

**FDA Webinar Series:
Respirators for Health Care Personnel Use during COVID-19 Pandemic**

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

Coordinator: Welcome and thank you for standing by. At this time all participant lines are in a listen-only mode. The question-and-answer portion will follow today's presentation. And at that time, you may press Star then 1 on your phone's keypad to ask a question during today's conference call. Today's conference is being recorded. If you have any objections to this, you may disconnect at this time. And now I would like to turn the call over to your host for today, Ms. Irene Aihie. Ms. 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.

Today's discussion will focus on the topic of respirators for healthcare personnel's use during the COVID-19 pandemic. Today, Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health here in the CDRH at the FDA will be joined by FDA Commissioner Hahn and members of CDRH. We are also joined by our colleagues from OSHA and NIOSH.

Together we will share information and answer questions about emergency use authorizations and decontamination of respirators and the overall actions

that have been taken to help ensure healthcare personnel on the frontlines have the necessary supplies of respirators to meet the demand.

Following the presentation, we will open the lines for your questions related to the information provided during today's presentation. Now, I give you Dr. Shuren.

Dr. Jeffrey Shuren: Thank you and hello everyone. I'd like to welcome you to the first in a series of biweekly webinars on personal protective equipment. Our goal is to provide you with information and with the latest updates as well as to address your questions.

Today's inaugural session is focused on respirators, our authorizations, our policies, the changes we've made and why. Just as the clinical community in caring for patients with COVID-19 has been learning on the job and adapting as new information becomes available, we too are learning as we go, modifying our approach as new information and changes on the ground warrant. None of us has the luxury of time. We have to do the best we can with what we know and what we have available, recognizing that circumstances will change, and we will adapt with them.

To begin our dialogue with you, it is my pleasure to introduce the FDA Commissioner, Dr. Stephen Hahn. I'll turn the microphone over to him now.

Dr. Stephen Hahn: Yes, thank you, Jeff, very much and also for the opportunity to be with all of you today and help welcome everyone to this first of a series of FDA webinars today on respirators for healthcare use during the COVID-19 pandemic response.

I also want to thank our federal partners, CDC, NIOSH, and OSHA for their

collaboration and for joining this important dialogue. As we are all well aware, it has been an extraordinarily challenging time for the nation and the world. And a crisis of such unprecedented magnitude requires all of us joining together to work.

Our partnership with NIOSH and OSHA is a good example of how we work together towards a common goal in this assuring that our healthcare workers have the necessary personal protection that they need to serve on the frontlines of care. And my many thanks to those frontline healthcare workers who have just done an extraordinary job during this difficult time.

And I want to thank everybody else on the line today who's with us for your commitment and hard work during the pandemic. A special thank you to the manufacturers who are on this call, whether a traditional device manufacturer or one who is new to healthcare. Your continued efforts to increase the supply of respirators for healthcare workers and serve the American public during the pandemic are greatly appreciated.

And finally, I want to give a shout out to the FDA staff and the agency's exemplary leadership team, our center directors, and our other commissioner groups. They have been just extraordinary during this time. I'd barely begun my work as FDA's Commissioner when the COVID-19 virus appeared and really changed our world.

And having had the opportunity to watch, work with, and rely on the FDA's staff during this public health emergency has just been an extraordinary experience. And I hope this is a once in a lifetime experience, of course. But it has been just remarkable to see the FDA team at work and how the collaboration has been with all of you on the phone. I can say that both I, personally, but also the American people are in great hands with the FDA.

We continue to be involved on many different fronts to ensure that we keep pace with the ever-changing landscape. And Dr. Shuren made a really important point which is that this will continue to change as we learn more and more about the pandemic. And our commitment, Dr. Shuren's commitment, and CDRH's commitment is that we will use all data available to us at the time it's available to reassess what we've done and to be flexible moving forward.

Special kudos to Dr. Shuren at the FDA Center for Devices and Radiologic Health. We've seen just how essential medical devices are to countering this pandemic. And CDRH has been at the forefront of our efforts to ensure that health professionals and others have the appropriate access to personal protective equipment. A major shout out to the 24-7 work that they have done.

The webinar series that we've launched today is another example of our continuing commitment to protect and promote the public health of all Americans. It underscores our focus on providing the public with the best possible information about the disease and have transparency in what we are learning about it and what we are doing to treat and prevent it.

We promise that we will continue with this level of transparency and today is just the start of these dialogues that we'd like to continue. One of my most important and fundamental professional beliefs in medicine has been the importance of promoting integrity and transparency in the scientific process. And that is an essential aspect of our work at FDA.

But to do this in the most effective way it requires a dialogue. And that's why it's critical that we hear from and engage with you today. And we will continue to do that, as I mentioned, moving forward. We want and we need to

know what you're observing, learn from the challenges you are facing, and how you're dealing with them.

This information will inform us and enhance our ability to serve the American people in the most useful way possible during these times of immense need. Our experience during COVID-19 has made clear that successful response is dependent in part on having respirators for which there has been such high, unprecedented demand to have it available for healthcare workers.

And since the early days of the crisis we have worked hard to ensure that there is adequate supply of N95 respirators, engaging with many different organizations and agencies in both the public and private spheres. We will continue to do our best to communicate our policies and to be transparent. And today is really the first step in engaging in this bilateral dialogue with large groups such as today.

I hope this webinar series supports that effort. And provides you and the public as a whole with increased understanding and clarity about FDA's ongoing efforts and our strong partnerships with NIOSH and OSHA as well as the opportunity to provide us with your feedback. We very much value the bilateral dialogue and exchange of information.

And we look forward to continuing our work together to ensure access to high-quality respirators for healthcare workers and other personal protective equipment. I want to thank you for allowing me to take a bit of your time. And now I'd like to turn it over to Bill Maisel. Thank you very much.

Bill Maisel: Thank you Dr. Hahn and Dr. Shuren. We very much appreciate your comments and your leadership during the COVID-19 pandemic. My name is Bill Maisel. I'm Chief Medical Officer and Director of the Office of Product

Evaluation and Quality at FDA's Center for Devices and Radiological Health.

We're glad that you're able to join us for today's webinar on respirators for healthcare personnel use during the COVID-19 pandemic. And what we hope to cover today is again, a quick overview of the webinar series objectives. We'll provide introductions both to some of the people and the organizations that are participating.

We'll cover the terminology and provide an overview of facemasks and respirators just briefly so that we're speaking the same language. We will provide an update on FDA emergency use authorizations for respirators, our strategies for optimizing the supply of N95 respirators, and policies and authorizations for respirator decontamination and bioburden reduction.

That's a big agenda. But we will also save some time for questions and answers to make sure that we're able to address some of your questions. Next slide please.

We've already covered some of the webinar series objectives. But I think it's important for us to recognize that there can be an overwhelming amount of information - at times confusing and rapidly changing - concerning the safe and effective use of respirators for healthcare personnel.

It's our hope that this webinar series will help provide you with the information you need and answer questions you may have about respirator use. Because of the volume of information, it's not possible to cover every respirator topic in-depth during a single webinar. And we intend to conduct a series of webinars so that we may continue to provide updates on important actions impacting the needs and availability of respirators. And take deeper dives and more time on topics that are of interest to you.

After today's event, the next webinar in the series is scheduled for two weeks from today, June 23 from 12:00 pm to 1 pm Eastern time. The bottom line is we all want to be able to provide support to make sure our nation's healthcare personnel and first responders have the information they need and the supplies they need to meet their demands. Next slide please.

FDA, CDC's National Institute of Occupational Safety and Health or NIOSH and the Occupational Safety and Health Administration or OSHA collaborate to assure the safe use of respirators. We are very grateful for the close working relationship and collaboration with our sister organizations.

We're on the phone with each other quite literally daily and sometimes multiple times per day. We provide complementary perspectives and oversight. And have been working together very closely both before and during the pandemic.

We're very fortunate to have the leadership and scientific experts from each of the organizations present on the webinar today. And they'll be available to answer questions during the question and answer period at the end.

Clearly, the other important piece of background information is that the COVID-19 pandemic has created significant challenges to the availability of personal protective equipment including respirators. And each of our organizations has taken steps to address the shortages.

And today we'll be talking about FDA's emergency use authorizations of certain respirators and decontamination systems. FDA has also issued guidance on enforcement policies that together provide substantial regulatory flexibility to help facilitate access to critical, quality medical supplies. Next

slide please.

We'd like to take a few minutes to let you know who is on the webinar today from each of our organizations. And as I mentioned previously will be available later in the webinar to address questions. I'll also ask one person from each organization to take a couple of minutes to provide a brief overview of their organization's responsibilities.

I already mentioned I'm Bill Maisel from FDA. And we're joined today by Elizabeth Claverie, Assistant Director of the Personal Protective Equipment Reprocessing and Disinfection Devices team in CDRH as well as John Verbeten, Acting Deputy Director, Office of Enforcement and Import Operations in the Office of Regulatory Affairs.

We're also joined by Dr. Suzanne Schwartz who's Acting Director of the Office of Strategic Partnerships and Technology Innovation. And I'd like to ask Dr. Schwartz to provide a brief overview of FDA's responsibilities.

Dr. Suzanne Schwartz: Thanks so much, Bill. It's a pleasure to participate in this webinar. So again, I serve as the Acting Director of CRH's Office of Strategic Partnerships and Technology Innovation here at FDA. And FDA's oversight of respirators for use in healthcare spans the total product lifecycle from premarket review, postmarket surveillance, and compliance.

And during this COVID-19 pandemic response, FDA has employed tools that allow us to be far more agile in responding to a public health emergency of this scale so that we can be fluid when new information comes to light that warrants taking different approaches. In today's presentation, you will hear about some of the actions we have taken and our overarching effort.

To meet the needs of the public health, we engage in broad outreach with many stakeholders that span the entire supply chain from manufacturers, to importers, distributors, group purchasing organizations, healthcare associations, professional and clinical societies, healthcare providers, patients, and our caregivers. Our work includes a broad array of cost-cutting efforts which includes close collaboration with our government partners, CDC, NIOSH, and OSHA.

We are delighted to have them participate in this webinar with us. And it's now my pleasure to turn to our agency partners starting with NIOSH. John Howard, can you please introduce yourself and your organization.

Dr. John Howard: Thank you Suzanne. NIOSH CDC is pleased to participate in this town hall with our colleagues from OSHA and FDA. As everyone knows, respirator use in American workplaces must be evaluated and approved for use by staff at NIOSH's national personnel protective technology laboratories under the direction of Dr. Maryann D'Alessandro who will be answering your questions today.

Some of NIOSH's COVID-19 respirator related activities include One, addressing over 3000 PPE related inquiries. Two, tripling the rate of respirator approval and denial decisions from 30 to over 100 decisions per month. Three, collaborating with the FDA which has developed several emergency use authorizations to significantly expand the inventory of respirators available for use in healthcare settings.

Four, promulgating an Interim Final Rule that created a new PAPR class to enable the approval of PAPRs more conducive to healthcare environments. Five, evaluating over 130 international respirator models in the past two months, finding that more than 50% of the models tested were substandard,

providing data needed to support the FDA's EUA decisions.

Six, publishing available research about respirator decontamination procedures. And seven, working with the Non-profit Center for Medical Interoperability to enhance an effort initiated in 2011 to develop the information technology architecture necessary to enable PPE data to transition from government-owned and secured system to one where hospitals are willing to share and exchange their respirator supply and utilization data.

Thank you again for the opportunity to highlight some of NIOSH's COVID-19 activities in respiratory protection.

Bill Maisel: Thanks Dr. Howard. And now I'd like to turn it over to Amanda Edens on behalf of OSHA.

Amanda Edens: Thank you. This is Amanda Edens, I'm the Deputy Assistant Secretary for OSHA. And I'd like to start off by joining Dr. Hahn's thank you for all the workers on the frontlines that are working through this pandemic. Their work is really heroic and much appreciated.

Also, I'd like to thank FDA for the invitation to participate in this series. And also, we truly appreciate the collaboration we've had with NIOSH and FDA. And I think as mentioned earlier, sometimes we're on the phone multiple times a day trying to sort out the science as it becomes available.

Where OSHA sits in this area, as many of you probably know, we have set and enforce respiratory protection standards that regulate the selection, use, and maintenance of respirators in the workplace. However, OSHA also provides compliance assistance with various types of webpages and tools to help employers and employees understand how respirators work, how they're

to be put on and taken off and all that comes with that.

And in particular for COVID-19, we have issued guidance to help these employers and employees understand the types of respirators and other types of PPE that might be needed and are appropriate in certain types of workplace exposure to COVID-19 and how the OSHA standards would apply in those situations.

And we have also been working closely with FDA and NIOSH to help address some of the shortages in filtering face piece respirators that we've seen in healthcare. And in that respect, OSHA as issued a number of enforcement guidance memoranda to our compliance staff in the field on ways that OSHA can use our enforcement discretion, when appropriate, to address some of these shortages in the filtering face piece N95s.

We've issued a few of those and I can take questions on those. But I think as we have heard there is new science coming available. We'll continue to work with our colleagues at FDA and NIOSH to look at the changes in the pandemic and adjust our enforcement posture or our guidance as necessary. And I'll turn it back over.

Dr. Bill Maisel: Great, thanks for those comments and again, just thank you for the very collaborative spirit and nature of the cooperation between the agencies. Next slide please.

Before we get too far into the webinar series, we wanted to make sure that we were using the same terminology. We know we're joined by many different stakeholders today with different backgrounds, different knowledge bases pertaining to respirators. And we wanted to take a couple of minutes to set the foundational components of some of the terms we'll be using. Next slide.

So a facemask is a mask with or without a face shield that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks are to be used for source control only and are not personal protective equipment.

An N95 respirator is a disposable half-mask filtering face piece respirator that covers the user's airways, nose and mouth and offers protection from particulate material at an N95 filtration efficiency level both 42 CFR 84.181. Generally, an N95 FFR used in a healthcare setting is regulated by the FDA under 21 CFR 878.4040 which is FDA product code MFH.

And is either a Class 2 device that is exempt from premarket notification or is a Class 2 cleared device. And NIOSH, of course, also provides oversight and can evaluate and approve N95 respirators. Next slide please.

A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes of potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic that covers the user's eyes and face.

And a surgical mask is a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards in certain Class 1 and Class 2 (flammability) tests. Next slide.

For the rest of today we'll be predominately focusing on the N95 respirators. However, I did want to make sure everyone was aware of FDA's facemask and respirator guidance. An update to the guidance was published last month which summarizes our enforcement policy for facemask and respirators

during the COVID-19 public health emergency.

It provides regulatory flexibility. And some information regarding when certain products require FDA review prior to marketing and under what circumstances the products can be marketed without FDA review. They also assure that the products are appropriate for their use.

There is also a description of the enforcement discretion as to certain FDA requirements. And as mentioned, it's in effect for the duration of the public health emergency. We also held a webinar on April 6 concerning the topics contained in this guidance. The slides and transcript are available on FDA's Web site. Next slide.

I will now hand it off to Dr. Suzanne Schwartz to cover the emergency use authorizations for respirators.

Dr. Suzanne Schwartz: Thanks Bill. Bill just mentioned the enforcement policy guidance that we've issued for face masks and respirators during the COVID-19 public health emergency. A complementary tool that FDA has used extensively in this pandemic response is the EUA.

The EUA has a specific construct which is based on the statutory authority given to FDA. We'll break that down into its component parts on the next slide; next slide please.

What is the basis for EUA and how does it work? Before FDA may issue an EUA, the HHS Secretary declares that circumstances exist justifying the authorization. During the COVID-19 response, this declaration has been based on a determination by the Secretary that there's a public health emergency.

The specific statutory language can be found in Section 564(b) of the Federal Food and Drug Cosmetic Act for those who are interested. You will note that this information is included in the introductory framing of every letter of emergency use authorization that FDA issues.

The EUA authority allows FDA to help strengthen the nation's public health protections by facilitating the availability and use of critical medical products during public health emergencies when certain criteria are met. The criteria of issuance are the very foundational elements of the EUA;

and similarly, are included in this template of every letter of authorization. Number 1, that the condition is serious or life-threatening. Secondly, that there's evidence of effectiveness in diagnosing, treating, or preventing the serious life-threatening disease or condition.

The language which appears in the EUA is crafted as “may be effective”. And this is important to note because the EUA establishes a different threshold for evidence that is distinctly different from an FDA clearance or approval.

Third, that the known and potential benefit for the authorized product when used as authorized, outweigh the known and potential risks. And finally, that there is no adequate, approved and available alternative to the emergency use of the product.

This applies at times of respirator shortages for healthcare personnel as we have experienced during the COVID-19 pandemic. Next slide please.

The presence of significant national shortages of respirators during the height of the pandemic with rapidly increasing numbers of COVID-19 cases and inadequate supply to protect healthcare personnel serves as a very important

backdrop to further contextualize why FDA issued three respirator EUAs, each of which has specific criteria outlining eligibility as well as denoting the scope and conditions of authorization.

The first EUA we issued in early March covers all NIOSH approved respirators. The second EUA we originally issued in late March authorized non-NIOSH approved disposable FFRs imported to the US, exclusive of product manufactured in China. It has since been updated and we'll cover those updates shortly.

The third EUA we originally issued in early April. And it authorized non-NIOSH approved disposable FFRs manufactured in China. It has also been updated and we'll cover those updates shortly.

The issuance of these three EUAs illustrates FDA's constant attention to the evolving needs of healthcare personnel, making every effort to address shortage concerns, and at the same time, ensuring that product which is made available to our healthcare workforce is indeed providing adequate respiratory protection. Next slide please.

Included within the scope of the NIOSH EUA are: NIOSH approved, non-powered air-purifying particulate FFRs. Most commonly, these are the N95s as well as reusable respirators such as elastomerics. Number two, NIOSH approved PAPRs. Number three, FFRs that have since passed their recommended shelf life, that are not damaged, and they've been maintained in conditions that are appropriate in strategic stockpiles. And finally, FFRs that have been decontaminated by an authorized decontamination system. Next slide please.

On June 6, we updated the EUA for imported non-NIOSH-approved

disposable FFRs. The updates included revisions to the Scope of Authorization as well as the Criteria for Eligibility. Authorized respirators are listed in Exhibit 1 of the EUA.

Of note, no changes to Exhibit 1 resulted from the revisions to the EUA. FDA has however revised the Scope of Authorization in that decontaminated respirators with exhalation valves are no longer in the scope of product authorized by this EUA. Next slide please.

This second slide pertaining to the imported non-NIOSH approved disposable FFRs depicts the updated eligibility criteria. Criterion 1 remains as is. Criterion 2 was revised to confer eligibility to those FFRs that conform to either the PPE directive or to the PPE regulations depending upon the date when the FFR was put into distribution, as evidenced by a CE mark.

And Criterion 3 was newly added and confers eligibility to those non-NIOSH approved FFRs manufactured by NIOSH approval holders. Those of you who've been closely following the issuance of FDA's EUAs on respirators will recognize this criterion as it mirrors one already included in the EUA for FFRs manufactured in China. Next slide please.

On June 6, we updated the EUA for non-NIOSH-approved disposable FFRs manufactured in China. The update included revisions to the Scope of Authorization, Conditions of Authorization and Eligibility Criteria. Let's walk through the Eligibility Criteria changes first.

Criterion 1 remains unchanged. Criterion 2 was revised to limit the jurisdictions to only those FFRs that conform to either the PPE directive or the PPE regulation, as evidenced by CE mark or it has an NMPA registration certification.

Criterion 3 was further revised from the May 7th EUA update to state that for respirators sampled by FDA and tested by NIOSH per the FDA NIOSH sampling plan of 30 respirators, should one respirator's filtration performance be less than 95%, that results in a failure of that model and the respirator will not be authorized.

In addition to the revised Eligibility Criteria, FDA revised the Scope of Authorization to remove decontaminated respirators. And also added new Conditions of Authorization to require samples for testing when requested by FDA and to prevent distribution of shipments that failed testing, as I previously described.

Next slide please. We have now completed a high-level walkthrough of the three respirator EUAs and their recent updates. The corresponding lists of authorized respirators are dynamic, and we encourage you to periodically check these lists for additions and removals as they are posted publicly.

For the NIOSH approved respirators, a link to the NIOSH's publicly facing CEL, Certified Equipment List, is embedded in the EUA.

Exhibit 1 and Appendix A are updated regularly as the FDA team receives new requests and evaluates them for authorization under the corresponding EUA.

Through these respirator EUAs we continuously strive to meet the evolving needs of healthcare personnel. We are continuously re-examining the supply landscape by engaging with our federal partners and the private sector to best understand the state of product availability for healthcare across the nation.

And with an unwavering commitment to our public health responsibility, we are continuously redoubling our efforts to ensure that our healthcare workforce who put their own lives at risk have access to respirators that provide the necessary respiratory protection. Next slide please.

Our efforts are not in a vacuum. We work closely with our federal partners, CDC NIOSH and OSHA so that strategies for optimizing the supply of N95 respirators are broadly disseminated and communicated whenever we have the opportunity. Next slide please.

These strategies are well detailed in the CDC NIOSH recommendations and explain recommended measures healthcare facilities can take commensurate with the circumstances, be they conventional, contingency or crisis.

Of highest preference, FDA cleared or NIOSH approved N95 respirators should be used when they are available. However, when they are not, FDA recommends using FDA authorized respirators before any other alternative.

Based upon the data we have evaluated that has informed and will continue to inform our EUA revisions, we do not recommend using a product as a respirator if it has not been FDA-cleared, NIOSH-approved or authorized by FDA for emergency use as a respirator. Such a product could instead be used as a face mask to improve source control and help stop the spread of COVID-19.

While much emphasis has been placed on filtration efficiency performance, proper fit of a respirator is paramount in order for it to protect properly. Healthcare personnel should ensure that respirators fit adequately before every use. It is therefore, important to consider that it may be difficult to achieve an adequate fit with respirators that have ear loops instead of head straps.

I would now like to turn the presentation back over to Bill Maisel who will provide an overview of FDA's ongoing efforts to further the optimization of supply of respirators.

Bill Maisel: Thanks Suzanne. Next slide please. As mentioned, FDA cleared or NIOSH approved N95 respirators should be used when they are available. And when they are not available, we recommend using FDA authorized respirators before any other alternatives.

A decontaminated respirator should only be used when there are insufficient supplies of new approved, cleared or authorized respirators. I want to spend a few minutes now talking about some of our policies that we have published regarding respirator decontamination and bioburden reduction. Next slide please.

Approximately two weeks ago, FDA issued guidance on recommendations for sponsors requesting EUAs for decontamination and bioburden reduction systems of surgical masks and respirators during the COVID public health emergency.

The guidance contained evidence-based approaches to decontamination and bioburden reduction. It provides an overview and a proposed recommended tiered approach for decontamination and bioburden reduction systems. And it provides the recommended content of a pre-EUA submission and EUA request. Next slide.

The guidance and our review approach rely on an evidence-based approach to assessing decontamination and bioburden reduction. It relies on the well-established hierarchy of resistance of microorganisms to germicidal

chemicals.

So bacterial spores and mycobacteria are more resistant than non-lipid or small viruses are more resistant still than vegetative bacteria and lipid or medium sized viruses. And importantly the SARS-CoV-2 virus that causes COVID-19 falls into the category of lipid viruses.

And so, this hierarchy is applicable to most established microbiocidal processes. And the guidance uses the tiered approach for processes that follows its hierarchy. If you are using a process about which less is known or that is known not to follow this hierarchy, then we recommend that you reach out to FDA directly to discuss the evidence that will be needed to support your authorization.

But for those processes known to follow this hierarchy, the following slides will walk through the type of evidence that is needed for the validation data. Next slide please.

The FDA guidance recommends use of a tiered approach to assessing the validation data associated with a decontamination process and system. And the proposed use of the decontamination system will determine the level of evidence needed to support the use. And it is a three-tiered approach.

Tier 1 is the most stringent criteria and that is for decontamination of surgical masks and/or respirators for either single or multi-user use. It requires or is recommended that you provide at least 6-log reduction of the most resistant spores for the proposed process or greater than or equal to 6-log reduction of mycobacteria species.

Tier 2 is for decontamination for single user reuse and is recommended that

you provide at least 6-log reduction of three non-envelope viruses or at least 6-log reduction of 2 gram positive and 2 gram negative vegetative bacteria.

And then Tier 3 is for bioburden reduction. Because the level of reduction is lower it is only intended to supplement existing CDC reuse recommendations and it is not intended to be used in lieu of CDC reuse recommendations.

You can think of it as a belt and suspenders approach. And we recommend providing evidence demonstrating as least 3-log reduction of non-envelope viruses or at least 3-log reduction of 2 gram positive and 2 gram negative vegetative bacteria. Or other evidence such as published literature and other scientific studies demonstrating a similar affect. Next slide please.

The validation of decontamination is only one piece of the information that is necessary to provide authorization and the recommended content of the pre-EUA submission and EUA request.

I am not going to walk through each of these items here today, but they are described in our guidance in great detail. I will call out a couple of them however. Item Number 3 is a description of the process controls including the critical cycle parameters.

This includes information such as concentration, time, heat, relative humidity. We will want to know about the use of the chemical or biological indicator. We will want information that demonstrates that the process is reliable and well controlled.

Number 5, the material and respirator compatibility is also key and very important obviously for the process. Respirators can vary in design and this can have an important impact on the safety and effectiveness of the

decontamination system.

Other evidence supporting the number of decontamination or bioburden reduction cycles that the respirator can withstand is needed and we will review that. And it is important that there be a reassessment of respirator performance after a number of cycles including filtration performance, breathability and fit testing.

Again, I recommend that you look at the content of the guidance if you are considering submitting a pre-EUA or EUA request. Next slide please.

FDA has issued several EUAs for decontamination systems. Each one is authorized for use only with compatible N95 respirators. And those respirators must meet all of the criteria and this is based on the revised EUAs that were issued this past week.

The respirator must be a non-cellular respirator and without an exhalation valve. And it must either be authorized in the NIOSH approved air purifying respirator EUA or authorized and identified in Exhibit 1 of the EUA for the imported non-NIOSH approved disposable filtering safety respirators that Dr. Schwartz was talking about.

And again, decontaminated respirators are only for use when there are insufficient supplies of FFRs resulting from the COVID-19 pandemic. Next slide please.

This provides a list of the currently authorized decontamination systems. The details of each system are described in the letter authorizing the EUA as well as in the publicly available fact sheet and information sheets that are available on FDA's Web site.

I have provided a link here, but you can go to FDA's EUA Web site. We update it daily. We list every authorized system. If there are updates to the EUAs they will be posted there and the information that healthcare personnel and healthcare facilities need to safely use these products are listed there. Next slide please.

I know we provided a whirlwind tour of some of the important updates and aspects contributing to the safe use of respirators. We did want to save some time for questions. And so, at this point I will turn it over to Suzanne Schwartz as we open up the Webinar to the audience for questions.

Suzanne Schwartz: Thanks Bill. Again, at this time we've concluded the formal presentation portion for today's Webinar. We have our subject matter experts from across all three agencies available on standby as well. Operator may I have the first question please.

Coordinator: And once again if you would like to ask a question over the phone please press star then 1. Please unmute your phone and record you name. If at any time your question has been answered you can remove your request by pressing star 2.

Once again that is star 1 for questions at this time. Please stand by Miss. Our first question is from Ms. (Hewett). Your line is open.

Ms. (Hewett): Good afternoon. Thank you so much for taking my question and for organizing the Webinar series. My question is associated to a comment that Dr. Schwartz had mentioned that the respirators that did not pass fit testing could be used as face masks for source control.

My question is associated to that statement. How does that fall or how would you consider that considering that the FDA has said face mask EUA associated to labeling for face masks? There are six requirements associated to the labeling for face masks before that - that these face masks need to comply with for them to be used as source control.

Suzanne Schwartz: Thank you for the question. So, I would certainly refer you to the guidance that we referenced during the context of the Webinar which includes face masks and respirators and has links to the face mask EUA, umbrella EUA.

It is certainly something that you can follow and identify if you have any particular questions beyond what is included within the EUA itself or within the guidance. Please write to the email address that is on this slide right now and we can provide further clarity.

Ms. (Hewett): May I ask...

Suzanne Schwartz: Let me also just add one other point and that is that cloth facial coverings and face masks do not need to be under an EUA. There are plenty of them that are being used that are not under an EUA. So, let me hear what your follow up question was.

Ms. (Hewett): And the follow up question is actually to that point, the comment that you just made. There is a lot of confusion if I could be frank with you associated to the EUA face mask umbrella. And I have submitted some questions through your consumer services and to the email and I have been awaiting some answers.

It seems that the language is not, or the guidance may not be aligned with the CDC and also with the EUA umbrella. An example would be that we do have various respirators that have not either met the fit testing criteria, the imported

respirators or have not been NIOSH approved and have passed the modified testing.

That there is a statement that from the FDA stating that they could be used as source control. However, we are not clear though if we would want to use these (unintelligible) 95 specifically that have not met any (unintelligible) criteria of source control. If they would have to fall under this EUA umbrella, face mask umbrella.

It seems that there is some communication, a point that they have to fall under that umbrella. But other messaging and messages that are coming across that they do not need to fall under that umbrella to be used as source control in a healthcare setting.

Suzanne Schwartz: Thank you for that. I am going to ask if one of the subject matter experts from FDA wouldn't mind taking that question further. It might be either CAPT Claverie or Dr. Ashar.

Binita Ashar: Sure, this is Binita Ashar. So as Dr. Schwartz mentioned there are two documents that you have referred to. One is the guidance allowing increased supply of face masks. And the second is the umbrella EUA for face masks.

If the company or if the Sponsor wants to go ahead and market these as a face mask they should follow the guidance. And there are certain recommendations there pertaining to the labeling. It is very important to us and I think to others using these devices that they know what these devices are doing, and they should not be used as surgical masks for example.

So, we have some labeling recommendations included in that guidance that I would advise your colleagues to follow. Now if the individual that is

marketing this mask seeks to go one step further and assure that they have the liability protections associated with emergency use authorizations, then they should follow those conditions laid out in the emergency use authorizations.

So they may not entirely match the stipulations of the guidance and the emergency use authorization but they are very closely aligned.

Coordinator: Thank you. The next question comes from - the next question comes from *(Jennifer Bettencourt). Your line is open.

(Jennifer Bettencourt): Hi good afternoon everybody. Thank you so much for this informative Webinar and update. At our organization we did put together a pretty thorough for the reprocessing of the N95 disposable masks. We will be stopping that - actually this week because we have adequate PPE and we will not continue reprocessing those masks.

However, we are now exploring the process for the disinfection and cleaning of the elastomeric half face respirators as well as using air powered purifying respirators. And we have been in contact with the vendor. They have been very forthcoming and helpful.

However, for my quality piece which is what I try and help and provide support here for the organization on. Should we be providing the decontamination or cleaning of these half elastomeric respirators or should we be leaving that responsibility up to the end user that will own the face mask?

Suzanne Schwartz: Thank you for that question and I am actually going to turn that over to NIOSH. I am wondering if Dr. D'Alessandro, one of your colleagues might address the reprocessing, disinfection reprocessing of the elastomerics.

Maryann D'Alessandro: Hello Suzanne and thanks for doing this. Yes, we have prepared guidance for those who are decontaminating respirators per the crisis capacity strategy situation.

So, our recommendation would be that you allow the users to make that decision in working with the manufacturers and if they are in that crisis capacity strategy using the guidance that we have on the Web. We understand that some are enabling that guidance to be used for conventional operations as well. This is not our intent.

Jennifer Bettencourt: Thank you.

Suzanne Schwartz: Thank you. Next question please.

Coordinator: Yes, the next question comes from (Victor Schwartz). Your line is open.

(Victor Schwartz): Thank you just a basic question. Do any of the N95 masks and this is a common question that I am asked all the time. Actually protect the user? Regardless of what is said in some of these TV shows. Do any of them protect the user against the virus as well as providing protection to those around them?

Suzanne Schwartz: Maryann do you want to answer that one?

Maryann D'Alessandro: Yes, this is Maryann. Actually, respiratory protection is meant to protect the user not to be a source of control. For example, if a respirator does have an exhalation valve then you would not use that as protecting a patient or those around the individual. So, at this point in time we are conducting research to evaluate comes out of the exhalation valve and all. But the respirators do protect the wearer not those around them.

(Victor Schwartz): Thank you.

Coordinator: Thank you. The next question comes from (Meg McGucci). Your line is open.

(Meg McGucci): Yes, good morning. I have a very specific question. Is the exhalation valve the same thing as the cool flow valve that can be a 8511 N95 respirator?

Suzanne Schwartz: NIOSH I think this question is for you please.

Maryann D'Alessandro: This is a manufacturer specific question. I do not know that specific valve, but I expect that it is. Whoever your manufacturer is of that respirator I would suggest that you talk to them, but I believe that is an exhalation valve.

(Meg McGucci): And so, this is a NIOSH approved equipment and we are currently using UV sanitizing. Is this something that we are not able to do anymore? This is the update. Is that what we are talking about?

Maryann D'Alessandro: Is that - so I am sorry what is that product? It is a NIOSH approved device but what is the product itself?

(Meg McGucci): (Unintelligible) 8511 NIOSH approved. It is on the list of approved products. It has a cool valve in the center of the mask and currently we are UVC sanitizing these masks. And my question is are we no longer able to do that?

Maryann D'Alessandro: If you are still in the crisis capacity situation you should be able to do that. Otherwise you should leave it up to the manufacturer who I believe is 3M for that product. You can check with them on whether or not that would be authorized.

Suzanne Schwartz: And this is Suzanne Schwartz. Let me also add a little clarification. The decontamination systems that FDA has thus far authorized that we covered in this update happen to all be related to hydrogen peroxide or vaporized hydrogen peroxide excuse me. They do not cover UV light.

So, the discussion that we have had, the update is in the context of the decontamination systems. The modalities that have been thus far and have been authorized thus far.

(Bill Maisel): Suzanne this is (Bill Maisel) just to clarify. We have also authorized one steam decontamination system.

Suzanne Schwartz: Yes. Correct thank you.

Coordinator: Thank you. The next question comes from (Mike Nolan).

Maryann D'Alessandro: I am sorry before you get to the next question this is Maryann. 3M also has published a fact sheet on their Web site regarding what products are able to be decontaminated with their respirators. So I would suggest you look at that as well.

(Mike Nolan): Okay this is (Mike Nolan). Thanks for taking the question. The COVID emergency calls for many more respirators but the next emergency may call for something entirely different.

So my question is, is the FDA going to manage the EUA type situation using the existing FDA's UDI or Unique Device Identifier systems which are designed for medical devices? This is a system that is now being used by manufacturers, healthcare providers of Class 1, 2, and 3 medical devices. It is intended to provide quality assurance and traceability of medical devices.

It relies on the FDA's GUDID database and many companies are integrating the UDI system into their supply chains. So, it seems to make sense to help manage these products. Even the emergency products as well as the normal activity using the same methods that are now being implemented in healthcare supply chains. So, the question is, is that under consideration?

Suzanne Schwartz: So I will start off but then I am going to ask if (Bill Maisel) might want to add or further enhance the response. FDA will use all these different types of tools and leverage existing databases and mechanisms to help support our emergency response, regardless of what the hazard is. There is no question around that. And UDI would be a tool that could be utilized.

I think what is unusual in terms of COVID-19 - - and the criticality of the shortages that have been observed - - is that some of the products that we are talking about expand well outside the bounds of what has been in a traditional medical device manufacturing space in terms of whether it would have even been in UDI.

So, you know, we have to pull out all the stops, if you will. And use the various levers that we have, UDI being one of them, but to the extent that there are three EUAs for the very reason that limiting it to, for example, FDA cleared or NIOSH approved respirators, was going to be thoroughly short of what the needs are, what the demand is, and needing to expand that out and out further is illustrative of how we have to, you know, consider other avenues and other approaches.

Coordinator: Thank you. Our final question for today will come from (Cory) your line is open.

(Cory): Thank you. I work for a manufacturer, a non-NIOSH-approved manufacturer. We are going through the formal process to become a non-NIOSH approved manufacturer in addition to getting our factories registered. We submitted our original EUA application for non-NIOSH approved built-in safety system from China on 3/31 and have received, I would say less than desirable communication from the FDA.

And I was wondering if you could speak and provide some clarity and visibility as to what the process internally looks like once you receive an EUA request, specifically looking at the 40-plus manufacturers that were removed from the Appendix A during the April 7th revision.

In addition to - or was it the May 7 revision - but also an understanding of how those manufacturers were able to get their products added back onto the Appendix A, as there are still manufacturers like mine that has yet to receive a formal response on our EUA dated back to 3/31.

Thank you.

Suzanne Schwartz: Thank you. Thank you for the question.

So, first of all here, we want to be able to provide you a timely response. In some cases - - and potentially this falls into the circumstances you're describing - - the documentation that was received by the agency has not been - we've not been able to full vet the information. And the Criterion 3 as you described in the China EUA has provided a fair amount of challenge to this space.

We'd be happy to engage you further in a separate conversation to better understand exactly the circumstances that you're facing and try to, you know,

to resolve that.

So, I think that we are over time. And I do want to say that on behalf of FDA, I want to first acknowledge our valued partners from NIOSH and OSHA. Between us - we together have been able to, and will continue to, drive towards meeting our common vision and mission of protecting the public health.

Thank you to everybody who has tuned into this webinar. It's the first of many in this series. We're looking forward to exchanging dialogue and keeping you informed and hearing your perspectives and questions.

The next session, as (Bill) mentioned, will be June 23rd, in two weeks at noon Eastern, and announcements of topics will be forthcoming.

I'd now like to 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 webpage at www.fda.gov/training/CDRHLearn by Wednesday, June 17th.

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 slide webinar.

Again, thank you for participating. And this concludes today's webinar.

Coordinator: Thank you all for your participation on the conference call today. At this time, all parties may disconnect.

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