DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-5200
Fax: 412-386-4089

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LETTER TO ALL MANUFACTURERS

SUBJECT: Filtering Facepiece Respirator Label

The purpose of this letter is to clarify the label requirements for NIOSH-approved air-purifying filtering facepiece respirators (FFR). It addresses the certification and use markings required by NIOSH to identify certified FFR classified under Subpart K, non-powered air-purifying particulate respirators, and § 84.33 (a-g) of Title 42, *Code of Federal Regulations*, Part 84. This letter suppliments the Letter to All Manufacturers dated September 26, 1997, Subject: Clarification on Five Approval Label Issues.

NIOSH is providing this clarification because current abbreviated label markings on FFR do not provide information necessary to properly identify certified FFR. Insufficient label information, lack of a testing and certification (TC) approval number marking, and the identity of the respirator manufacturer are three areas of labeling that require clarification. Significant confusion exists as to the manufacturer of FFR and as to the specific approval covering a product. FFR appear in the marketplace in small lots or are redistributed without their original bulk packaging. NIOSH receives inquiries on FFR from users who have access to none of the packaging containing the approval number and manufacturer information.

Individual FFR labels will be required to have the following five distinctive markings on their exterior surface:

(1) Name: Approval holder/manufacturer business name, a registered trademark, or an easily understood abbreviation of the applicant/approval holder's business name as recognized by NIOSH. When applicable, the name of the entity to which the FFR has been private labeled by the approval holder may replace the approval holder business name, registered trademark, or abbreviation of the approval holder business name as recognized by NIOSH.

(2) NIOSH: Block letters for the acronym "NIOSH" or the NIOSH logo.

(3) TC-Number: NIOSH Testing and Certification approval number, e.g. TC-84A-XXXX.

(4) Filter Designation: NIOSH filter series and filter efficiency level, e.g. N95.

(5) Model Number: Applicant's designation of the respirator model number, matching part number, or compliant name that is represented by a series of numbers or alphanumeric markings, e.g. 8577 or 8577A.

A sample of a generic FFR that reflects this guidance is provided as Figure 1.

FFR that are private labeled are required to have the following statement on the packaging as a special "S" caution and limitation statement identified on the full label and located in the respirator user instructions: "Marketed by the private label company name and produced by the approval holder company name." This private label related statement does not need to appear on the exterior surface of the respirator as part of the required name marking.

In addition to the requirements identified above, manufacturers may wish to consider the following items in the development of their unique labels:

Font: All labeling information is in a legible, typeface font.

P100 Designation: NIOSH-approved P100 series of FFR are required to be magenta/purple or to be marked with a magenta/purple identifier.

Exterior Surface: The exterior surface is that surface area that is external, outward, or considered the outside surface of the respirator. The exterior layer of the head straps and exhalation valve covers are considered part of the respirator exterior surface.

Interior Surface: Interior surface is that surface opposite of the exterior surface. Applicants should consider marking it in a distinctive manner to support the user donning the respirator correctly.

Visibility: All label markings must be visible to the user when inspected prior to donning.

Lot Number: The lot number is required to be on the packaging. Applicants may add a lot number marking to the exterior surface of the respirator. The addition of a FFR production lot number on the NIOSH-approved abbreviated label is expected to assist the owner of the respirator in product inventory management while aiding NIOSH in the conduct of post-approval activities.

Orientation Marking: NIOSH has observed FFR being incorrectly worn by users. Respirator orientation markings, user instructions, and training should assist purchasers and workers in determining the proper orientation for donning. Examples of FFR labeling requirements and guidance are enclosed as Figure 1, Markings. The orientation marking design selected by the applicant must be submitted to NIOSH during the application process.

This policy is effective 60 days from the date of this letter for future approval requests. All currently approved FFR must meet this labeling requirement for new production within two years from the date of this policy letter. Re-labeling of existing inventory of FFR products available for purchase is not required. For additional information, please contact the NPPTL Policy and Standards Development Branch at (412) 386-5200.

Jonathan V. Szalajda
Chief, Policy and Standards Development Branch
National Personal Protective Technology Laboratory

Enclosure

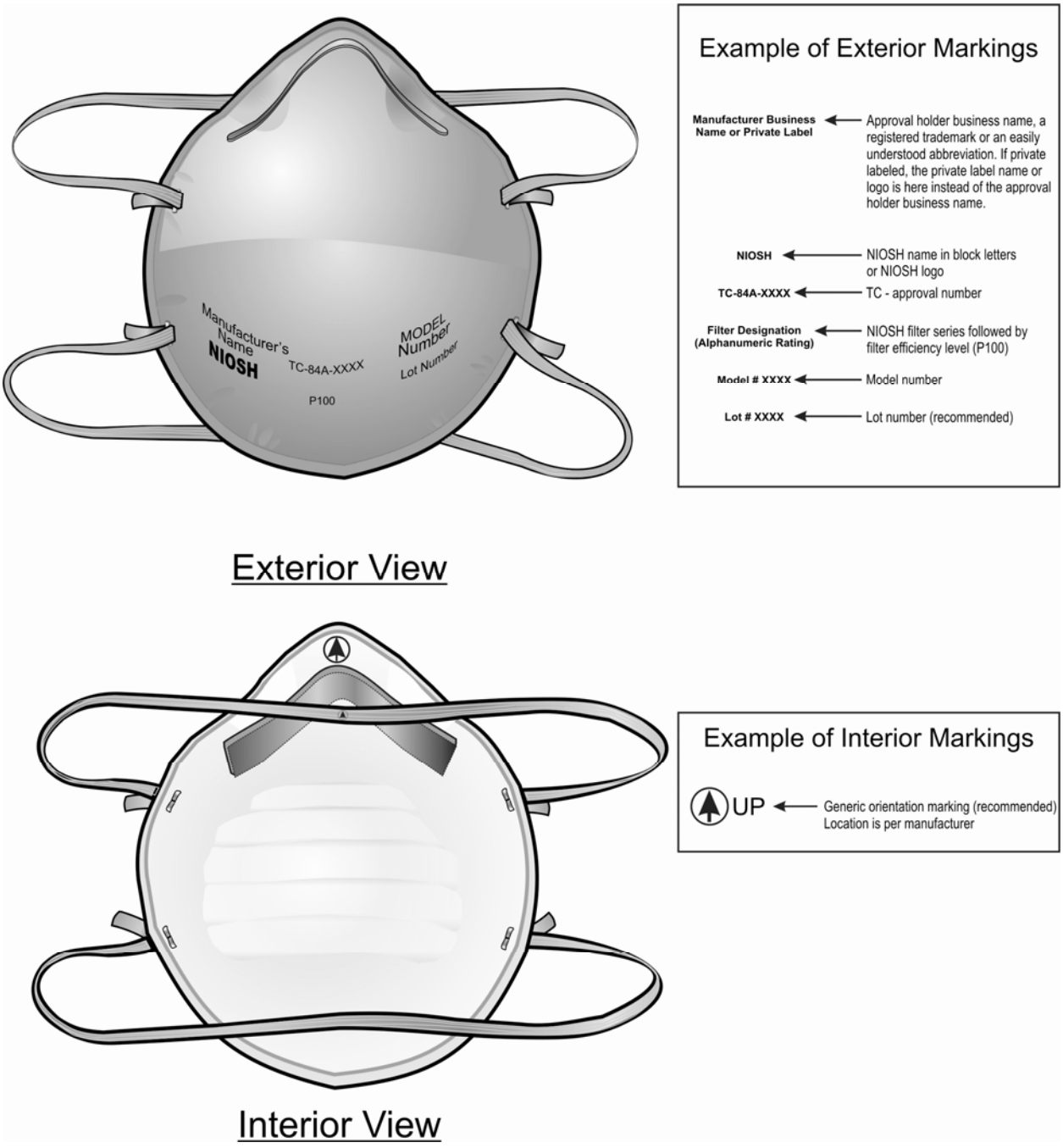

Figure 1. Markings. A NIOSH-approved filtering facepiece respirator depicting generic exterior and interior surface views and example marking guidance.