

October 6, 2006

SUBJECT: Voluntary Program for Acceptance of Applications for the Testing and Evaluation of Powered Air-Purifying Respirators (PAPR or PAPRS) for Use Against Chemical, Biological, Radiological and Nuclear (CBRN) Agents

With the ongoing concern of potential terrorist events and the need to provide the emergency responder and receiver communities with alternatives to respiratory protection as quickly as possible, the National Institute for Occupational Safety and Health (NIOSH) is instituting a voluntary approval program for Powered Air-Purifying Respirators (PAPR or PAPRS) for Use Against Chemical, Biological, Radiological and Nuclear (CBRN) Agents on an expedited basis. NIOSH will begin processing applications 30 days from the date of this notice to test and evaluate PAPRS for use against CBRN agents. This letter informs manufacturers of voluntary requirements that PAPRS must meet in order to obtain NIOSH CBRN approval. It also provides the procedures for the submission of applications for these approvals.

In April 2000, NIOSH entered into a Memorandum of Understanding with the National Institute for Standards and Technology (NIST), the Occupational Safety and Health Administration (OSHA), and the National Fire Protection Association (NFPA) to work on the development of standards for all types of counter-terrorism respiratory protective equipment. NIOSH and NIST initiated Interagency Agreements with U.S. Army Research Development and Engineering Command (RDECOM) for development of respiratory protection standards, test procedures and laboratory support. The new requirements for PAPR certification have been developed under these agreements, and are responsive to public comments NIOSH received during numerous public meetings, stakeholder meetings and to the NIOSH docket.

NIOSH initiates this voluntary approval program pursuant to Title 42, Code of Federal Regulations, 84.60(b), 84.63(c), and 84.110(c). These sections provide NIOSH with the authority to issue approvals for respirators not specifically addressed in Part 84 and to develop additional requirements that the agency determines are "necessary to establish the quality, effectiveness and safety of any respirator used as protection against hazardous atmospheres." NIOSH will issue an approval and approval labels identifying the PAPR as appropriate for use against CBRN agents.

Requirements for Approval

To be approved for use in providing protection against CBRN agents, NIOSH has determined that a PAPR must be evaluated against the criteria defined in the [Statement of Standard for Chemical, Biological, Radiological and Nuclear \(CBRN\) Powered Air- Purifying Respirator \(PAPR\)](#) dated [date of HHS signing when concept becomes the Statement of Standard](#). Test procedures used in these evaluations can be found at [NIOSH CBRN PAPR Standard Test Procedures](#).

Applications received within the next 30 days will be processed on the 30th day based on a random selection of all CBRN PAPR applications received with this 30-day time frame. Following this 30-day time frame, applications will be processed in the normal NIOSH fashion which is on a daily basis.

The applicant shall provide a sufficient number of systems as described in the [Hardware Requirements Guide](#). If the PAPR has not been previously 42CFR84 approved, the manufacturer must submit additional samples as would be done for an industrial PAPR approval (please reference the Respirator Selection Guide contained in the [Standard Application Procedures](#) for this information). Costs for the CBRN PAPR approval are contained in the [CBRN PAPR Fees](#). The [Complete list of Cautions and Limitations](#) contains a complete listing of cautions and limitations for all respirator types including CBRN PAPRS and details which cautions and limitations are appropriate for which type of respirator. The [CBRN Test Selection Guide](#) contains a complete list of applicable tests for all types of CBRN respirators.

Notification to Users and Regulatory Agencies

NIOSH will maintain and disseminate an approval list for respirators approved under this program. This list will be maintained within the NIOSH [Certified Equipment List](#).

NIOSH will also disseminate the list of approved CBRN PAPR Respirators by maintaining the list on its website, www.cdc.gov/niosh/homepage.html, and seek to have it placed on or linked to other appropriate

websites that disseminate information to the first responder community. In addition, NIOSH will supply the list to the Occupational Safety and Health Administration for dissemination to its district offices.

Respirator Identification / Labeling

In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels shall be marked with a CBRN notation and indicate the appropriate cautions and limitations as outlined in the [Complete list of Cautions and Limitations](#). The canister/label color shall be olive (Munshell notation 7.5 Y 5/6). For canisters where the color markings are achieved by labeling, the canister body may be any color.

If you need additional information, please contact the NIOSH NPPTL Technology Evaluation Branch at 412-386-4000 for certification processing questions, the NIOSH Policy and Standards Development Branch at 412-386-5200 for all other questions or E-mail NPPTL at npptl@cdc.gov.

Sincerely yours,

William A. Hoffman
Branch Chief
Policy and Standards Development Branch
National Personal Protective Technology Laboratory