

FDA PPE Webinar Series

Moderator: Irene Aihie
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12:00 pm ET

Coordinator: Good morning and thank you all for holding. Your lines have been placed on a listen-only mode until the question-and-answer portion. At that time if you would like to ask a question, please press Star 1, and I would like to remind all parties the call is now being recorded. If you have any objections, please disconnect at this time. And I would now like to turn the call over to 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 Communication and Education. Welcome to the 13th CDRH webinar in our PPE webinar series. During today's webinar, the FDA will share information about the enforcement policies of bioburden reduction systems using dry heat to support single user reuse of certain filtering face (unintelligible) respirators during the COVID-19 public health emergency.

Representatives from the FDA and the occupational safety and health administration will be available to answer your questions. Following a few opening remarks, we will open the lines for your questions related to the information provided during today's discussion.

Now, I give you Dr. Cynthia Chang from CDRH's Office of Surgical and Infection Control Devices.

(Cynthia Chang): Good afternoon, everyone and welcome. As Irene mentioned, this is the 13th session in our webinar series on personal protective equipment or PPE. In prior webinars, we have discussed the regulation of a variety of devices including PPE, facemasks and protective barrier enclosures during the COVID-19 pandemic.

Today Dr. Devashish Shrivistava a biomedical engineer in our Office of Surgical and Infection Control Devices will provide an overview of our guidance which covers our enforcement policy for bioburden reduction systems using dry heat to support single user reuse of certain filtering facepiece respirators during the COVID-19 public health emergency.

After his presentation, we will turn to the operator for live Q&A. With that, I'm pleased to introduce Dr. Shrivistava.

Dr. (Devashish Shrivastava): Thank you. Hello and welcome to today's FDA webinar. I am (Devashish Shrivastava) of CDRH's Office of Health Technology for Surgical and Infection Control Devices. Today's discussion will focus of the topic of the enforcement policy for bioburden reduction systems using dry heat to support single user reuse of certain filtering facepiece respirators during the COVID-19 pandemic.

FDA has enacted this enforcement policy to help address the urgent public health concerns caused by shortages of filtering facepiece respirators or FFRs used as personal protective equipment. Per this policy, FDA does not intend to object to the use of dry heat systems, to reduce bioburden and support single user reuse of compatible filtering facepiece respirators without

marketing authorization when existing CDC reuse recommendations are followed, where such devices do not create an undue risk in light of the public health emergency. FDA believes that the use of dry heat system as a bioburden reduction method to support single user reuse of compatible respirators will not create such an undue risk where the critical (cycle) parameters and labeling elements as described in the guidance are met.

Unlike (tier 1) systems authorized for FFR decontamination which achieve equal to or greater than (six log) reduction in a mycobacterium species or the most heat resistant spore and tier 2 systems which achieve equal to or greater than (six log) reduction in three nonenveloped viruses are two gram positive and two gram negative bacteria, Tier 3 bioburden reduction systems are those which achieve equal to or greater than three log reduction in a nonenveloped virus or two gram positive and two gram negative vegetative bacteria.

Please note that these systems are to be used only to supplement CDC's reuse recommendations. Additional information on the contamination and bioburden reduction could be found in our guidance titled recommendations for sponsors requesting EUAs for decontamination and bioburden reduction systems for surgical masks and respirators during the coronavirus disease public health emergency.

Filtering facepiece respirators, FFRs, that fall within the scope of this policy are those that do not have exhalation walls, do not incorporate a duckbill design and do not contain antimicrobial antiviral agents. These FFRs should either one, have been authorized under the emergency use authorization for (NIOSH) approved FFRs or two, have been authorized under the EUA for non (NIOSH) approved FFRs that are not manufactured in China or three are FDA cleared as intended for use by healthcare personnel.

Dry heat systems have only two critical parameters, temperature and time. Critical parameters for dry heat systems that are intended for bioburden reduction are consistent exposure of 70 degree C for 60 minutes or 75 degree C for 30 minutes. Please note that for these systems the chamber temperature should be monitored closely and recorded throughout the cycle to confirm accurate and even distribution of heat.

The system should have highly controlled (convective) heat transfer to avoid the risk of localized overtemperature. Further, please note that household appliances for example home ovens, pressure cookers, multicookers should not be used due to the lack of accuracy and precision in temperature control and the risk of cross contamination from mixed use.

Deviating from critical cycle parameters may result in damage to the FFR or inadequate bioburden reduction. One can note that we have prescribed only the final temperature and exposure duration. We determine these critical parameters based upon our review of publicly available data and literature. It is understood that to produce a consistent highly controlled temperature field of 70 degree C for 60 minutes or 75 degrees C for 30 minutes these systems based upon their size may take anywhere between five and 30 minutes or more before they reach the target temperature and another 10 to 30 minutes or more at the end to cool down before healthcare personnel may safely retrieve FFRs.

Also closely monitoring and recording the system temperature over time is important for these systems because this will help determine if the cycle was run for the intended duration at intended temperature or not. If not, the cycle will need to be repeated to make sure that bioburden reduction was successfully achieved. And also if the cycle failed, the failed cycle will count toward the total number of FFR (reuse).

Labeling for these systems include three parts; labeling for bioburden reduction system, handling instructions and labeling for bioburden reduce FFRs. Regarding bioburden reduction systems, labeling should be provided either by a manufacturer if manufacturing ovens for bioburden reduction of FFRs or a healthcare organization that is reprocessing ovens for bioburden reduction to convey information to help users better understand the device.

Such information, for example, should include what is bioburden reduction, the critical parameters, how to record and verify critical parameters for each cycle, compatible FFRs and that such systems should be used only to supplement CDC's reuse recommendations of FFRs.

Additionally, the labeling should advise (HCPs) to follow existing healthcare organization protocols regarding the use and reuse of FFRs.

Handling instructions should include instructions for the handling of both contaminated and bioburden reduced compatible FFRs provided by the healthcare organization to personnel managing the process. Additionally, a description of chain of custody and safeguards should be provided to (prevent) inadvertent personal exposure to contaminated FFRs and eliminate potential cross contamination (between) FFRs.

Healthcare organization should provide labeling of the compatible FFRs that have been bioburden reduced using dry heat to inform healthcare personnel or HCP of proper procedures and precautions for using bioburden reduced FFRs. For example, such labeling should state that HCP should follow CDC's reuse and extended use recommendations as appropriate. Bioburden reduced FFRs are only to be reused by single users. Respirators that have been bioburden reduced are no longer considered (NIOSH) approved until a (NIOSH)

approval holder confirms otherwise and their performance might not meet (NIOSH approved standards. In accordance with CDC recommendations, users should perform visual and tactile inspection of the respirators to verify no loss of respirator fit or function and should perform seal checks.

Labeling should also include information regarding when to discard respirators and that adverse events can be reported to Med Watch by submitting the online FDA form 3500 or by calling 1-800 FDA 1088.

Given here are a few resources that you may find helpful if you need additional information regarding the use of bioburden reduction systems. Thank you so much for your time.

(Irene Aihie): Operator, we'll now take questions.

Coordinator: Thank you. At this time if you would like to ask a question, please press Star 1 on your touchtone phone. Please ensure that your line is unmuted and please record your name when prompted so that I may introduce you to ask your question. Once again, it is Star 1 at this time. Please stand by.

Dr. (Devashish Shrivastava): As the questions are coming, there are a few things - there are a few questions that we have received before that we are going to read and answer thereof. The most common question has been what happens to my dry heat systems after current public health emergency is lifted.

The answer to that question is that the enforcement policy guidance is only in effect for the duration of the public health emergency. FDA is developing a plan for how enforcement policy will transition after the pandemic is over. The plan will be communicated but we do not have the details at this time.

Another question that we receive commonly is are FFRs that are manufactured in Hong Kong and Taiwan included in this policy. The answer to that question is that only the FFRs authorized under the two EUAs listed in the guidance and FFRs that are 510(k) cleared are included in this policy. You may check the links available with each of the FFR EUAs to find the list of the specific devices that are authorized under each EUA.

Another question that sometimes comes up regarding dry heat bioburden reduction systems is if control of humidity is important for my dry heat bioburden reduction system. And the answer to that question is no, dry heat systems only have two critical parameters; temperature and time. Therefore control of humidity is not important for a dry heat bioburden reduction system.

Irene Aihie: Thank you, (Dev). I believe we have a few questions in queue.

Coordinator: Thank you. Our first question is from (Nicky Panish). Your line is open.

(Nicky Panish): Hi, my question is, did you say that the bioburden reduction system could also be used for surgical masks in addition to N-95.

(Cynthia Chang): Hi, this is (Cynthia Chang). So thank you for the question. The question is whether the enforcement policy applies to surgical masks or just N95 masks with respect to what the bioburden reduction system may be used with. And I will turn that over to Dr. (Shrivastava) to address.

Dr. (Devashish Shrivastava): The answer to your question is that per this policy FDA cleared FFRs are included in this policy if they're intended for use by healthcare personnel.

(Cynthia Chang): Right, and this is (Cynthia Chang), the enforcement policy does not cover surgical masks. It only covers the listed compatible FFRs as described in the guidance. Thank you.

Irene Aihie: We'll take our next question.

Coordinator: Our next question is from (Caroline Johnson). Your line is open.

(Caroline Johnson):Hi, thank you for the information today. So for the decontamination system, I noticed in the updated or reissued EUAs there are a number of cycles identified as a maximum number of cycles. Is there a maximum number of cycles for bioburden reduction using dry heat? Is there any guidance on that?

(Cynthia Chang): This is (Cynthia Chang). So thanks for the question which is about whether there's any guidance on the number of cycles that may be used for bioburden reduction. And I will turn that over to Dr. (Shrivastava) to address that question.

Dr. (Devashish Shrivastava): Hi, the dry heat systems have to be used in accordance with CDC's reuse recommendation. And as per their recommendation as of now, that number is five. So you cannot use, you cannot bioburden reduce your FFR for more than five times. And again it is coming from CDC.

Coordinator: Once again, if would like to ask a question, please press Star 1 on your touchtone phone. Please be sure to record your name when prompted to be introduced.

(Cynthia Chang): This is (Cynthia Chang) just to follow up on that previous question. Let me turn also to our colleagues from OSHA to see if they have any comments to

add regarding the number of reuses or donnings that are recommended by CDC.

(Andy Levinson): This is (Andy Levinson) with OSHA and the short answer is no, our general recommendations are whatever is acceptable to the guidance that's been issued. The one thing that I did want to emphasize is that the decontamination and reuse of filtering facepiece respirators is only acceptable under crisis mode operations and should not be the normal mode of operations. Employers are required to try and provide normal, fresh, new filtering facepiece respirators and/or try and use (elastomerics) or (PAPRs) and that the crisis mode operations are only allowable when there is no other alternative available.

(Dionne Williams): This is (Dionne Williams) also from OSHA. I would just add one thing to what (Andy) just said is that if you are bioburden reducing FFRs, you do still need to inspect those FFRs for reuse. The CDC guidance does permit up to five times but that's only if those respirators are in good condition. So inspection is necessary. If let's say reuse fewer than five times would render a respirator defective; if it is visibly defective, that respirator would not be allowed to be reused up to five times.

(Cynthia Chang): This is (Cynthia Chang). Thank you very much to our OSHA colleagues for providing those comments.

Coordinator: We have no further questions at this time. So I will turn the conference back over to our host, Ms. Irene Aihie.

Irene Aihie: Thank you. Before I give closing remarks, (Cynthia), do you have any closing remarks for the group?

(Cynthia Chang): We very much appreciate everyone tuning in today to listen to our presentation on this important enforcement policy. Thank you.

Irene Aihie: Thank you. Again, this is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn webpage at www.fda.gov/training/cdrhlearn by Wednesday, February 10. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's webinar, please complete a short, 13-question survey about your FDA, CDRH webinar experience. The survey can be found at www.FDA.gov/cdrhwebinar immediately following the conclusion of today's (live) webinar.

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

Coordinator: This does conclude today's conference call. We thank you for participating. You may now disconnect and have a great rest of your day.

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