

*clinem/dgad484.*

2. Snyder PJ, Bhasin S, Cunningham GR, Matsumoto AM, Stephens-Shields AJ, Cauley JA, et al., 2016, "Effects of Testosterone Treatment in Older Men," *N Engl J Med*, 374(7):611–624. Available at <https://doi.org/10.1056/nejmoa1506119>.

(Authority: 21 U.S.C. 355.)

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2025–D–7121]

**Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators." This draft guidance document provides a proposed compliance policy for and information about respirators approved by the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) in accordance with 42 CFR part 84, specifically: surgical N95 respirators and N95 filtering facepiece respirators (FFRs) classified under 21 CFR 878.4040; other NIOSH approved, non-surgical respirators including powered air-purifying respirators (PAPRs), non-powered, air-purifying particulate FFRs, and reusable respirators (e.g., elastomeric half and full facepiece respirators); and FFRs for use by the general public in public health medical emergencies classified under 21 CFR 880.6260. These devices are collectively referred to in the guidance and this notice as "certain FFRs and reusable respirators." This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by June 22, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA–2025–D–7121 for "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or between 9 a.m. and 4 p.m., Monday through Friday, at the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Enforcement Policy for Premarket and Other Requirements for Certain NIOSH Approved Respirators" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive

label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6353.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA has a long history of coordinating with NIOSH to help ensure that respirators used for medical purposes are safe, effective, and available. All the devices that are within scope of this guidance document are also subject to approval by NIOSH in accordance with 42 CFR part 84.

Since 1988, surgical N95 respirators that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material generally have been classified as class II devices under 21 CFR 878.4040. Likewise, N95 FFRs used in healthcare settings during other procedures, including dental, isolation, and other medical procedures, to protect both the patient and healthcare personnel, are also generally classified as class II devices under 21 CFR 878.4040. In November 2017, FDA entered into a Memorandum of Understanding (MOU) with NIOSH, which outlines an agreement between the agencies conditioned on certain surgical N95 respirators and N95 FFRs becoming exempt from premarket notification requirements under section 510(k) of the FD&C Act. The MOU became effective on May 17, 2018, when FDA issued a final order exempting from 510(k) requirements certain surgical N95 respirators and N95 FFRs (product code MSH), subject to certain conditions and limitations.

FDA considers other types of non-surgical respirators, including: PAPRs, non-powered air-purifying particulate FFRs (e.g., N95, N99 FFRs), and reusable respirators (e.g., elastomeric half and full facepiece respirators), that are NIOSH Approved and intended to prevent wearer exposure to pathogenic biological airborne particulates and used in healthcare settings, to be

postamendments devices. A postamendments device for which FDA has not issued a classification order (or reclassification order under section 513(f)(3) of the FD&C Act) is referred to as a “not-classified device,” and is one for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application. In 2020, FDA addressed its policy regarding not-classified, NIOSH Approved FFRs and reusable respirators when it took a number of actions to help address the COVID–19 public health emergency, including issuing emergency use authorizations (EUA) for such devices with a medical purpose. On March 2, 2020, FDA issued an EUA authorizing NIOSH Approved FFRs to be distributed to healthcare personnel for use in healthcare settings intended to prevent wearer exposure to pathogenic biological airborne particulates. On March 11, 2020, FDA clarified that such respirators are devices because they are intended for a medical use, i.e., to mitigate further transmission of COVID–19.

In 2007, FDA issued a final rule that classified FFRs for use by the general public in public health emergencies under 21 CFR 880.6260 as class II devices. In issuing the classification regulation for this type of device, FDA also issued a special control requiring that, among other things, this device type be certified by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95.

FDA is proposing the compliance policy described in the draft guidance for certain FFRs and reusable respirators based on NIOSH’s regulatory oversight of these devices, including the performance characteristics of these devices, and FDA’s review of its postmarket data. These devices may provide a public health benefit in accordance with current CDC respiratory virus prevention recommendations. This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices.

This draft guidance is being issued consistent with FDA’s good guidance

practices regulation (21 CFR 10.115). This draft guidance, once finalized, will represent the current thinking of FDA on “Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007063 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910–0120
800, 801, and 830 .....	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
803 .....	Medical Device Reporting .....	0910–0437
806 .....	Medical Devices; Reports of Corrections and Removals .....	0910–0359
807, subparts A through D .....	Medical Device Registration and Listing .....	0910–0625
814, subparts A through E .....	Premarket approval .....	0910–0231

21 CFR part; guidance; or FDA form	Topic	OMB control No.
860, subpart D ..... "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	De Novo classification process ..... Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910-0844 0910-0756
820 .....	Current Good Manufacturing Practice (CGMP); Quality Management Systems (QMSR) Regulation.	0910-0073
"Emergency Use Authorization of Medical Products and Related Authorities" and section 564 of the FD&C Act.	Emergency Use Authorization .....	0910-0595

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Network Development Planning Program Performance Improvement and Measurement System**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than May 20, 2026.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at

[paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-3983.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Rural Health Network Development Planning Program Performance Improvement and Measurement System, OMB No. 0915-0384—Revision.

*Abstract:* HRSA administers the Rural Health Network Development Planning Program (Network Planning Program), which is authorized under 42 U.S.C. 254c(f), 330A(f) of the Public Health Service Act. The purpose of the Network Planning Program is to promote the planning and development of integrated health care networks to address the following legislative aims: (1) achieve efficiencies; (2) expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and (3) strengthen the rural health care system as a whole. The Network Planning Program supports 1 year of planning and brings together key parts of a rural health care delivery system, particularly those entities that may not have collaborated in the past, to establish and/or improve local capacity to strengthen rural community health interventions and enhance care coordination. HRSA currently collects information about the Network Planning Program grants using an OMB-approved set of performance measures and seeks to revise that approved collection. The proposed changes are a result of keeping this instrument relevant and responsive to the Network Planning Program's needs and to improve clarity and ease of reporting for respondents.

A 60-day notice published in the **Federal Register** on February 9, 2026, vol. 91, No. 26; pp. 5773-5774. There were no public comments.

*Need and Proposed Use of the Information:* HRSA developed performance measures to provide data on the Network Planning Program and to enable HRSA to provide aggregate program data required under the Government Performance and Results Act of 1993. Data from this information collection will help support program compliance, inform rural needs, guide the delivery of technical assistance, and

shape federal program decisions. The measures cover the principal topic areas of interest to HRSA, such as Capacity/Organizational Information and Sustainability. All measures will evaluate HRSA's progress toward achieving its Network Planning Program goals.

The proposed collection will reduce the total number of measures from 24 to 15. The following sections will be removed: Network Infrastructure, Network Collaboration, and Network Assessment. In the proposed collection, grantees instead complete two sections titled "Capacity/Organizational Information" and "Sustainability." The "Capacity/Organizational Information" section will include 10 measures, and HRSA will modify the current "Sustainability" section by reducing the number of measures from 10 to 5 measures.

Although the proposed total number of measures has been reduced, there is a proposed increase in the estimated total burden hours compared to the previous ICR package. There are several contributing factors to the increase in estimated total burden. The increase in burden is to account for a new set of awardees who will be new to this data collection. The new set of awardees represent a group of organizations who are funded in the 1-year Network Planning Program. These organizations vary in data collection and reporting capacity as well as vary in the number of member organizations it must coordinate with to report this data to HRSA. The amount of time it takes to build processes to coordinate and collect data from network partners will vary. Larger networks with multiple partners across different organizations are expected to report higher burdens due to the wait time in between requests. Networks who already have established working relationships with its member organizations may already have existing processes in place to effectively collect data for this program.

*Likely Respondents:* The respondents for these measures are Rural Health Network Development Planning Program award recipients.