Official websites use .gov A .gov website belongs to an official government organization in the United States. Secure .gov websites use HTTPS A lock ( ) or https:// means you've safely connected to the .gov website. Share sensitive information only on official, secure websites. This notice has been superseded. For the latest NIOSH guidance on this topic, please see the updated notice: https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html NIOSH CA 2018-1010

November 2018 Beginning December 1, 2018, the National Institute for Occupational Safety and Health (NIOSH) will accept applications to implement the coordinated regulatory process to exempt a subset of filtering facepiece respirators (FFRs) from Food & Drug Administration (FDA) premarket notification requirements. The N95 FFRs and data provided by the applicant must demonstrate: Any device approved under this Guidance will be labeled with a protection of “N95-F.” This protection indicates that the NIOSH-approved device meets the intended flammability, fluid resistance, and biocompatibility requirements and can be used in healthcare settings. Monthly NIOSH Certified Equipment List updates will include searchable information about approved N95-F respirators. Additionally, N95-F respirator approval labels will have a new caution and limitation “WW” defined as: This respirator conforms to recognized standards for biocompatibility, flammability, and fluid resistance. The approval label is no longer required to have the caution and limitation “P” – NIOSH does not evaluate respirators for use as surgical masks. Four specific situations are noted: If an applicant has never previously submitted any type of respiratory protective device for NIOSH approval, the applicant must first apply to NIOSH for a three-character Manufacturer’s Code by completing the Prospective Approval Holder Form and returning it to the NIOSH NPPTL Records Room. Obtain this form by contacting the NIOSH NPPTL Records Room at recordsroom@cdc.gov. After obtaining the Manufacturer’s Code, the manufacturer seeking approval for an N95-F must follow this Guidance. The applicant will use the

NIOSH Standard Application Procedure (SAP) to complete the Standard Application Form. When completing the reason for application section (C.9), the applicant will indicate they are using the consolidated process and seeking approval within the terms of the FDA Final Order and the MOU. The approval label provided as part of the NIOSH application must include the new caution and limitation “WW” defined as: This respirator conforms to recognized standards for biocompatibility, flammability, and fluid resistance. Applicants are required to provide documentation to NIOSH to indicate conformance to the FDA thresholds for flammability, fluid resistance, and biocompatibility. All data must be received in electronic formats as indicated in the NIOSH SAP. While NIOSH completes testing of hardware in accordance with 42 CFR 84 Subpart K, NIOSH is not conducting testing to verify the flammability, fluid resistance, or biocompatibility performance of the respirator as part of the N95-F approval process. During the NIOSH document review process, NIOSH will review flammability, fluid resistance, and biocompatibility test data and results provided by the applicant and in accordance with the FDA Threshold Criteria. In accordance with the MOU, N95-F Approval Holders are required to fulfill the general control provisions, under section 510 of the FD&C Act, including annual registration and listing obligations. Claims exceeding the threshold criteria defined in the MOU will result in a denied application for N95-F approval (MOU Appendix, Section 2). A manufacturer making such claims and seeking approval must apply using the current, pre-MOU, process for approval by NIOSH, as an N95 FFR, and clearance by the FDA, with finalization of the labeling by NIOSH. The FDA will continue to be responsible for the review of 510(k) submissions for N95 FFRs regulated under 21 CFR 878.4040 that exceed the conditions and limitations of exemption outlined within the Final Order and ensuring manufacturers comply with applicable regulations. Note: Tuberculosis protection claims in accordance with CDC Guidance are allowed. Applicants are reminded to consider FDA recommendations for labeling medical products to inform users that the product is not made with natural

rubber latex. NIOSH is developing a methodology for conducting product audit evaluations of NIOSH-approved N95-F FFRs. These product audit evaluations will include NIOSH assessment of the flammability and fluid resistance performance. FDA Final Order

FDA Postmarket Requirements (Devices)

Approval of Respiratory Protective Devices, 42 C.F.R, Part 84

MOU 225-18-006 (also included below) Reference: MEMORANDUM OF UNDERSTANDING (MOU) 225-18-006), November 2017 This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA), acting through its Center for Devices and Radiological Health (CDRH), and the Centers for Disease Control and Prevention (CDC), acting through its National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL) (herein referred to as “the Agencies”), provides a framework for coordination and collaboration between the Agencies relating to their regulation of Surgical N95 Respirators and N95 Filtering Facepiece Respirators (FFRs)1 used in healthcare settings (herein collectively referred to as “N95s”).1 A coordinated process will help to ensure that the various regulatory activities of each agency related to N95s are streamlined and harmonized when possible. The intent of this MOU is to help reduce conflicting and duplicative premarket processes for these devices so that stakeholders can easily and seamlessly discern what steps must be taken to satisfy the applicable regulatory requirements. Specifically, this MOU (1) describes the mechanisms by which specific information pertaining to N95s may be exchanged between the two Agencies and (2) provides a framework for efficient and coordinated regulatory oversight of N95s intended for use in healthcare settings. Definitions of specific terms used in this MOU are provided in this section. Also, please note that the respirators described in this section and throughout this MOU are designed to be used in the context of a comprehensive respiratory protection program as required by the Occupational Safety and Health Administration

(OSHA) in 29 CFR 1910.134. Applicant: An individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval [from NIOSH] for such respirator.2 Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: Hazardous Atmosphere: Any atmosphere containing a toxic or disease producing gas, vapor, dust, fume, mist, or pesticide, either immediately or not immediately dangerous to life or health; or any oxygen-deficient atmosphere.4 Healthcare Personnel (HCP): All persons, paid and unpaid, working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP include, but are not limited to, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual personnel, home healthcare personnel, and persons not directly involved in patient care (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, chaplains, and volunteers) but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.5 Healthcare Settings: Healthcare settings include, but are not limited to, acute-care hospitals; long-term care facilities, such as nursing homes and skilled nursing facilities; physicians’ offices; urgent-care centers, outpatient clinics; and home healthcare. Examples of settings that are not included in this definition are schools and worksites. However, elements of this MOU may be applicable to specific sites within non-healthcare settings where care is routinely delivered (e.g., a medical clinic embedded within a workplace or school)). Labeler: A “labeler” is any person who causes a label to be applied to a device, or who causes the label of a device to be replaced or modified, with the intent that the device will be commercially distributed

without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.7 Labeling: As defined in section 201(m) of the FD&C Act. N95 Filtering Facepiece Respirator (FFR): Single-use, disposable half-mask respiratory protective device (RPD) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH). N95s: Includes N95 Filtering Facepiece Respirator (FFR) used in healthcare settings and Surgical N95 Respirator. NIOSH Approval: Approval means a certificate or formal document issued by NIOSH stating that an individual respirator or combination of respirators has met the minimum requirements of 42 CFR Part 84 and that the applicant is authorized to use and attach an approval label to any respirator, respirator container, or instruction card for any respirator manufactured or assembled in conformance with the plans and specifications upon which the approval was based, as evidence of such approval. Particulate Material: Solid or liquid particles found in the air. These particles may include dust, dirt, soot, smoke, and drops of liquid, and airborne particles transmitted to and from HCP and patients. Respiratory Protective Device (RPD): Any device designed to protect the user's respiratory tract against the inhalation of a hazardous atmosphere.8 Surgical N95 Respirator: Single-use, disposable respiratory protective device (RPD) used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).9 FDA and NIOSH are sister Agencies within the Department of Health and Human Services (HHS). Both Agencies' missions

include protecting the public health. Both Agencies are authorized to regulate certain RPDs, but have different statutory authorities and responsibilities. The distinctions between NIOSH and FDA regulation of N95s may create confusion among stakeholders. The collaboration outlined below, which is intended to streamline regulatory oversight of N95s used in healthcare settings, is expected to help ensure the availability of safe and effective products, particularly during times of increased demand. The Agencies may update this MOU to include other RPDs utilized within the healthcare setting at a future date. However, note that any updates to the MOU will not automatically revise the conditions or limitations of exemption from 510(k). We note that the MOU is drafted on the assumption that FDA has issued a notice in the Federal Register exempting certain N95s from 510(k) review (subject to applicable conditions and limitations of exemption, such as 21 CFR 878.9 and 21 CFR 878.4040(b)(1)). Generally, 21 CFR 878.4040(b)(1) exempts those N95s that (1) are determined not to exceed the threshold evaluation criteria and (2) have met the approval criteria and have NIOSH approval under its regulation. If such a notice is not finalized this MOU would not become effective (see section IX) or may need to be amended before becoming effective. a. FDA The FD&C Act grants FDA authority to regulate devices, as defined in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). FDA classifies devices into one of three regulatory classes – class I, II, or III – based on the level of control necessary to ensure the safety and effectiveness of the device. Class I devices are subject to the fewest regulatory controls and class III devices are subject to the most regulatory controls. Generally, class II devices must receive premarket clearance from FDA under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) before they can be legally marketed.10 FDA provides premarket clearance for devices that are “substantially equivalent”—as the term is defined in section 513(i)(1)(A) of the FD&C Act (21 U.S.C. 360c(i)(1)(A))—to a predicate device. In certain circumstances, FDA can exempt class II devices from this 510(k) requirement (see section 510(m) of the FD&C Act (21 U.S.C.

360(m))). N95s are regulated by the FDA as class II devices under 21 CFR 878.4040 (FDA product code MSH). As of the effective date of this MOU (see section IX), N95s are exempt from 510(k) requirements (subject to applicable conditions and limitations to the exemption, such as those in 21 CFR 878.9 and 21 CFR 878.4040(b)(1)). Generally, 21 CFR 878.4040(b)(1) exempts N95s if (1) they are determined not to exceed the threshold evaluation criteria and (2) have met the approval criteria and have NIOSH approval. b. NIOSH NIOSH is responsible for approval of RPDs intended for occupational use. The authority is granted to NIOSH in accordance with standards established in 42 CFR Part 84. NIOSH also addresses quality assurance requirements for the manufacturing of respiratory protective equipment. Enforcement agencies, such as OSHA, require employers to provide NIOSH-approved respirators. In addition, private sector certification scheme owners such as the National Fire Protection Association use the NIOSH approval as the basis for their certification. This MOU applies to N95s used in healthcare settings, which protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material.11 Future iterations of this MOU may extend this scope to other RPDs utilized in a healthcare setting based on concurrence between the Agencies. However, note that any updates to the MOU will not revise the conditions or limitations to the exemption for 510(k) as identified in the Federal Register Notice. Under this MOU, the Agencies agree to the following roles and responsibilities: 1. FDA and CDC recognize and agree that information exchanged under this MOU that contains any of the following types of information must be protected from unauthorized use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C.

1905)), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191), Section 319L(e) of the PHS Act (42 U.S.C. 247d-7e(e)), and disclosure restrictions subject to 41 U.S.C. 2101-2107 (Procurement Integrity Act) and 48 CFR 3.104 (Federal Acquisition Regulation). 2. Both parties will establish safeguards to ensure that any nonpublic information shared under this MOU is protected from unauthorized disclosure or use. Those safeguards should include the marking of any confidential materials as “confidential” prior to disclosure to the other party or the use of encryption technologies when appropriate. Information consisting of confidential commercial information or trade secrets may be shared pursuant to the procedures set forth in the Memorandum of Understanding Between FDA and CDC, which describes information sharing procedures between FDA and CDC (FDA MOU No. 225-24-0017, available at http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm402130.htm). 3. Each agency agrees to promptly notify the other of any actual or suspected unauthorized disclosure of information shared under this MOU. 4. If records provided by either party under this agreement are the subject of a FOIA request submitted to the party that received the records, that party will refer the FOIA request and relevant records to the party that provided the records for processing. If the FOIA request seeks both parties’ records or if the request is for records created by one party that incorporates information provided by the other party, in accordance with the HHS FOIA regulations at 45 CFR pt. 5, the party receiving the FOIA request will forward all such requests to the respective FOIA offices for disposition. This MOU does not affect fees assessed by NIOSH and FDA in alignment with their current fee structure. N95s that are exempt from 510(k) requirements are not subject to the medical device user fees associated with submission of a 510(k) (i.e., fees under section 738(a)(2)(A)(viii) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(viii))). Director,

National Personal Protective Technology Laboratory (NPPTL)

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Pittsburgh, PA Director, Emergency Preparedness/Operations and Medical Countermeasures

Center for Devices and Radiological Health

Food and Drug Administration

Silver Spring, MD 1. Review Processes for N95s: NIOSH and FDA review processes for N95s consist of the following steps (also see Figure 1): NIOSH Approval Review. NIOSH will perform its approval review of these N95s using the mutually agreed upon approval criteria (see Appendix Section 3 for specific criteria) and share information from this review with FDA such that it can be considered in FDA's 510(k) review. Figure 1. N95 Review Processes Flowchart * NIOSH makes a recommendation regarding whether an applicant's device exceeds the threshold evaluation criteria, this recommendation does not change any requirements of a device manufacturer under the FD&C Act. This includes general controls under the FD&C Act and the requirement for manufacturers to assess whether their device exceeds the conditions and limitations of exemption as identified in 21 CFR 878.4040(b)(1) and 878.9. **Refer to Appendix Section 2 for threshold evaluation criteria 2. Threshold Evaluation Criteria: An N95 EXCEEDS the threshold evaluation criteria (and thus would likely not be exempt from 510(k) requirements even if subsequently approved by NIOSH), if: 3. Approval Criteria: NIOSH will assess the performance of the N95 with respect to differential pressure, particulate filtration efficiency (PFE), exhalation valve leakage, biocompatibility, flammability, and fluid resistance. The evaluation of flammability, fluid resistance, and biocompatibility on the final finished N95 will be new assessments for NIOSH; they have historically been a part of FDA's premarket evaluation only. The mutually agreed upon approval criteria are described in greater detail below. An N95 intended to be used in healthcare settings

will be evaluated for the following approval criteria: Approved and Accepted CDC/NIOSH

Maryann D’Alessandro, Ph.D

Director

National Personal Protective Technology Laboratory

November 2017 Approved and Accepted FDA

Jeffrey Shuren, M.D., J.D

Director

Center for Devices and Radiological Health

November 2017 Interim guidance regarding applications for NIOSH Approval of Filtering Facepiece Respirators in accordance with the Food and Drug Administration (FDA) Final Order published May 17, 2018, and FDA/NIOSH MOU 225-18-006, dated November 2017 [PDF – 359 KB]

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