FDA Webinar Series-
CDC/NIOSH's Surgical N95 Respirator Guidance
Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's call. At that time if you would like to ask the question please, press star 1. Today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn our meeting over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communications and Education. Welcome to the seventh CDRH Webinar in our Respiratory Webinar series. During today's webinar, CDC NIOSH will present information on the recent release of its updated surgical respirator guidance, and representatives from CDC NIOSH, FDA, and OSHA available to answer 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. Suzanne Schwartz Director of CDRH's Office of Strategic Partnerships and Technology Innovation.

Suzanne Schwartz: Thank you and welcome everyone. As Irene mentioned, this is the seventh session in our biweekly webinar series on personal protective equipment or

PPE. At our last webinar on August 18, Dr. Binita Ashar -- Director of the Office of Surgical and Infection Control Devices or OHT 4 in CDRH's Office of Product Evaluation and Quality or OPEQ -- discussed the Umbrella EUA for surgical masks and how it fits into FDA's holistic regulatory approach to surgical masks.

Today I'm pleased to introduce Colleen Miller -- Deputy Chief Conformity Verification and Standards Developing branch from CDC NIOSH's National Personal Protective Technology Laboratory -- and Heidi Sewchok -- NIOSH Approval Coordinator -- who will provide an overview of the recently updated NIOSH guidance on surgical respirators.

After their presentation, we will turn to the Operator for live Q and A. Our federal partners and colleagues from CDC NIOSH and OSHA are on the line with us and they're available to field questions relevant to their respective mission, roles, and responsibilities. At this time I'd like to turn the webinar over to Colleen Miller.

Colleen Miller: Thank you, Suzanne. I am happy to be here today. It is my pleasure to be representing my branch and the National Personal Protective Technology Laboratory. I will be giving a brief overview of our agency and then dig into the topic of interest today. Surgical N95 filtering facepiece respirators and the guidance we recently updated regarding NIOSH approval for them. Next slide, please.

I am pleased to have two colleagues in the speaker room with me today. As Suzanne mentioned our Approval Coordinator -- Ms. Heidi Sewchok -- is with me and one of our new General Engineers -- Ms. Ashley Whitson -- is also here. Heidi has been involved in this effort for the last two years and is working with Ashley to review these types of applications, and we are just so fortunate to have achieved getting Ashley on board during this COVID response. Next slide, please.

Just to give a very brief introduction to our agency for those of you less

familiar with the National Institute for Occupational Safety and Health -- NIOSH -- the National Personal Protective Technology Laboratory -- NPPTL -- is a division of NIOSH and is charged with executing the functions of the NIOSH respirator approval program. NIOSH is part of the Centers for Disease Control and Prevention, and along with the Food and Drug Administration, is part of the Department of Health and Human Services. Next slide, please.

NIOSH has several divisions of laboratories across the United States. The NIOSH Office of the Director -- Dr. John Howard -- has staff located in Washington, D.C. and Atlanta, Georgia. NPPTL has offices in Pittsburgh, Pennsylvania, and Morgantown, West Virginia. Other NIOSH locations include Cincinnati, Ohio, Denver, Colorado, Spokane, Washington, and Anchorage, Alaska.

The bulk of the respirator approval program work is completed in Pittsburgh, Pennsylvania. Virtually now for those of us involved in the documentation review side of the program and on-site for our colleagues in the Evaluation and Testing Branch, that are conducting the respirator testing required. Next slide, please.

NIOSH approved all respirators used in U.S. occupational settings in accordance with the Code of Federal Regulations 42 CFR Part 84, standard test procedures, standard application procedures, and policies. Today's focus is on surgical N95 respirators.

As you can see from this slide, surgical N95's are a very small fraction of the work we accomplish in the NIOSH respirator approval program. We approve self-contained breathing apparatuses, supply air respirators, power air-purifying respirators, closed-circuit escape respirators, and other air-purifying respirators.

As described today, a surgical 95 respirator is a NIOSH approved N95 filtering safety respirator that additionally conforms to recognized standards for biocompatibility, flammability, and fluid resistance, and is thus intended

for use in healthcare settings within as well as outside of the operating room. A surgical N95 is therefore not limited to use during surgery but is intended for use in all other healthcare settings where this type of respiratory protection is indicated. Next slide, please.

I need to set the stage a bit so everyone can understand how we arrived to be here today. As I said, in the U.S., the Occupational Safety and Health Administration -- OSHA -- requires that respirators used in these occupational settings are NIOSH approved.

Additionally, respirators used in healthcare-specific to our topic today -- N95 filtering facepiece respirators -- are considered medical devices by the FDA and are cleared through the 510(k) Premarket Notification program. As we speak, all surgical N95's used in healthcare today are approved and cleared for use by both agencies NIOSH and the FDA. The applicant first applied for and obtained NIOSH approval and then sought and achieved FDA 510(k) clearance.

Back in 2016, NIOSH NPPTL sponsored a National Academy of Medicine workshop to discuss surgical N95 regulatory and performance requirements. After the workshop in 2017, the agencies NIOSH, NPPTL, and the FDA Center for Devices and Radiological Health -- CDRH -- finalized a memorandum of understanding with the intent to streamline this regulatory process and reduce redundancy.

We worked together to develop a process for NIOSH to complete the full review of devices submitted to NIOSH under the terms of the MOU, and in late 2018, NIOSH posted guidance outlining the process for executing the MOU. At that time, the guidance said the devices approved under the consolidated MOU process would be labeled and referred to as N95-Fs.

NIOSH discussed the guidance and process with stakeholders but did not receive any applications to review. Then as the COVID-19 response started gaining momentum, approval holders and potential applicants began to ask

more about the MOU consolidated process. Next slide, please.

We became concerned during the COVID-19 response that we as a nation did not need yet another classification to identify this type of basic respiratory protection used by healthcare workers, so we discussed this concern with our FDA colleagues and began to update our guidance.

The guidance was revised and now better aligns with the MOU and refers to these devices as surgical N95 filtering facepiece respirator as SN95's, our focus for today's webinar. NIOSH posted an updated guidance about two weeks ago and this August 2020 guidance supersedes what we posted in November of 2018.

In the fall of 2018 when we posted this guidance, we expected to be working through the process with the first applicant and yet we did not receive any applications, so here we are. I'm sure some of you attending today are already working on your application or plan to apply for surgical N95 FFR approval. I am providing the slides so that you can see - excuse me. Next slide, please.

I am providing this side so that you can see what the guidance looks like. This is the cover page for the NIOSH Conformity Assessment Letter to Manufacturers. This is the document that I have referring to as the NIOSH guidance. You can see it is marked as being posted for the first time in November of 2018 and then revised in August 2020. NIOSH applicants must use this updated guidance since -- as I said -- it supersedes the 2018 version. Next slide, please.

This is the cover page for another NIOSH Conformity Assessment Letter to Manufacturers. This one was published a week or so ago to inform about NIOSH NPPTL's prioritization process for applications as we begin to accept surgical N95 approval applications. Our top priority is domestic approval holders submitting a new or an extension application, including a new or extension application using the SN95 guidance.

We also continue to prioritize quality assurance applications from existing approval holders to facilitate filtering facepiece respirator, air-purifying respirator and powered air-purifying respirator production at additional manufacturing sites in accordance with established and NIOSH approved quality assurance systems. I encourage participants interested in reading the complete notice to visit our website. Next slide, please.

So, I have been referring of it to the term applicant or application. Just to clarify, NIOSH defines the applicant is an individual, a partnership, a company, a corporation, an association, or other organization. The applicant designs or controls the respirator design, manufacturers assembles or controls the assembly of a respirator and may apply to NIOSH to become an approval holder. Thus, once approved, the applicant becomes the approval holder. Next slide, please.

So, as I said, we have updated our surgical N95 filtering facepiece respirator guidance and our prioritization process. So in our revised guidance, we have defined four scenarios to guide applicants and approval holders. In the first scenario, we state that no immediate action under this guidance is required for an existing device that has previously obtained NIOSH approval and FDA 510(k) clearance.

The existing approval will remain effective as long as the approval holder continues to one, pay the annual NIOSH maintenance fees; two, register and list your company with the FDA; and three, meet NIOSH and FDA postmarket requirements.

The approval holder will be expected to revise their user instructions and packaging to include the new cost in limitation S and remove the P's as defined in this guidance -- and Heidi will talk about that a bit later -- the next time that approval is submitted for an extension for approval.

And in some cases, the approval holder must update the abbreviated label as well. Additionally, if the device is private labeled, the approval holder seeks

to update their labeling, they must submit an extension application to update their approval and all the private labeled versions.

The second scenario is defined as if a manufacturer of an existing NIOSH approved N95 filtering facepiece respirator has not previously sought FDA 510(k) clearance and now seeks to label a device with the additional protection of flammability, fluid resistance, and biocompatibility, the manufacturer must follow the guidance to achieve a new NIOSH approval for the surgical N95 respirator.

The third scenario identified is if a manufacturer of an existing NIOSH approved N95 filtering facepiece respirator has not previously sought FDA 501(k) clearance and does not seek to label the device for those additional protections of flammability, fluid resistance, and biocompatibility, the existing NIOSH approval will remain effective as long as annual fees are paid.

And the final scenario, if a manufacturer of a new N95 filtering facepiece respirator seeks NIOSH approval for a surgical N95, the manufacturer must follow this updated guidance. Now I will turn the mike over to Heidi Sewchok so she can continue to inform you about the approval process.

Heidi Sewchok: Next slide, please. Hi, everyone. I'm Heidi Sewchok, the Approval Coordinator for the respirator approval program. Along with Ashley Whitson, we will be conducting the reviews of the surgical N95's that are submitted to NIOSH. I'm going to walk you through some of the basic steps for surgical N95 approval under the MOU. The process follows a similar path to the typical NIOSH N95 approval. However, there is more information that needs to be provided.

The first step that an applicant must take is to perform the required presubmission testing. This is often erroneously referred to as precertification testing. While it is required prior to approval, it does not indicate that the respirator is capable of achieving NIOSH approval. This is because the NIOSH approval encompasses both the performance and the quality assurance

aspects and they cannot be considered independently from one another.

The testing required from NIOSH for an N95 filtering facepiece includes inhalation resistance, exhalation resistance, and particulate filter efficiency. This testing can be performed by a third party or the applicants themselves if they are capable and have the appropriate equipment.

The additional tests to achieve the surgical designation for an N95 must be performed by a lab that is certified to the FDA's Good Laboratory Practices requirement. The additional tests are fluid penetration, flammability, and biocompatibility. The biocompatibility test itself consists of three individual evaluations which are cited toxicity, sensitization, and irritation. Next slide, please.

The second step is to prepare the required documents and submit the application to NIOSH following the standard application procedure and the updated guidance. Final packaging should also be included with the application package. After the application package is received by NIOSH, the FDA requirements defined by the MOU will be evaluated by NIOSH.

After the application package is determined to meet the MOU requirements, the NIOSH evaluation and testing will continue per our typical process, including initial review, quality assurance review, testing, and final review. If a site qualification is required, that will also be coordinated during quality assurance and final review.

If the application package is deemed to meet the requirements of 42 CFR Part 84 and the MOU, a surgical N95 approval will be issued and the NIOSH CEL -- Certified Equipment List -- will be updated to reflect the approval as a surgical N95. After receiving approval from NIOSH, the approval holder is responsible for listing the device with the FDA. Next slide, please.

Ashley and I wanted to include a bit of information about the quality assurance requirements found in 42 CFR Part 84 because it is an often

overlooked aspect of the NIOSH approval that raise many - leads to many application failures. We are hoping to post more detailed information -- perhaps as a frequently asked question and answer page -- to better guide applicants.

Today I am able to give a broad overview of some of the information that we expect to see from applicants. The quality requirements are different than other certification bodies that many are used to working with and the requirements that we look for are outlined in our regulation and are very specific. The quality manual submitted to NIOSH must meet the requirements outlined in our Conformity Assessment interpretation notice NIOSH CA 2019-1019 and 42 CFR Part 84.

In addition to the quality manual, a comprehensive quality control plan must be supplied and must be sufficient to determine that the respirator meets the NIOSH performance requirements and the specifications that were presented for approval.

For a filtering facepiece, inspections receivers should include incoming and final inspections. These inspections must be assigned classification of defects. This is a hang-up that many experience as the classification of defects defined in 42 CFR Part 84 are different from those used by the common sampling plans. The definitions in the regulations must be appropriately applied to be acceptable.

Incoming inspections procedures must be clearly defined and serves to verify that the materials received conform to the specifications that were ordered. Final inspection procedures must be clearly defined and serves to verify that the fully assembled respirator conforms to the specifications on the drawing and ensure that the required performance specifications are met.

Product quality control plans and sampling plans should also define what the manufacture or applicant considers to be a lot or a batch. The sampling plan used for each inspection should be clearly stated.

If a sampling plan other than those commonly recognized by NIOSH is used, the equivalency must be explained in the application. The September 24, 2012 letter to all manufacturers provides more information on the sampling plans that are commonly recognized and how to successfully utilize them to meet the requirements and expectations. In general, it is expected that the applicants meeting NIOSH quality assurance requirements are also able to satisfy the FDA quality assurance requirements. Next slide, please.

We also think that it's important to remind everyone that the surgical N95 approved under the streamlined process must not exceed the threshold evaluation criteria outlined in the MOU. Respirators that have certain designs or claims are not 510(k) exempt and will need to be evaluated by the FDA. Some examples are respirators with exhalation valves or designs that are different from what the FDA has previously cleared.

This includes those with novel head suspensions such as adhesive masks and those with ear loops, specific disease and/or infection prevention claims, specific viral or bacterial filtration performance claims, antimicrobial or antiviral functions -- including nanoscale technologies -- (hypoallergenicity) claims, filtration of surgical smoker plumes, nanotechnology, drug delivery systems, claims of sterility, and any respirator that is not a filtering facepiece with the protection of N95. The MOU has a more comprehensive list if you're still curious. Next slide, please.

The surgical N95 guidance has specific information about how the respirator must be labeled. This information is probably the biggest difference from what was posted in 2018. Surgical N95 respirator approval labels must include the caution and limitation (S) defined on the approval label as special or critical user instructions and/or specific use limitations applied refers to user instructions before donning.

The user instructions and packaging must state that this respirator has been approved as a NIOSH N95 filtering facepiece respirator for use in healthcare

settings as a surgical N95 respirator conforming to recognize standards for biocompatibility, flammability, and fluid resistance.

This statement will be found under the (S) special or critical user instructions heading. The approval label should no longer have the caution and limitation "P", which is NIOSH does not evaluate respirators for use of surgical masks, which is common on all existing N95 respirators.

The updated guidance also provides specific information that will appear on the abbreviated label, which is the label that is printed on each individual filtering facepiece. The abbreviated label will include additional wording to inform users that the respirator is appropriate for use in healthcare settings.

The abbreviated label will have the words surgical N95 respirator directly on the filtering facepiece. All new surgical N95's will have this on their abbreviated label. At the moment, we are not requiring manufacturers who already have surgical N95's to make this update immediately.

If they do wish to update their labeling, an extension of approval application can be presented to update the abbreviated label, approval label, and user instructions. Next slide, please.

We realize we've shared a lot of information today is intended for respirator manufacturers. We are working on a respiratory protective device information notice to inform users, and the FDA and NIOSH want to remind users that the NIOSH approved surgical N95 offers the same respiratory protection as the NIOSH approved N95 filtering facepiece respirator.

Additionally, the surgical N95 conforms to FDA specified flammability, fluid resistance, and biocompatibility requirements and is intended for use in healthcare settings inside and outside of the operating room. A surgical N95 is not limited to use during surgery but is intended for use in all healthcare settings where respiratory protection is needed to protect the wearer and it provides an appropriate level of respiratory protection. Next slide, please.

Here we have included some links for you today including the links to our NIOSH certified equipment list, which is updated at least monthly. We are working to define how the CEL can be searched to identify approved surgical N95's. The first choice for confirming whether or not a respirator is approved should always be the CEL, but we do have an additional page -- the surgical N95 trusted resource page -- which can be found using the second link.

You can easily access the electronic version of our regulation 42 CFR Part 84 and our standard test procedures for air-purifying respirators using the third and fourth links. The conformity assessment notices we mentioned throughout this presentation and general information about the NIOSH respirator approval program can be found using the fifth and final links, respectively. Next slide, please.

In closing, I want to let you know as September 5 9-5 as in N95 approaches, we are gearing up to celebrate Respiratory Protection Week. You can check that out on our NPPTL web page. Our NPPTL health communications team has been busy preparing social media content, developing webinars, and informational products. We hope you can check out our web page and consider joining us next week. Next slide, please.

Along with myself and Ashley, NIOSH FDA and OSHA experts are standing by to answer your questions. Questions specific to an applicant or an applicant's specific situation will be identified for follow-up by NIOSH or the FDA after the webinar.

If you have a question specific to your situation, please reach out to myself using the e-mail address provided on Slide 2. If you do not wish to ask questions specific to the approval process in this forum, please reach out to myself or Ashley. Thank you for your time and attention, and I think we're ready for questions.

Suzanne Schwartz: Thank you. Operator, we'll now take questions.

Coordinator: Thank you very much. If you would like to ask a question over the phones, please press star 1 and record your first and last name. To withdraw your question, you may press Star 2. Once again to ask a question, please press star 1 and record your first and last name. Thank you. Just a few minutes for questions. All right and our first question I do apologize if I mispronounce your name I have (Sadhna Denver). Your line is open

(Sadhna Denver): Great. Thank you very much. One question with the new guidance do you define whether if N95 are going to be sterile prior to use or if they are to be sterilized are you doing to set a standard of what type of sterilization techniques are going to be appropriate. Thank you

Heidi Sewchok: Hi this is Heidi Sewchok. There is no requirement from NIOSH or the FDA that surgical N95 be sterile. If you want to make that claim it will be outside of the streamlined process.

(Sadhna Denver): So if a hospital decides they like to sterilize an S95 or just a regular N95 what you're saying is this that the (unintelligible) hospice it's up to them to define whatever they want to sterilize the mask or not. Is that correct?

Heidi Sewchok: Correct. Currently outside...

(Colleen): Hi this...

Heidi Sewchok: Go ahead

(Colleen): Hi this is (Colleen). I was just going to say that from the NIOSH perspective we expect you to honor the user instructions that are provided by the manufacturer and consult with them because ultimately you could be reducing the protection that we are approving the respirator to provide to the user.

(Sadhna Denver): Great. Thanks very much for your answer. Appreciate it.

Coordinator: Thank you. Our next question is from (Adam Allbright). Your line is open.

(Adam Allbright): Hi, thank you. We are manufacturing masks and going for the approval but prior to that we were actually manufacturing the raw materials like (E4) tracing materials and if we had - if we currently are selling the (E4) tracing materials to a company that had sent out those exact products to GLP certified laboratories and already did the proof penetration, credibility and biohazard credibility would we be able to piggyback off of that being that we are the manufacturer so we could confirm the feedback of the materials or will we need to do our own but there are company that had done their own testing and things like that.

(Colleen): So from that - this is (Colleen) from the NIOSH - perspective we expect that the samples would be made under your quality system.

(Adam Allbright): Okay.

(Colleen): So and I think that perhaps my FDA colleagues might have kind of an idea on piggybacking.

Suzanne Schwartz: Hi it's Suzanne this is Suzanne. OHT4, can you take that?

Cynthia Chang: Hi this is Cynthia Chang. I'll start. Typically we request testing on the final finished device and not on raw materials. If there's anything else that my colleagues want to add to that, please feel free to jump in, but typically we do request testing on the final finished device.

(Adam Allbright): Okay. Thank you.

Coordinator: Thank you. Our next question is from (Dennis Hahn). Your line is open.

(Dennis Hahn): Yes, thank you. Had a question on the connection between of the NIOSH approval and then the FDA listing. You have mentioned once the NIOSH CEL is updated manufacturers responsible for listing the device, does NIOSH

issue the K number for the 510K or is that a separate process for the FDA or is there a different identifier for 510K devices joining the listing process.

Suzanne Schwartz: Hi this is Suzanne Schwartz from the FDA. I'm going to ask Marjorie Shulman to provide a little bit more information or clarity regarding the MOU-described 510K exemption and what therefore is necessary, process-wise, for the manufacturer to do upon receipt of NIOSH approval and listing on the CEL.

Marjorie Shulman: Hi good afternoon this is Marjorie Shulman. If a - if a 510K is exempt from regulation then through listing you enter the exemption number, the CFR number, so for example 878.5400 that would go in there we - and the product code and that's tied to the regulation that shows that it's an exempt device. So if I continue number would not be needed. If anyone wants to add anything that's fine.

Suzanne Schwartz: And Marjorie, this is Suzanne I believe that that product code for the exemption is going to be MSH as a surgical respirator.

(Marjorie Shulman): Perfect. So that's go in there and then that will show, if exempt 510K number is not needed, unlike the products that require 510K then the 510K number would go in there. But if it is exempt then that product is exempt and that's what's needed.

(Dennis Hahn): Thank you.

Coordinator: Thank you once again as a friendly reminder to ask the question on the phone please press Star 1 and record your first and last name. Our next question is from (Evan Prekoshure). Your line is open.

(Evan Prekoshure): Hello can you hear me?

Coordinator: Yes.

(Evan Prekoshure): Hello can you hear me?

Suzanne Schwartz: Yes we hear you.

(Evan Prekoshure): Hi it's (Prekoshure) mispronouncing my name that's why I wasn't sure. Questions regarding the MOU and then the extension period that locate the specific viral bacterial infiltration performance this would be sent and you would have to do a 510K but if under the MOU with this respirator is already called a surgical respirator how do you differentiate if you had (unintelligible) performance. Is that different name?

Suzanne Schwartz: Can you repeat the last part of the question how to differentiate - I didn't - I don't know that we caught what you said.

(Evan Prekoshure): Yes. Under your new process, you've already called it a respirator a surgical respirator. If somebody has, in addition, a disease or infection prevention or bacterial infiltration performance and would like to claim those is it still a separate respiratory or how do you differentiate in the market that your respirator has more than just some ability and the other two of performances.

Suzanne Schwartz: this is Suzanne Schwartz so Colleen and Heidi I think this is an FDA related question and I'm going to turn to OHT4 to provide a response as to, you know, first of all what would be required since it does trip the exemptions for under the MOU what would be necessary for to the respirator that is intending to include additional claims as were specified in the listing.

Cynthia Chang: Hi this is Cynthia Chang, I can start. So if you wish to make some of these additional claims such as antiviral or antibacterial, antimicrobial claims as noted in the presentation and in the guidance document then you would need a 510K that would need to be submitted to us at FDA and then you would go through that process.

NIOSH approval is still a requirement as part of the special controls for the

device. I hope that's helpful and unless my FDA colleagues has anything to add please jump in.

(Liz Claverie): Hi this is Liz Claveriethank you, Dr. Chang. Just a few other points in addition to what Dr. Chang has said so when you would submit your 510K to FDA we would you want to have already worked with NIOSH to seek your certification of a respirator and where you would submit to FDA you would want to make certain that you had supporting performance that is to support any claims that you're making as relates to antimicrobial antiviral antibacterial any those types of claims as Dr. Chang mentioned.

Suzanne Schwartz: And Captain Claverie and Dr. Chang could maybe comment a little bit further then with respect to how then that impacts on labeling of the product, as I think the questioner was also wanting to know with regard to the marketing - how it would be differentiated. So if specific test results, going through the review process, were there could you explain, given to the 510K what that allows in regards to labeling?

Liz Claverie: That's short of a great follow up. Thank you so much. So yes the label would actually be a combination label that it has to be approved by both agencies. So NIOSH would approve the respirator section of the label we would approve the FDA section of the label and the label would be very specific for whatever claims the sponsor has made that has been supported by performance data and we would allow those claims on the label.

(Evan Prekoshure): Okay and the last question to previous listing I would also understand the question so if I (unintelligible) retention and then it's listed as a surgical respirator listing it under FDA what does that really mean and how do you list it then under FDA after you get the NIOSH (unintelligible) N95?

(Liz Cleverly): So if I may ask you a clarifying question sir. So are you still speaking of the respirator that would have antimicrobial claim...

(Evan Prekoshure): No

(Liz Cleverly): ...or you speak...

(Evan Prekoshure): No

(Liz Claverie): ...so if you're speaking of just a respirator that doesn't have anti-microbial claims...

(Evan Prekoshure): Yes.

(Liz Claverie): ...then it should fall under the MOU with NIOSH and you would follow all of the processes and et cetera per NIOSH and (Colleen) I don't know if you want to pick up anything from there.

(Colleen): Hi (Liz) I think there's still some misunderstanding about this, even though I do appreciate what Marjorie provided I think there's a bit of misunderstanding about how they list with you, if I'm understanding the question correctly?

(Evan Prekoshure): Yes. It's submitted to New York because the approval of respirator N95 what is the next step to get it listed as a surgical respirator under FDA. What is that process?

(Colleen): So what I heard was you would enter MSH still as the product code correct (Liz)?

(Liz Claverie): That's exactly correct and you would need to be registered and listed with FDA and you would list as Colleen just mentioned the pro code MSH in our systems and we would also be working hand in hand, FDA would also be working hand in hand with NIOSH as they approve those.

So you would have to make sure on your end that you are registered and listed with FDA and that's the first name go and then we would walk hand-in-hand with NIOSH and the sponsor as they get approved for the surgical N95

respirators under the MOU.

(Evan Prekoshure): Okay so no additional testing necessary? Is that correct?

(Liz Claverie): So as long as...

(Colleen): So as long as you say within the limitation listing. Yes, sorry (Liz).

(Liz Claverie): Exactly. No we were saying same thing (Colleen) thank you so much.

(Evan Prekoshure): Okay thank you.

Suzanne Schwartz: Let's take a moment. It's probably going to be helpful to all of - our listeners with regard to FDA's registration and listing process. I'm going to ask Cesar Perez who is available to us in FDA maybe you can provide a little bit further information and background to help with regard to the registration and listing process. You may be muted. We're not hearing you.

Sean Boyd: This is Sean Boyd maybe I can jump in real quick and say those on the line you can add or elaborate. If you've been on our registration and listing websites at fda.gov it does provide specific instructions for what data, what fields would you need to complete or what information you need to provide through that process.

You can also reach out to our Imports and Registration and Listing team using a general e-mail address that you can send specific questions to if you're having difficulty in navigating that process [which is reglist@cdrh.fda.gov]. I know that team is very responsive and likely would get back to you and resolve any questions or issues that you're having within a day or so.

(Evan Prekoshure): Okay. Thank you.

Sean Boyd: And thank you for the question.

Coordinator: Thank you. Our next question is from (Karen Milroy). Your line is open

(Karen Milroy): Thank you. Good afternoon. I was just wondering given what I imagine is an exceptionally large case of, I mean, NIOSH approval and how long is it taking to go from kind of the submission of the application through the approval process?

(Collen): Is this a new application?

(Karen Milroy): Yes.

(Colleen): You've never had a NIOSH application?

(Karen Milroy): Yes.

(Colleen): Okay. So during the pandemic, we have been trying to increase efficiency as much as we can. At this time I would say, you know, we would, you know, accept your application we would begin the initial review and the quality insurance review.

And depending on, you know, the state of your documentation and how many applications are in-house at the same time and whether or not my NIOSH overworked staff has needed leave we would say, you know, like, we would like to take two to three weeks.

Again it's subject to change depending on how many come in the door at the same time -- will also control that. At that point, we would be looking to if you are domestic manufacturer we would be discussing how to do a virtual initial site qualification visit we would be preparing to do the testing that NIOSH requires and we would be reaching back to schedule those things.

How things proceed after the virtual site qualification visit is completed is somewhat in the hands of the applicant. We do identify observations minor a nonconformances and major nonconformances. An observation gets zero

points, a minor just one and a major just three.

So let's say that you have one site where you're - you're doing your design development and manufacturing and you're really we would, you know, do our inspections and if you receive zero to one point you would - you can achieve your approval. If you receive, you know, two to 11 it would be provisionally you have some corrective action and if you have more than 12 points it is considered nonconforming.

So what happens depends a lot on what those corrective actions are and how long they take you to address them. So it's really in your hands at that point and, you know, (Karen) if things are good you can issue the approval in probably in a week or two of having, you know, gotten through everything based on the virtual visit and all the documentation. Heidi do you - actually do you have anything to add?

Heidi Sewchok: No that was it you did the overview and really do ask if you have corrective actions on your site qualification that you don't rush through them because that doesn't do anyone any favors.

(Colleen): Especially, for example ,if training of your employees is involved. That takes time and it's worth the time.

(Karen Milroy): Okay. That was very helpful. Thank you.

(Colleen): You're welcome.

Coordinator: Thank you once again as a friendly reminder to ask a question please press Star 1 and record your first and last name. Next question is from (Michael Sterling). Your line is open.

(Michael Sterling): Hi, hello. So I had a question regarding the exemptions from review under the MOC - MOU I should say I believe that someone said designs which are different such as novel head suspensions and you mentioned ear loops. Can

you elaborate on why ear loops has not been cleared before or that's the case?

Suzanne Schwartz: Hi this is Suzanne Schwartz...

(Colleen): Hi this is...

Suzanne Schwartz: ...I'm going to address this to NIOSH rather than FDA.

(Colleen): Hi this is (Colleen). So we actually do, in our regulation have a requirement for the head suspension, and also OSHA requires that tight fitting facepieces such as filtering facepiece respirators be tested on the individual user prior to assigning that respirator to protect them.

So particularly during the pandemic, we feel that we must focus on those devices that we know can achieve the fit needed and the protect - provide the protection expected. So we are really focusing on traditional head suspensions at this time.

(Michael Sterling): Okay. But ultimately isn't the criteria that something fits not how it fits?

(Colleen): Actually I'd have to provide you the reference from the regulation for the head suspension. I'd be happy to follow up with an e-mail to you.

(Michael Sterling): Sure, sure. Appreciate that.

(Colleen): Next question, please.

Coordinator: Thank you. Our next question I do apologize I was not able to discern the name if you already press Star 1 your line is now open.

(Lloyd Soong Hi this is (Lord Sunghia). So can you hear me?

(Colleen): Yes (Lord) we can hear you.

Suzanne Schwartz: Yes we can.

(Lloyd Soong): Hi. Hi. Thank you very much. Appreciate it. Sorry I - maybe I'll speak a little too fast. I just have - have a question for you. Either we have the approval which is for general public use and that is under the NZJ and it used to be on the website of FDA because we need to (unintelligible) it has the approval for general public use surgical N95 respirator for use during public health medical emergencies and I think just during the pandemic.

I think sometime in March or April that would actually have thickened up and I had some clients who actually have stocks of this product and suddenly they're asking me so is this now surgical or is this N95 or is it for public use, you know, and so I was just trying to figure how to explain this to them because I don't see that the product listed.

But it is both NIOSH N95 and FDA approved. So I don't how to categorize this with them now even though I know is used for general public use but there is no more category in as far as I can see on the FDA website. So my question is that where is this respirator now fitting into the category?

(Liz Claverie): (Unintelligible) may I take it.

(Colleen): Yes go ahead.

(Liz Cleverly): Sure. Thank you so much. Hi (Lord) how you doing. This is (Liz Claverie).

(Lord Sunghia): I'm good what about you.

(Liz Claverie): Hi. I'm fine. Thank you.

(Liz Claverie): So (Lord) the pro code still exist the product still exists and if you have any further direct questions about that particular pro code and your particular conditions that we worked with you on you have my contact info feel free to

send me an e-mail and I'll try to work with you directly as relate to those particular submissions that have been cleared by the agency.

(Lord Sunghia): Okay. Okay, I'll do that. Thank you very much. I have a - sorry go ahead.

Heidi Sewchok: If you also have a NIOSH approval your respirator will also appear on the NIOSH certified equipment list.

(Lloyd Soong): Yes it's already on the list on NIOSH just that like I mentioned before it's like the surgical but it's an N95 but it's very unique in the sense that it is what we did see that this and just so that there's no protest required but then it's not for occupational use or for public use. But now under this category, it doesn't exist anymore. So was just wondering where it falls into. So but I like what (Liz) said I would probably like (unintelligible).

Heidi Sewchok: Okay thank you.

Cynthia Chang: Hi this is Cynthia Chang from FDA, just to clarify there is a separate regulation. That product code NZJ is under the respirator for use by the general public and that is separate than the surgical N95 category that we're talking about today.

So that is a separate intended use and I can understand it can be confusing because there are obviously similarities but that is a separate device classification and that's under regulation 21 CFR 880.6260. Thank you.

Coordinator: Thank you. And our last question is from (Jordyn Ross). Your line is open

(Jordyn Ross): Hello. I have a question. It's a hypothetical question dealing with this (unintelligible) and product sampling. So if an entity was to purchase a machine from China that would later be will be subsidized for domestic production. Could we manufacture the first sample in China and submit it as the product example for NIOSH reviewer approval.

So in short so the manufacturers submit a sample for NIOSH approval that was manufactured in a foreign country but the machinery that will be used for domestic production would be the same.

(Colleen): Hi this is (Colleen) I'm happy to answer. All right go ahead, Heidi.

Heidi Sewchok: Go ahead.

(Colleen): So as I said previously we expect it's not just about, you know, making it it's about how you make it and your quality control while you're making it so the samples that are sent to us must be made under your quality assurance system.

So in this case you're meeting your designing and developing and producing a device to meet the NIOSH N95 performance requirements and the additional FDA requirements for biocompatibility for resistance and flammability. So we expect those samples to be made under your system that you are documenting to us. Not made in China and then sent to us and everything passes and we're good and then you go on and make it. Okay

(Jordyn Ross): Okay so just to clarify.

Heidi Sewchok: We expect to be able to see evidence of all of those activities that (Colleen) just mentioned when we view your site qualification.

(Jordyn Ross): Correct so just so I completely understand if I create a quality system and have that implemented, you know, with a partner in China to do the first sample because basically the reason I'm asking is, you know, to streamline the process and not delay for shipment because if the machine is in China I don't want to have to delay NIOSH approval processes if not necessary. So...

(Colleen): Are there companies have already been in this situation and they have respected the integrity of the process and they've gotten the equipment and they've run it, it's not as easy as you think.

You have to run it, you have to make sure you're doing an incoming inspection, you have to, you know, make sure you're tracking the things that you say you're going to check in order to produce that, you know, reliability that the NIOSH approved respirator users expect. And then you would say okay, I'm ready and you would submit to us and it's good to be in contact with us when you're getting into the process.

(Jordyn Ross): Correct. So my last follow up on that would be, you know, if it turns out that we wanted to have production entirely in China would you do a site qualification test in China? Or is it only limited to domestic production?

Heidi Sewchok: We would do a site qualification but you would have to consider our prioritization notice and take that into consideration with your timing plans.

Suzanne Schwartz: So this is Suzanne Schwartz in FDA I think that further discussion particular to your individual case may be best handled off-line directly with Colleen and her team. I see that we're at 1:00 pm and I want to take this time to first of all say, you know, a huge thank you to (Caileen) - Colleen. excuse me, and Heidi for an extremely comprehensive and informative presentation with respect to the updated surgical respirator guidance and asking so many questions with regard to the process that's been put in place. And we want to really recognize all of the subject matter experts who've been with us today to support the Q and A session.

Thank you to everybody who's tuned in. The next session is scheduled to take place in two weeks on Tuesday, September 15 at noon Eastern. The announcement of the topic will be forthcoming. Please don't hesitate to share with us 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, Suzanne. This is Irene Aihie and we do appreciate your participation and thoughtful questions today. Today's presentation and transcript will be made available on the CDRH's web page at www.FDA.gov /training/CDRHlearn by Wednesday, September 9.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation, and as always, we do appreciate your feedback. Following the conclusion of today's live webinar, please complete a short 13 question survey about your CDRH FDA 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: Thank you for everyone's participation. This now concludes today's conference. All lines may disconnect at this time.

END