

Attachment D

Procedures for Applying for CBRN SCBA Approval

Application may be made by submitting a request by e-mail to respcert@cdc.gov or by mail to:

Attn: Records Room
Technology Evaluation Branch
NIOSH
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Cochrans Mill Road, Pittsburgh, PA 15236

Each application must state that it is an application for approval of an SCBA for use against CBRN agents and contain a unique application reference number. The first three digits of this applicant-assigned reference number must be the NIOSH-assigned applicant's code. This number must also appear on each hardware sample package. The cost for processing a completed application is determined by the testing fee schedule in effect when the project is submitted. The costs are estimated to be approximately \$55,000 to \$60,000 for a new approval, with charges assessed only for those tests and evaluations performed. The Institute will advise applicants of the actual total cost of processing the application upon completion of the examinations, inspections, and tests. The applicant-assigned reference number or NIOSH-assigned task number must appear on the payment check, bank draft, or money order. These costs must be paid to the Institute as a condition of approval.

An application for approval of an SCBA for use against CBRN agents can be accompanied by an application for an extension of Part 84 approval to cover any modifications made to meet the additional CBRN requirements. Sample respirators, as needed, must be submitted to the Technology Evaluation Branch in Pittsburgh, PA for testing under the extension of approval application (number of units and shipping address as identified in the Standard Applications Procedures). Both applications (Part 84 extension and CBRN SCBA) must be sent under a single cover letter referencing both applicant-assigned reference numbers to ensure coordination of their processing. Each application for an extension of existing Part 84 approval must be submitted in accordance with the NIOSH Standard Applications Procedures.

The NIOSH-assigned task number for each application can be obtained either by requesting it in the e-mail submission or by submitting a stamped, self-addressed post card with the applicant-assigned reference number with the mailed application. NIOSH will note the assigned task number and promptly return the post card or provide an e-mail notification. Foreign manufacturers may send a completed fax form that NIOSH will fax to them with the assigned task number. Subsequent inquiries must refer to the NIOSH assigned task number (TN) or the applicant-assigned reference number.

Each application for approval of an SCBA for use against CBRN agents must include the following:

1. Documentation that NIOSH has approved the SCBA in the configuration that the applicant wishes to have tested under this program. This can be accomplished by identifying the NIOSH certification number with all applicable component parts, major subassemblies, and accessories. The application may include modifications to an existing device that will result in an extension of an existing approval.
2. An application must be submitted to the National Fire Protection Association under NFPA 1981:2007. CBRN approval will not be issued until all NFPA requirements are also met. This effort will be coordinated with NFPA and SEI.
3. Documentation that demonstrates that the applicant has quality assurance requirements in place to control the variability of parameters that affect the performance of the respirator materials and components evaluated under this program. These parameters may include material, design, and performance specifications.
4. A fee to initiate the required testing and evaluation of the extension of approval for the modified components under Part 84. No fee should be included with the application for the CBRN application. NIOSH will notify the applicant if additional payments will be required to complete the testing. NIOSH will not issue a final certificate of approval under this program until all fees are paid in full.
5. Sample respirators must be submitted to the U.S. Army Soldier and Biological Chemical Command at the following address:

Attn: Adam Seiple
US Army RDECOM
Soldier and Biological Chemical Command
Building E5604:
Aberdeen Proving Ground, MD 21010-5424

The number of tests samples submitted must be consistent with the quantities identified in the attached test procedures (Attachments B and C). For example, samples submitted for the Laboratory Respiratory Protection Level Test consist of a full facepiece with P100 filters and any needed adapters to assemble a nonpowered particulate filter configuration. A prepaid shipping label should be included if return of test materials to the applicant is requested. The apparatus used in the penetration and permeation tests will not be returned.

NIOSH may request additional documentation or test samples from a manufacturer if it determines that such documentation or samples are necessary to evaluate the application.