA from the EUA holder.

Another question: What modes of decontamination have been authorized thus far, and what are the scientific considerations for review of the various modes? The answer is: FDA has authorized EUAs for respirator decontamination using several methods. The majority use vaporized hydrogen peroxide. One authorization uses moist heat. Another uses hydrogen peroxide and ozone. It's important to note that the safety and effectiveness of a decontamination method varies, not just by the modality, but also by the specific device used and even by the specific settings or cycles within a particular device or decontamination system. Please refer to the guidance that we published. And note that there are three tiers of decontamination claims that are presented in that guidance.

The third question: Is there an EUA for US manufacturers that do not have NIOSH approval? And the answer to that is: US manufacturers need to obtain a NIOSH approval in order to be covered under the NIOSH-approved air-purifying respirator EUA.

Fourth question: If my product appears on the NIOSH International Respiratory Assessment with a filtration efficiency for all the respirators of greater than or equal to 95%, am I automatically added to the FDA EUA? And the answer is: No. You would need to submit information to FDA

demonstrating that you meet one or more of the EUA eligibility criteria.

I'm going to now move on to a few questions that have come into NIOSH, as well, as a sampler. So, the first question is: Can a NIOSH-approved respirator with an exhalation valve be used as source control? And I'm going to ask Colleen Miller if she could provide a response.

Colleen Miller: Hi, thank you, Suzanne. Respirators with exhalation valves provide protection from COVID-19 for the individuals wearing them, but they may not prevent the spread of the virus from the wearer to others, as a source control. Until data are available to demonstrate the extent to which respirators with exhalation valve also slow the spread of the virus from the wearers to others, a respirator without an exhalation valve should be worn when both source control and respiratory protection are required. If only respirators with exhalation valves are available, the exhalation valve should be covered with a surgical mask, a procedural mask or a cloth face covering that does not interfere with a respirator fit - when the individual is unable to maintain social distance from others who are not wearing respiratory protection.

Dr. Suzanne Schwartz: Thank you Colleen. Another question: Does decontamination extend the life of a respirator? And I'm going to ask if Ed Fisher is available from CDC NIOSH to provide a response.

Ed Fisher: Sure, thank you. Does decontaminates extend the life of a respirator? Well, there are many factors that can limit the life of a respiratory including fit, filtration performance and the presence of pathogens trap on the FFR which can present the cross-contamination hazard. FFR decontamination will reduce or eliminate the risk of cross decontamination, but it will not increase the number of times or hours that an FFR can be worn. FFR performance will decrease as the number of hours of use and number of times (unintelligible)

increases. The number of times the FFR to be reused would likely be limited by fit because the coverage can become weaker or stressed after each time is placed on the face of the user.

Manufacturer guidance on how many times an FFR can be gone is not available. The CDC recommends limiting the number of users to no more than five per device. This recommendation is based on limited data per FFR fit over multiple bodies.

Fit performance during limited reuse which may include decontamination should be monitored by the respiratory protection program manager or appropriate safety personnel. Thank you.

Dr. Suzanne Schwartz: Thank you very much Ed.

So why don't we go ahead now and turn to the live Q&A. Operator, may I have the first question, please?

Coordinator: Thank you. As a reminder for those on the phone, if you would like to ask a question, please press star 1 and record your name. Your name is needed in order to introduce your question. If you choose to withdraw your question, please press star 2. Again, if you would like to ask a question, please press star 1. It will take a few moments for questions to come through. Please stand by.

The first question will come from and allow me to announce the name.

(Greg Ounion): (Greg Ounion).

Coordinator: Your line is open.

(Greg Ounion): Hi, I've got a question and this might be for a combination of the hosts there. First, CDC recommended guidelines for extended use of N95 respirators. It seems there's a fair amount of anecdotal evidence that suggests the health care professionals are now routinely using their N95 respirators for eight hours or more for an entire shift. My question is assuming that an aerosol-generating event or other obvious soiling of blood or other bodily fluids, et cetera does not exist on the outside of a respirator, subjects extended use by definition, when does that respirator become quote-unquote soiled masks, considering this load of sebaceous secretions and facial oils?

Dr. Suzanne Schwartz: Thank you very much. I'm going to turn to our NIOSH colleagues. I don't know if it's Ed that wants to address that, or Colleen.

Colleen Miller: I would actually -- this is (Colleen). I would appreciate it if Harold, Jonisha or Ed could answer this question.

Dr. Suzanne Schwartz: Okay.

Ed Fisher: This is (Ed). So, I think the extended use currently we recommending 8 to 12 hours of use. Again, I'm not sure I mean if it's obviously visibly soiled, though we would say you should discard the mask. As soon as you notice that it is soiled. But, you know, we have an 8 to 12-hour recommendation for the extended use you affirm that addresses specific for this question.

(Colleen Miller): I would also consider user instructions as well.

(Greg Ounion): Okay, thank you.

Dr. Suzanne Schwartz: Can we have the next question, please?

Coordinator: The next question comes from (Jessica), your line is open.

Jessica: I have two questions. One is that I have a really hard time justifying throwing away a perfectly good N95 mask because it's been on and off five times, especially if it has been left in the bag for five days and it's supposed to be decontaminated. And then my second question is that I was reading yesterday on the CDC Web site where they were saying that if you've been using a mask in an aerosol-generating situation that it should be discarded. And we have been having many people that were, you know, either unknowns or nebulizer aerosol treatments. You know I worried that (unintelligible) throw away every time that you've been in a room with aerosol treatment. Thank you.

Dr. Suzanne Schwartz: All right, thank you for that. I think this question goes back to NIOSH again regarding the recommendations regarding repeated usage.

(Ed Fisher): Yes, so the recommendation for five times is based on a study that looked at most of the FFR. You know, over the model, most models (unintelligible) to perform sufficiently for five (dawnings). Obviously, there were some models that performed fine after five (dawnings) and, you know, up to 20 (dawnings). But that was a limited number of models. And some FFR models weren't unable to perform up to five (dawnings). So, this recommendation is based on what we thought would provide the safest, a little bit of security and the number of dawning these respirators can be used. It's a recommendation. If these respirators are able to perform and fit after five (dawnings), obviously, we would encourage people to use those. But those should be assessed by the respiratory program manager or some other safety personnel.

And I apologize. The second part of the question.

(Jessica): The second part of the question was that I was reading about how on the CDC

they were saying that N95 should be discarded in situations and one of them was after an aerosolized treatment. And my question here is you have like several patients and they are just unknown, or negative test and you're going into an aerosol treatment situation, are you supposed to then discard that after every single time that you're in the room with this treatment?

(Ed Fisher): We would recommend that you discard the respirator after an aerosol-generating procedure. That just based on trying to limit the risk, reduce the risk of self-contamination. Assuming that aerosol during a procedure is creating a highly concentrated aerosol with the virus (unintelligible) become the trap on the surface with a respirator. So that will be the reason, the only reason we would say to - why we recommend that you discard the record after aerosol during procedures.

(Jessica): Well I understand that, but like, we will be discarding, a lot of N95s for that reason.

(Colleen Miller) We understand your concern and at this point, we can certainly take it forward to our CDC colleagues that are working on the guidance and ask them if they can better address your question.

Dr. Suzanne Schwartz: Okay, thank you. Can you take the next question, please?

Coordinator: As a reminder for those on the phone, if you would like to ask a question, please press star 1 and record your name. For those asking questions from the net conference, please address all questions to Irene Aihie and not to the host. Again, to ask a questions on the phone, please press star 1 and record your name. The next question comes from (Joe), your line is open.

(Joe Marker): Yes, this is (Joe Marker). I'm curious to the reaction, that its ironically, it was

published the day of your last WebEx, which is on July 7, a test study that was published in JAMA. And it pertained to a revisit of the subject of decontamination respirators particularly using the hydrogen peroxide system. And, were there any comments from March to that study because they seem to demonstrate a significant concern about repeat decon, particularly more than once, actually. So, any remarks to that. I don't know if it goes to Dr. Fisher or whom.

Dr. Suzanne Schwartz: Thank you very much. This is Suzanne. I'm going to direct that question to FDA colleagues to start here and Liz Claverie, can you take that question?

Liz Claverie: Sorry Dr. Schwartz, I am going to ask my colleague, Dr. Clarence Murray or Dr. Jon Weeks if they are able to field that question for us, please.

Dr. Clarence Murray: This is Dr. Murray. So, first of all, thank you for the question. I haven't read the latest version, just as the update to that report, can you share a little bit more information and rephrase your question for me, please.

(Joe Marker): You bet. So published in JAMA, July 7 and the study was a correlation between N95 extended use (unintelligible) and fit failures in emergency departments. And they, so UCSF they did testing on 58 subjects and found to be a failure rate, particularly among duckbills somewhere in the range of 70.6% after anywhere from one to four reuse or decontamination. A little less though in domed masks, so about 38% failure rate.

So, in both those cases. That's significantly higher failure rates compared to several other studies that were out there. So, I'm curious to the reaction and or if there's an opportunity later to come back to that.

Dr. (Clarence Murray): So, this is Dr. Murray. I appreciate you giving me a little bit more context. One other quick question that would be helpful. Did they describe what platform was used to do the decontamination for the hydrogen peroxide?

(Joe Marker): Not that I saw. It just simply states that they did - that's the process that they use. They used to qualitative (unintelligible) which has its own challenges in and of itself, but they did not describe the actual decontamination process.

Dr. Clarence Murray): So, this is Dr. Murray again. So, thanks thank you so much. One thing I would say is we will look into that. One thing I would say is that all platforms are not equal. So, each hydrogen peroxide has its own unique challenges. And so, they can range from being as gentle as a lamb to being pretty violent like the Tasmanian devil. And so, that would be a critical piece of information to understand clearly about these decontamination platforms that was used.

(Joe Marker): Understood. In fact, what I've got now is I have a group of about 50 or 60 emergency room physicians who got their hands on to this study and they're adamantly opposed now to any decontamination process because they believe that this is a significant risk. So, I would look forward to any further remarks.

Dr. Clarence Murray): This is Dr. Murray again. I think if you would like to pose that as a question, please feel free to send that question into our email address that we have and that would be something we would be interested in discussing maybe offline.

Dr. Suzanne Schwartz: Dr. Ashar, I am wondering if there's anything that you might want to add, in addition to what Dr. (Murray) provided?

Dr. (Ashar): Thank you, Dr. Schwartz. You know, we really appreciate that question. When the pandemic started, we did everything that we could think of doing to

increase the availability of our respirators. Whether that was increasing the supply of new respirators or making available systems for their decontamination. As time has gone on, we have learned more information. And this report is evidence of that. And so, this is why we recommend that individuals need to use respirators always choose a new respirator over a decontaminated one, that they always self-perform a self-test to ensure appropriate fit. And, that they monitor--if they have to use a decontaminated respirator-- they monitor the number of cycles that that respirator has undergone for decontamination.

I think, you know, it is important to understand as Dr. Murray mentioned that not all decontamination systems are the same. Some of them they've been authorized for more decontamination rounds than others. However, as we know, just even without decontamination there is wear on the respirator. So again, we would recommend the lowest number of reuses. That being said, we are continually evaluating the information and modifying our recommendations and this study is among the things that we are considering. So, thank you very much for the question.

(Joe Marker): Thank you.

Coordinator: The next question comes from (Momtha Tasay). Your line is open.

(Momtha Tasay): Hi, thank you for taking my question. We have a question. Can we allow staff to bring in their own N95 respirators from home? And if yes what are the guidelines.

Dr. Suzanne Schwartz: Thank you for this question. I'm going to start off by asking our OSHA colleagues if you have any, you know, thoughts or considerations here, with regard to worker safety that would pertain to this question.

(Andy Levinson): Sure, this is (Andy Levinson) from OSHA. So, the respirator needs to be used within the context of an OSHA Respiratory Protection Program, and the employer absolutely can allow employees to bring in their own devices, there's nothing that prohibits that. The only thing that would have to happen in that case is that the employer was making sure that when it was used in the context of the setting where respirators that were required, like for COVID in health care workplace, that the respirator was properly fitting and fit tested for the employee, that they were taking care of maintenance and cleaning and decontamination. So, the employer just think that if the employee is bringing it in doesn't get a pass on all of the other requirements for the rest of their Respiratory Protection Program. But absolutely, yes that's allowable. If it's a voluntary use situation where the employee is not required to wear a respirator but wants to and pre-COVID that was most commonly, for example, people who were doing cleaning and we're worried more about dust. There are very limited requirements in terms of just making sure that the respirator doesn't become a hazard, in and of itself.

(Momtha Tasay): Thank you and is this information available on OSHA website? Can you direct us to that link?

(Andy Levinson): Yes, you can find that within the OSHA respiratory protection standard which is 29 CFR 1910 134. You can find the link to that, from OSHA's website. And then we also have a number of frequently asked questions that are also up on OSHA's website.

(Momtha Tasay): Thank you.

Dr. Suzanne Schwartz: Thank you.

Coordinator: So next question comes from (Laurie Rasul), your line is open.

(Laurie Rasul): Hi this is (Laurie Rasul), thank you for taking my question. I wanted to ask. I want to go back to the aerosols and procedures and discarding the N95. Is there any allowance for wearing a surgical mask over the N95 to protect N95 and then throwing the surgical masks away but being able to retain the N95 itself?

Dr. Suzanne Schwartz: Ed, do you want to take this question or anybody from NIOSH regards to recommendations that have been either provided on the CDC website or through Q&A that you've already received?

(Ed Fisher): So, you know, again, our recommendations obviously don't cover every situation that has been presented or you know, that arises when the questions come up. So again, so we recommend that the FFR are discarded when used in the presence of an aerosol generating procedure. But we also recommend that you know facial preferably in a surgical mask can be placed over FFR to reduce contamination. You know there's limited data on how effective that is especially, you know, in the presence of an aerosol generating procedure. You know, we expect the critical masks to provide some protection to the FFR in terms of limiting contaminations. But again, these are, you know, situations that are not covered in the recommendation and as written right now the recommendation is to discard the FFR.

(Andy Levinson): This is Andy from OSHA. Let me also jump in. I think one of the concerns about putting face masks over a respirator, particularly filtering facepiece respirator, is that you can deform the respirator and effect the fit of the respirator. For example, if somebody tied a face mask too tightly over the respirator. So the preference for face shields is also to reduce contact and reduce pressure so that the respirator sits on the face as intended, and as fit

tested, while still providing some barrier between the aerosol-generating medical procedure and the respirator.

(Laurie Rasul): Thank you very much.

Coordinator: The next question comes from (Wendy Stevenson). Your line is open.

(Wendy Stevenson): Thank you for taking my question. I was calling in regards to- of course in working at a hospital we have a critical shortage at this point in time of N95s and we're not able to get additional N95s in. I'm sure that's a common situation. We're currently using a BioQuel machine, designed to disinfect rooms with vaporized hydrogen peroxide. We're using this to clean our N95s. Currently, we don't have a EUA for that. What would your recommendation be for us in the interim until we can get additional N95s in?

Dr. (Suzanne Schwartz): FDA group, Binita and others, is there a response that you'd like to provide to this question?

Binita Ashar: This is Binita Ashar. I can potentially address it and then turn to my colleagues to see if they have anything to add. So thank you for this question. I'm sorry to hear that your hospital is facing this dire shortage. Our recommendation would be that you utilize an authorized decontamination system over one that has not been authorized simply because the system has been very carefully evaluated. The critical parameters of temperature, time, humidity and other factors has been taken into account to justify that it performs a high level of decontamination.

If it's possible for you to be able to partner with another hospital facility or other system where they are using an authorized system that would probably be something to pursue if you have that available. At this time we can't make

recommendations about systems that have not been authorized. And I don't know do others on the FDA team have other thoughts or suggestions?

(Andy Levinson): So this is Andy from OSHA. I think the other thing that I think is important for you to consider is looking at other types of respirators and trying to buy elastomeric respirators or trying to buy powered purifying respirators and things that are designed to be durable and reusable as opposed to looking only at filtering facepiece respirators. There's a lot more on the market than just filtering facepiece respirators that will probably actually help you in the long run manage your respiratory protection needs.

Dr. Suzanne Schwartz: And this is Suzanne just to add also reference to the conservation strategies or the optimization strategies that both FDA has posted on its Web site as well as the guidance from that, that CDC has posted in order to, you know, extend the use life of any single respirator. And that, you know, can serve as a good resource in case you have not seen those documents as yet.

Woman 1: Great, thank you.

Coordinator: The next question comes from Greg. Your line is open.

(Greg Ounion): Hi. This is Greg. I'd like to have a follow-up question on the soiled mask that I asked about earlier. The question is: Given extended-use respirators become soiled by facial secretions, by definition, how can you decon - - the efficacy of contact decontaminants say like HPV or any other chemical for that matter be assured? And can you point me to any science studies that document this? Thank you.

Dr. (Suzanne Schwartz): Thank you. FDA team Dr. Murray would you like to provide a response to this question?

Dr. Murray: So thank you Dr. Schwartz. I think Dr. Weeks would provide a stronger answer than I would. Dr. Weeks?

Dr. Jon Weeks: Hi this is (Jon). So we have seen data to suggest that that soiled respirators can be decontaminated; and that in some cases, there are chemical reactions such as interactions with blood and hydrogen peroxide that would inactivate it, so that would not be recommended.

But we have seen that the - that peroxide is able to penetrate into the respirators and it adequately decontaminates respirators that have been inoculated. And so we are also requesting for other modalities that you provide evidence that demonstrates that soils presence do not interfere with the ability of the agent used for decontamination to prevent inactivation of microorganisms. So basically, we're asking for sponsors to be able to provide us with evidence that their mode of decontamination is not affected by soils. And that is something that we are concerned about and is part of our guidance.

Dr. Suzanne Schwartz: Thank you.

Dr. Suzanne Schwartz: Take the next question please.

Coordinator: The next question comes from (Monica). Your line is open.

(Monica): Hi. Thanks for taking my question. My question is can we allow ear loops to get N95 for our healthcare worker for COVID patients?

Dr. Suzanne Schwartz: Let me make sure I understand the question. Are you asking if KN95s with ear loops are okay to be utilized in a healthcare setting?

(Monica): Yes for airborne or for COVID patients?

Dr. Suzanne Schwartz: Okay. So I will start off and then I'll - FDA - will turn to CDC NIOSH as well and OSHA for that matter. All three can answer. There are - under the existing EUA for respirators manufactured in China - there are KN95s with ear loops that are authorized. FDA recognizes that there are - there can be limitations with regard to fit of those respirators as opposed to the N95s with head straps. And fit is, as you know, an extremely important consideration with regards to the functionality and the adequate protective barrier that the device is conferring.

So it becomes really critical to make sure that the fit of the respirator is appropriate and is adequate. We have included those respirators with ear loops under the EUA precisely because of the shortage situation that the United States has found itself in, and recognize that even having these respirators available becomes an important medical countermeasure, if you will, in protecting health care personnel. In the best of all possible worlds, it's preferred that the respirator be one with head straps that has an appropriate fit. I'm going to ask CDC and OSHA if you'd like to weigh in here as well.

Colleen Miller: Hi. This is Colleen from CDC NIOSH and, you know, I think that what Suzanne has just explained is right all along the way I was thinking in terms of how I would respond to your question. Obviously from the public health response perspective, CDC has included these types of devices for contingent and crisis need, as Suzanne explained.

From the respirator approval program perspective we are not accepting or prioritizing applications for NIOSH approval of devices that have ear loop suspension because we understand that the traditional two head straps suspensions provide better fit so we're focusing on those respirators that we

can, you know, approve and get out to the market quickly and have confidence that will fit better. And I think now if (Andy) or my colleagues at OSHA have anything to follow up with please do so.

(Andy Levinson): Yes this is (Andy) from OSHA. And I think the first thing that I would say is particularly with respirators they must be protective. Particularly we have had anecdotal evidence that people are not able to fit test their workers, were not able to achieve a fit test of workers wearing the ear loop KN95s. And so I think if you're even thinking about using that as an option, you need to be very careful about whether or not you're able to achieve a fit test.

Generally, if you're looking at a hierarchy or respirators, the ear loop KN95s are only slightly above essentially a facemask. So they are definitely, you know, we're looking at them as a lower quality alternative that would be much lower in the hierarchy of alternatives for respiratory protection.

((Crosstalk))

(Monica): One more thing so can we - like my question is we tried to use those for fit test and tried to fit test and we have like 30% failure rate on those masks for fit testing. So my question is we don't really use it unless the staff is fit tested they would use it for a high-risk procedure. But my concerns are can we use it routinely for going into COVID room as non-fit tested N95 mask?

(Andy Levinson): The requirement is when you're going into a COVID room to be wearing a respirator, so if it's not fit tested you don't know if it's providing any protection.

(Monica): But fit tested respirator is for aerosol generating procedure.

(Andy Levinson): No, fit testing is for any respirator. You only know that a respirator is providing protection when it's fit tested. If it's not fit tested you don't know if it's fits tightly enough to provide protection against small particles. Aerosol generating medical procedures are a higher risk procedure where, in general, the federal government has actually recommended higher levels of respiratory protection if possible.

(Monica): Yes so like I agree with you. So from droplet so, you know, we are using if it's a droplet then you move and to fit test a KN95s mask and of its airborne and you're doing aerosolize in your procedure then you move into the PAPR. So COVID for our local public health criteria is the droplet that contact isolation. So then our protocol is for any aerosolizing procedure you use fit tested N95 mask. But if the patient is in the room and it's is not creating any aerosol then you don't really have to have a fit tested KN95s mask.

(Andy Levinson): So...

(Monica): So is that my understanding or...

(Andy Levinson): No. So in healthcare settings when you're dealing with people who are known or suspected to have COVID you're supposed to be wearing a respirator - period, regardless of whether you're doing aerosol generating procedures or not. That patient, when they're coughing, talking or breathing, is still generating bio aerosols in their room. Aerosol generating medical procedures are a higher level of risk because you're doing sputum induction, bronchoscopy or some other nebulizer type treatment. But anywhere in a healthcare setting, with a known or suspected health COVID patient, you're supposed to be wearing a fit tested respirator and following the airborne precautions.

(Monica): Well we - I mean CDC and LA Department of Public Health has not changed from droplet to airborne yet. I know there's some controversy in the news lately about being airborne but the local public health and CDC has not changed it to airborne yet.

(Andy Levinson): Well I guess what I can say to you is if you're in California, Cal/OSHA is the enforcing agency. They have their own standards that in some cases are actually more protective than Fed/OSHA, and you should look at what Cal/OSHA is directing you to do.

(Monica): Okay thank you.

Coordinator: The next question comes from (Dan Dilly). Your line is open.

(Dan Dilly): Hi (Eileen). How are you? My question relates to NIOSH specifically and particularly as a result of the addressing growing need for as far as for our staff and teams is there an expedited NIOSH procedure to approve newly developed and manufactured PPEs? And is there a path and intermediate path of PPEs that have yet to be granted with the NIOSH be approved until the final NIOSH process is been completed?

Dr. Suzanne Schwartz: Colleen, I think this is for you.

(Colleen Miller): Yes thank you. So to answer that second question there is no intermediate step. We do not authorize anything to be labeled for use that has not been approved and received a NIOSH TC number, the TC number is the approval number. There is a lot of misconception out there in the world that getting a three-digit manufacturer code from us is somehow an intermediate step and it is not.

A three-digit manufacturer code is simply the way that we follow a particular approval application or approval holder's application through our process and how we refer all their documents. It really doesn't have anything to do with achieving what the NIOSH approval number is. It's just part of our process. So we are prioritizing existing manufacturers that are coming in with applications to can get more product to market soonest. And we are prioritizing new domestic applications particularly for air purifying particulate respirators that can be PAPR or APR air-purifying respirator, (half facepiece or full facepiece) elastomeric respirator with filters providing you know, particulate protection.

We do have a prioritization notice out there and we're working very much hand-in-hand with people. We have an innovation team that's working with folks that are coming in with things that are kind of outside of what we traditionally see because of the pandemic. So we are working to do things in an expedited way and we have some public health emergency approvals that we have posted on the certified equipment list, PHE PAPRs and filtering facepiece respirators. And those approvals are very specific for working with new domestic manufacturers that started contacting us way back in March and April.

Dr. Suzanne Schwartz: Thank you.

(Dan Dilly): Thank you very much.

(Colleen Miller): You're welcome.

Coordinator: The next question comes from (Kendra). Your line is open.

(Kendra): Hi there. There are circumstances where patients often with severe disabilities

like spinal cord injuries have caregivers provide healthcare in their home. An N95 respirator is intensely needed because they may have a COVID positive situation and many aerosol generating procedures are being performed in the home while caring for that patient.

When the caregiver is employed by the patient which is often the case, not by an agency or a healthcare facility or entity, are there options for fit-testing of the N95 respirator in the field? In this case the field would be potentially a home environment. Are there any recommendations for getting that fit-testing done appropriately?

Dr. Suzanne Schwartz: Andy, do you have any resources or directions for this questioner?

Andy Levinson: I think probably the only thing that I would suggest is that you may want to go to the American Industrial Hygiene Association Web site, AIHA. I believe it's .org and they may be able to direct you to local industrial hygienist who could do fit testing. But that's generally going to be a service provided by a third party, you know, private provider. That's not something that OSHA would do.

(Kendra): Right, right potentially through a contract or something like that.

(Andy Levinson): Yes.

(Kendra): So the American Industrial Hygiene Association for resources? Excellent. Thank you very much. It's been a challenging question just to find any information about. Thank you.

Andy Levinson: You're welcome.

Colleen Miller: (Andy) this is (Colleen). I think a face shield is also, you know, an additional

good option for personal protective equipment above and beyond the N95 FFR.

(Kendra): Thank you.

Coordinator: Our last question comes from (Mike Wright). Your line is open.

(Mike Wright): Hi. This is for the OSHA representative. Under what circumstances would federal OSHA cite a health care employer for violations related to respirator use in a COVID-19 environment first? And second, has such a citation in fact ever been issued?

(Andy Levinson): (Mike) I think I'm going to hand this off to Dion.

(Dr. Dionne Williams): Yes I'm on the line. I'm going to take that question. So we have actually recently issued respirator violations. The circumstances will depend on what we find at the facility. For the case where we have issued violations, the violations were related to not providing respiratory protections for employees who required respirator use.

So, there are going to be some situations, specifically in healthcare facilities, where respiratory protection might not be accessible due to shortages and so there might be some limitations on whether we are able to issue a violation. We have put out some enforcement guidance relating to the sections for which we are providing case-by-case enforcement discretions. So, I would direct you to look at the memoranda on our Web page that describe some of the conditions under which we would provide enforcement discretion. But, we would look at each of these cases on a case-by-case basis and weigh whether or not the employer has done due diligence to comply.

(Mike Wright): Thank you.

Dr. Suzanne Schwartz: I think we have time for one more question if the operator is able to provide another one.

Coordinator: One moment. We show no further questions at this time.

Dr. Suzanne Schwartz: Okay, all right. So on behalf of FDA I want to first off recognize all of the subject matter experts who joined us today from across our respective agencies from OSHA, from CDC NIOSH NPPTL and my FDA colleagues.

Thank you to all of you who tuned in today to the Webinar. The next session will take place in two weeks on Tuesday, August 4 at noon Eastern. Announcement of the topics will be forthcoming and please don't hesitate to share with us any topics of interest that you'd like to hear more about. I'd like to now turn the session back to Irene who will close it out.

Irene Aihie: 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 Wednesday, July 29.

If you have additional questions about today's discussion please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback. Following the conclusion of today's live Webinar please complete a short 13 question survey about your FDA CDRH Webinar experience. The survey can be found at www.fda.gov/cdrh Webinar immediately following the conclusion of today's live discussion. Again thank you for participating. This concludes today's Webinar.

Coordinator: That does conclude today's conference. Thank you for participating. You may disconnect at this time. Speakers, please allow a moment of silence and standby for your post-conference.

END