FDA PPE Webinar Series:
Updated Information on Respirator Decontamination Systems

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. All lines have been placed in a listen-only mode for today's presentation. The call is being recorded. If you have any objections you may disconnect at this time. I would now introduce your conference host, Ms. Irene Aihie. 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 14th CDRH Webinar in our PPE Webinar Series.

During today's Webinar the FDA will share information about the updated information on respirators and decontamination systems during the COVID-19 public health emergency. Representatives from the FDA, CDCs National Institute for Occupational Health, [excuse me] CDCs National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration will be available to answer your questions. Following a few opening remarks, we will open the line 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 14th session in our Webinar series on Personal Protective Equipment or PPE. In prior Webinars we have discussed the regulation of a variety of devices during the COVID-19 pandemic including Filtering Facepiece Respirators and decontamination systems for Filtering Facepiece Respirators including N95 respirators.

Today we will be discussing updated information regarding Emergency Use Authorizations or EUAs for respirator decontamination systems. Dr. John Weeks from CDRHs Office of Science and Engineering Laboratories and Dr. Anjana Jain from our Office of Surgical and Infection Control Devices will provide an overview of these updates.

After the presentation we will turn to the operator for live Q&A. Please note that we are joined by our colleagues from OSHA and NIOSH for the question-and-answer portion of the session. With that I am pleased to introduce Dr. Jon Weeks.

Dr. Jon Weeks: Thank you Dr. Chang. Good afternoon I'm Dr. Jon Weeks and we will be talking with you today about our recent updated information on respirator decontamination systems. Next slide please. In the presentation we will discuss reauthorized decontamination systems, the scopes of reauthorization, resources and finally we will take questions from the audience.

Next slide please. During the coronavirus disease 2019 COVID-19 public health emergency the FDA has authorized the use of certain devices for decontamination of Filtering Facepiece Respirators for healthcare personnel. The FDA considers decontaminated respirators as those that have been treated in an authorized decontamination system using an authorized decontamination

cycle. The decontaminated respirators should be used only when new NIOSH approved or FDA cleared or authorized Filtering Facepiece Respirators are not available.

Next slide please. We understand that during shortages of Filtering Facepiece Respirators healthcare personnel may not have access to new NIOSH approved or FDA cleared or authorized respirators. For such circumstances FDA has authorized through the Emergency Use Authorization the use of decontaminated respirators. We would like to reiterate that CDC only recommends for decontamination of respirators to only be used when new NIOSH approved or FDA cleared or authorized N95 Filtering Facepiece Respirators are not available.

Even during surges of COVID-19 infections we anticipate a reduction in the use of decontaminated respirators as there are more new respirators available. The ultimate goal is to get facilities back to conventional capacity strategies as the availability of NIOSH approved respirators increases. Please refer to CDC's resources linked on Slide 9.

Next slide please. Authorized decontamination systems have been reviewed for their ability to reduce microorganisms including SARS-CoV-2 on N95 respirators. Additionally sponsors have provided evidence to demonstrate the compatible N95 respirators may maintain their performance after decontamination.

To date FDA has authorized 14 decontamination systems for decontaminating of Filtering Facepiece Respirators. These systems use chemical or moist heat-based mechanisms of microbial reduction. For a complete list of authorized decontamination systems please refer to the FDA Web site provided later in this presentation.

Since the initial authorization of these decontamination systems FDA has continued to receive and review information regarding the use of decontaminated respirators. This includes recent publications regarding fit of respirators donned multiple times. In light of this additional information we have updated our thinking regarding the number of cycles that respirators may maintain their integrity through.

On January 21, 2021 FDA reauthorized EUAs for certain decontamination systems. These included decontamination systems using vaporized hydrogen peroxide, steam and a combination of vaporized hydrogen peroxide and ozone. The EUAs were reauthorized based on additional information received and reviewed by FDA regarding respirator fit following decontamination. I will now turn it over to Dr. Anjana Jain to further discuss the reissued letters. Dr. Jain.

Dr. Anjana Jain: Thank you Dr. Weeks. Next slide please. Now we will be talking about the reauthorizations for the EUAs of the decontamination systems and the updated conditions of authorization. These changes were based on the FDA's increased understanding of the performance and design of these respirators as well as based on review of additional data about device performance as it became available from NIOSH testing and other information on decontamination and reuse of Filtering Facepiece Respirators or FFRs.

The following are the changes made to the letters of authorization and authorized labeling. The revisions to the scope of authorization limit the number of decontamination cycles to four or less if the data provided in the EUA does not support up to four cycles. There is evidence demonstrating that significant respirator fit failure occurs after five donnings and doffings.

Compatible N95 respirators should not be reused more than five times regardless of whether they undergo to camp contamination unless there is explicit guidance from the respirator manufacture. If manufacturers of decontamination systems would like to request authorization for more than four decontamination cycles then respirator performance data should be provided to demonstrate that the respirators maintain fit and filtration efficiency.

A new condition of authorization is a post-authorization study to confirm that the authorized number of decontamination cycles remain appropriate. The revised letter of authorization requires that manufactures complete the study within 60 days which from the date of reissuance March 22, 2021 or before 1500 compatible N95 respirators have been decontaminated whichever is later.

The study results must be submitted to the agency for review within 15 days of study completion. The post approval studies must be conducted on compatible N95 respirators that have been used by healthcare personnel and sent to manufacturers of authorized decontamination systems for decontamination. This is real world use data.

In general the study will include fit testing, filtration efficiency and chain of custody markings with a minimum sample of ten respirators. The letters of authorization provided detailed information on the acceptance criteria and protocols. We expect that the post-authorization study will provide real world use data with while not being overly burdensome. Additionally it should be noted that timely communication of the post-authorization studies results must be included in your authorized labeling such as the instructions for use for healthcare facilities, healthcare personnel and the fact sheet.

Next slide please. Another new condition of authorization is that authorized labeling for decontamination systems authorized for multiple user reuse must instruct healthcare personnel to either receive the same model of decontaminated respirator for which they were fit tested or undergo fit testing if the healthcare personnel receives an alternate model of decontaminated respirator. The revision was made to ensure continued respirator fit for healthcare personnel who may receive a different respirator after decontamination.

Next the reauthorized labeling including the instruction for healthcare personnel and for healthcare facilities as well as fact sheets instruct healthcare personnel to perform an OSHA self-seal check upon donning a decontaminated respirator. This revision is aligned with OSHA standards for individuals who use tightfitting respirators to perform a user seal check to ensure that an adequate seal is achieved each time a respirator is donned.

Lastly the authorizations were revised to exclude respirators with antimicrobials and duckbill respirators from decontamination. This is based on available evidence regarding post decontamination, fit and performance.

Next slide please. Here are several links for resources that are available to you for further information regarding the decontamination and reuse of Filtering Facepiece Respirators. The first link is for the Division of Industry and Consumer Education Web site to access the previously recorded Webinars on Personal Protective Equipment. The second link was mentioned by Dr. Weeks on Slide 5 when he was describing the types of decontamination systems that were reissued. The other links provided helpful resources on the CDC and OSHA Web sites.

Next slide please. Please note that for any questions you may have after this Webinar may be sent via email to the address on the screen. Also for a copy of the presentation, transcript or the Webinar recording that may be found at the Website on the screen under the heading Specialty Technical Topics and subheading Personal Protective Equipment. We have come to the conclusion of our presentation and will be answering any questions that you may have now. Operator we would like to open the line for questions now.

Coordinator: We will now begin our formal question and answer session. If you would like to ask your question please unmute your phone press Star 1. Only record your first and last name.

Please be advised only limit yourself to one question. Once again if you do have a question you may press Star 1 on your telephone keypad. One moment for the first question.

Dr. Cynthia Chang: Hello. This is Cynthia Chang. While we are waiting for questions from the audience I would like to provide an opportunity for our colleagues from OSHA and NIOSH to share their comments on the presentation. Let me turn to OSHA first. Could OSHA please comment regarding your stance on respirator decontamination?

Dr. Dionne Williams: Yes. This is Dionne Williams from OSHA. Firstly, let me say that the decontamination of single use Filtering Facepiece Respirators for reuse is prohibited under OSHA's Respiratory Protections Standard. However, for the purposes of addressing severe shortages of Filtering Facepiece Respirators due to the pandemic, OSHA issued several enforcement memoranda providing specific enforcement discretion and one of these addresses decontamination of single use respirators.

Now the memos outlined some flexibility that OSHA compliance staff may consider when evaluating an employer's noncompliance with OSHA standards under crisis capacity scenarios. It should be made clear that OSHA has not waived its requirements and any discretions that are described in OSHA's memoranda, including those related to decontamination of single use respirators, are intended to be time-limited and applied on a case by case basis and they're applicable only under crisis situations.

So, as Dr. Weeks mentioned in his presentation, where new respirators are readily available OSHA's enforcement discretions are not in effect. Thank you.

Dr. Cynthia Chang: Thank you very much. Now I would like to turn to NIOSH. CDC has described different capacity strategies for optimizing the supply of N95 respirators and indicates that respirator decontamination is a crisis strategy. Can you please describe these strategies and what considerations healthcare organizations should take into account to determine which strategy is applicable to them?

Ed Fisher: Sure I'd be happy to do that. That's - this is Ed Fisher with NIOSH. So the CDC developed the framework and it's based on surge capacity to help the healthcare facilities plan for surges in demand for hospital-based services during the COVID-19 pandemic.

And surge capacity is comprised of three levels you have conventional which was talked about, contingency and crisis capacity strategies. It's important to note that each of these levels have an engineering, and administrative and PPE controls, you know, but I'll keep it to the PPE and specifically the respiratory protection and N95s.

So the first one is conventional capacity strategies, and these are things that should already be implemented in a general infection prevention and control plans in healthcare settings. So this is more of the normal operations but point out that healthcare personnel can use NIOSH approved alternatives to N95 respirators specifically Filtering Facepiece Respirators when feasible.

These would include other classes of Filtering Facepiece Respirators. There's the N class, P class and R class. You have 95's, 99's and 100's. There are elastomeric half masks, there are powered air purifying respirators. And all of these alternatives will provide equivalent or higher protection levels than N95 respirators.

So if you have supply of NIOSH approved respirators that provide a level of protection equal to or greater than N95s that can meet your demand then there is no need to move to the contingency crisis capacity strategy. So I think that's something very important to point out that there's other alternatives to N95s that can be used.

So once you get into contingency and crisis capacity strategies, you know, these are temporary, you know, that are used to help conserve respirator supplies during anticipated or experienced shortages. And going to these strategies is where we start to kind of deviate from I guess lack of a better word usable practices. So, you know, you want to really think about your status when you - before you go to these strategies.

So contingency capacity strategies may be used temporarily when there is an expected shortage of N95 respirators or other respirators and they should only be implemented after conventional capacity strategies have been implemented. So, you know, if you recognize that the future supply is not going to keep up with your demand you may want to move into the

contingency capacity strategies. And obviously this could be due to an increase in the number of respirators being used because you're having more patients' visit the hospital or healthcare facility or you recognize (unintelligible).

And the main contingency capacity strategy that's being used is an extended use of N95 respirators. And that's where you put on a N95 Filtering Facepiece Respirator and wear it for multiple patient encounters before it is doffed and discarded. And if extended use and other contingency capacity strategies are enough to keep up with demand then you should not be going and using crisis capacity strategies.

And crisis capacity strategies should only be implemented after considering and implementing obviously the conventional capacity and the contingency capacity strategies. And facilities could consider crisis capacity strategies when the supply is not able to meet the facilities current demand or anticipated utilization rates.

So some of the crisis capacity strategies (unintelligible) manufacturer designated shelf life for healthcare delivery, use of respirators that are similar to NIOSH approved respirators so we're talking about respirators that are not NIOSH approved that are approved according to standards used use in other countries. NIOSH has assessed the performance of some of these international respirators and has the results posted online.

And then there's also limited reuse. An N90 - N95s and this is when it's donned from one patient contact then doffed and stored before being used for another patient contact for a limited number of donning's up to five. Limited reuse may also include decontamination. And decontamination should be the last crisis capacity strategy employed if necessary.

And so, you know, this is kind of complicates how do you know when to move into these different strategies? And really there's two important factors the status as well as a number of respirators being used. And the CDC has developed a burn rate calculator that will allow the users to calculate the average rate of PPE consumption which is also referred to as burn rate, and the average rate of PPE consumption per patient and then the number of days' worth of remaining PPE.

So the supply chain and the other resources to obtain respirators should be checked frequently. This includes other types of classes of NIOSH approved respirator protection that are part of conventional capacity strategies that I spoke about.

And, you know, the goal is to get back to conventional capacity strategies and, you know, so it's very important that you weigh your utilization rate with the supply on hand and then what's in the supply chain so that you can get back to those conventional capacity strategies as soon as possible. Thank you.

Dr. Cynthia Chang: Thank you so much to our colleagues from OSHA and NIOSH for those very helpful responses.

Irene Aihie: Operator we'll go ahead and take our first question.

Coordinator: And the first question is coming from (Galen). Your line is open.

(Galen): Yes, I was just wondering if you have a non-disinfection method in mind like a - we have our home care staff waiting 72 hours before they re-don of mask that they may have worn in a COVID patient's house. Without the

disinfection cycles would it still be a recommended only five reuse for an N95?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So the question is about whether for home care staff if there's specific recommendations regarding donning and doffing and reuse. And with that question in mind let me turn to my colleagues from OSHA to see if they have any questions or any comments for that.

(Galen): Thank you.

Mike Bergman: Hello. This is Mike Bergman from NIOSH.

(Galen): Hi.

Mike Bergman: I can speak to that question. We recommend limiting the donning's to five unless the manufacturer has specific guidance to extend that. And it wouldn't matter if the donning's are 72 hours apart or if they're just a few minutes apart we recommend five donnings total.

(Galen): Okay. So with or without…

Mike Bergman: Thank you.

(Galen): …it's five re-donnings and that's it unless manufacturer states differently, got you.

Mike Bergman: That's correct. Thank you.

(Galen): Thank you.

Andy Levinson: All right sorry this is Andy from OSHA I was on mute. I think it's important to understand one of the reasons for concern in this type of method of decon is that these devices were never intended to be decontaminated and reused. And that the ways in which they could be damaged and/or not fit properly are not always obvious. And so the limitations are important because in the act of taking it on and off and storing it people could crease the face feel area and they may not realize that they're not getting an adequate seal.

(Galen): That makes sense. Yes thank you.

Coordinator: The next question is coming from (Russ Olmstead). Your line is open.

(Russ Olmstead): Yes, thank you for faculty for this session this is very helpful. I was curious if FDA has any EUAs issued for UVC methods for decontaminating N95 respirators?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So the question is whether FDA has issued EUAs for UVC methods for decontamination. So first I would like to point out that our authorized EUAs may be found on our Web site. And I believe we do have a link to the resource on the Web site and in the slides so you can check those resources specifically for each of the authorized EUAs.

I would like to note that we do have EUAs for decontamination systems of topic and the scope of today's Webinar. And in terms of the updated EUAs that we have issued they are specific to respirator decontamination systems using the modalities that we outlined which do not include UVC. However there - I will turn it over to my colleagues and OHT4 to comment on any additional EUAs that we have issued regarding UVC.

Dr. (Murray): Thank you Cynthia. To follow-up with that you are absolutely correct we have not authorized any decontamination systems for UVC. What you would find to the person who is asking the question you will find on that Web site that there is one system that's for bioburden reduction.

Dr. Cynthia Chang: Thank you very much Dr. (Murray).

Coordinator: The next question is coming from (Amy Fowler). Your line is open.

(Amy Fowler): Hello. This is (Amy Fowler). And actually I have a question related to the 510(k) performance testing requirements for surgical mask FXX. And I would like to just take a quick moment to direct a question to Dr. Chang. Industry is looking for clarity on the number of test samples and number of nonconsecutive lots required for a 510(k) for surgical mask FXX.

I have seen recently in January 510(k) summaries being posted where there was only like five test samples per performance test. But of course we've had communication since last summer saying that it was required to be 32 test samples of three nonconsecutive lots. And I think there's a lot of confusion out in industry. I would love to have some clarification on this point. Thanks.

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thank you for the question. The question is about the number of samples that are needed to be tested for products in Pro Code FXX which is surgical masks. So that is actually outside of the scope of today's Webinar which is specific to decontamination EUAs for respirators and nonsurgical masks.

However I would like to refer you to our prior Webinars which are available on our Web site as we have discussed this topic previously regarding surgical

masks. Thank you. And for any specific questions I should add you may consider reaching out to the review division specifically. Thank you.

Coordinator: The next question is coming from the (Natalia Gutierrez) your line is open.

(Natalia Gutierrez): Hi. Good morning. Can you hear me?

Dr. Cynthia Chang: Yes.

(Natalia Gutierrez): Okay perfect. Thank you. We are a new manufacture for the N95s here in South Florida. And I basically have almost the same question as the previous lady about the 510(k). We did several testing's actually with Nelson Labs. But it seems like when you go to the FDA and then NIOSH it kind of contradicts each other on the procedures to get these approved or certified. And I wanted to know if there is anyway do you guys have on the Web site or actual people or consultants that help you how to guide - that can guide me to get this certified basically or approved?

Dr. Cynthia Chang: This is Cynthia Chang. So thanks for that question. It is a about the approval process for N95 respirators I believe. And I do want to note that FDA has been working closely as you can see with our colleagues from NIOSH and OSHA throughout the pandemic and especially on these specific issues regarding respirators. And so it might be best if I turn it over to our colleagues at NIOSH to talk about the approval process.

Mike Bergman: Hi. This is Mike Bergman from NIOSH. The best way to get questions answered about NIOSH certification I'll give you an email address right now which is ppeconcerns@cdc.gov, ppeconcerns@cdc.gov. And if you send an email there that's a mailbox that has managed here at NIOSH which houses the National Certification Program.

Just send an email there and they can take care of any questions you have about NIOSH certification. NIOSH does review the data for the surgical N95 respirator certification. So I would just recommend sending an email there and they will get in contact.

(Natalia Gutierrez): Okay. I - can you specify one small thing…

Mike Bergman: Thank you, yes.

(Natalia Gutierrez): …for me please?

Mike Bergman: I could try. Yes.

(Natalia Gutierrez): Okay. I noticed that you have the N95 that are the folds right the one that has the little, you know, the nose wire right in the earlobes. And then you have the actual cup.

I know that the ones that are for the cup that have like a more fit to the face that has the headbands those are the ones that are being prioritized right now and not the ones with the earlobes. Will these eventually I mean are they still considered N95s and would eventually be approved just like the cup?

Mike Bergman: I think that's a better question for the certification program to handle.

(Natalia Gutierrez): Okay.

Mike Bergman: I'm actually in the research program so I can't answer too many questions about certification.

(Natalia Gutierrez): Okay, okay, okay. Thank you so much for everybody's time.

Mike Bergman: You're welcome. Thank you.

Dr. Cynthia Chang: Thank you very much. And I would also like to note -- this is Cynthia Chang -- that we have discussed respirator regulatory paths as well and in our PPE Webinar Series. And we do have information on our Web site regarding a variety of topics related to respirators and PPE. So those are some additional resources in addition to the information provided by our NIOSH colleagues. Thank you.

Coordinator: The next question is coming from (Carlos). Your line is open. The next question is coming from…

(Carlos Burdell): (Carlos Burdell).

Coordinator: Your line is open. You may ask your question.

(Carlos Burdell): Hi there. I was wondering if I can get a clarification of what a duckbill N95 FFR is?

Dr. Cynthia Chang: So this is Cynthia. Thank you very much for the question which is regarding clarifications on what respirators may be considered to be duckbilled. Respirators are FFRs. And we do want to start by saying the respirator manufacturers are best positioned to accurately describe their respirators and products.

And we do recommend that you reach out directly to manufacturers for specific questions about the products that they are marketing. And let me turn

to my colleagues from NIOSH and OSHA to see if they have anything to add on this topic.

Mike Bergman: Hi. This is Mike Bergman again. It's kind of a general term duckbill. You know, some of the other general terms are like cup shaped or flat folds. So I'd say from a NIOSH perspective it may not be an official NIOSH term but I would think yes it's best to check with the manufacturers of the products if they can provide a more official classification.

Andy Levinson: Right. And this is Andy Levinson from OSHA. We actually don't make a distinction at all. The only thing that matters to us is that it is a NIOSH approved respirator. And all half-mask respirators get the same assigned protection factor regardless of the design and construction.

Dr. Cynthia Chang: Thank you very much to our NIOSH and OSHA colleagues for the response there.

Coordinator: At this time we have no further questions in queue.

Irene Aihie: Thank you. Before we close out Cynthia did you have any closing remarks?

Dr. Cynthia Chang: Yes. This is Cynthia Chang. I do want to thank everyone for their time and attention this afternoon on this important topic. And I do want to extend a special thanks to our colleagues from NIOSH and OSHA who have joined us to address some of the questions today. Thank you.

Irene Aihie: Thank you Cynthia. Again 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/cdhrlearn by Thursday, March 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 today's 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: This concludes today's conference. All parties may disconnect at this time. Speakers, please allow for a moment of silence.

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