APR Retrofit Concept
November 15, 2004

This concept has been developed to evaluate components and identify procedures to retrofit previously deployed (field-deployed), NIOSH-approved full-facepiece, air-purifying respirators (APR) to chemical, biological, radiological, and nuclear (CBRN) approved configurations. The purpose of this program is to:

1. Test and evaluate kits used to retrofit field deployed APRs
2. Assure that retrofitted APRs comply with approved CBRN APR configurations
3. Assure the quality of the components and procedures used to retrofit previous versions of the APR establish the CBRN approved configuration

Background

In a letter dated April 4, 2003 and sent to all to all respirator manufacturers, NIOSH announced plans to begin accepting applications to test and evaluate full-facepiece, air-purifying respirators for use against CBRN agents. Some approvals have been issued and additional applications are expected to be received. Prior to the April 2003 NIOSH announcement, manufacturers and users expressed the desire and need to upgrade equipment placed in service. The CBRN APR retrofit kits should increase the number of emergency responders afforded the protection provided by the NIOSH-approved CBRN APR.

Requirements for the CBRN APR Retrofit Kit Program

1. Retrofit of field-deployed respirators to the CBRN protection must be performed by manufacturer-trained and authorized technicians, who ensure the retrofit complies with the approved CBRN-APR configuration, quality assurance and performance requirements.
2. The CBRN APR retrofit kit must, as a minimum, contain the following:
    - CBRN APR retrofit kit instructions
    - Replacement packaging, components, parts, materials, and operation instructions required to retrofit the APR's configuration to the approved CBRN configuration level
    - Registration materials for recording APR information as required by the manufacturer
    - CBRN APR retrofit approval label for the respirator facepiece
3. Retrofit kit instructions must include, as a minimum:
    - Identification of minimum technician qualifications, i.e., who can perform the retrofit and the level of manufacturer training required

- Information to identify specific respirator models that are capable of being retrofitted to the CBRN APR configuration as determined by the manufacturer
- Identification of the requirements for inspections and operational tests of the respirator prior to performing the retrofit that are required to verify that the respirator complies with manufacturer quality and performance specifications for respirators eligible to be retrofit
- Detailed procedures for replacing components, parts, and/or materials required to establish the CBRN APR configuration
- Guidance concerning the CBRN APR operating instructions and differences from industrial respirator operating instructions
- Post-retrofit inspections and tests required to verify work has been performed properly and that the CBRN APR operation is in accordance with both NIOSH and the manufacturer requirements. As a minimum, the post-retrofit inspection and test must verify leak tightness of the respirator assembly and components and exhalation resistance
- Directions for installation of the NIOSH CBRN APR retrofit approval label

The application must include the quality assurance provisions that will identify the resulting configuration and protections for each respirator updated under the CBRN APR retrofit Program. The manufacturer shall provide written evidence that the configuration of the full-facepiece is equivalent to the system that was evaluated as part of the CBRN APR approval.

NIOSH CBRN APR Approval Procedure

1. The NIOSH standard application form seeking an extension of approval will be used.
2. The approval application must clearly define the respirators eligible for retrofit and explain the configuration changes achieved with the retrofit kit.
3. The manufacturer provides four in-service respirator face-pieces from a single end user or multiple end users. The face-pieces must have been in service for less than five years. As a minimum, submitted respirators are to be from two different conditions of use:
    a. Two from a light condition of use category. Light use is defined as an APR primarily in a storage configuration; used intermittently throughout the service life.
    b. Two from a heavy condition of use category. Heavy use is defined as an APR used routinely for respiratory protection as part of an OSHA-compliant respirator program.
4. The manufacturer supplies respirator samples and appropriate retrofit kits to NIOSH. The manufacturer will make arrangements with NIOSH to have the retrofit kit procedures applied to the respirators in the presence of a NIOSH representative.

OR

The manufacturer provides respirators to NIOSH with the retrofit kit installed by a qualified technician. If supplied with the retrofit kit installed, the manufacturer must provide a notarized statement that the retrofit kit has been applied in accordance with manufacturer's instructions provided with the kit.

5. NIOSH testing performed on the respirators will be evaluated to the special tests for Chemical Agent Permeation and Penetration Resistance against Distilled Mustard (HD) and Sarin (GB) for each respirator use condition provided. The respirators will not require environmental conditioning.
6. Minimum contents for the retrofit kit are:
    a. CBRN APR retrofit kit instructions
    b. Materials required for performing the retrofit procedures
    c. Manufacturer record keeping materials
    d. CBRN APR approval label

Application Procedures

The application package shall include four CBRN APR retrofit kits and four NIOSH-certified, tight-fitting, full-facepiece APRs. Two of the respirators submitted are to be from the light-condition of use and the other two from the heavy-condition of use. The manufacturer shall provide written evidence that the configuration of the full-facepiece is equivalent to the system that was evaluated as part of the CBRN APR approval. The evidence should include identification of the NIOSH certification number(s) with all of the applicable component parts, major assemblies, accessories, and rationale in the reason for application.

The installation of the CBRN APR retrofit kits will be performed by a manufacturer trained and authorized technician in the presence of NIOSH representatives. The applicant may also retrofit the APR within their manufacturing facility using qualified technicians, and submit supporting documentation that the retrofit installation requirements have been followed. The application must include a description of the estimated frequency-of-use for the submitted APRs, and how this has been determined to be typical of the model's use. The submitted APRs will be tested and evaluated to the special tests for Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) without further environmental conditioning.

The application must include the quality assurance (QA) provisions for the retrofit kit and retrofit kit-applied-product configuration management in the form of all standard accountable QA documents and a listing of all applicable parts of the retrofit kit in the form of a bill of materials

The application must support the APR industrial NIOSH-approved assembly matrix document that identifies all current 42CFR84, approved APR; plus the submitted CBRN APR retrofit kit. This listed configuration for each APR retrofitted under the

CBRN APR retrofit program is linked to the assembly matrix via the specific drawing part number.

The cost for processing a completed application (four retrofitted APRs) is $21,000. In instances where the pre-existing facepiece was unchanged for CBRN approval and the canister is the only other component of the CBRN APR approval, CBRN APR retrofit testing is not necessary. The applicant fee for document processing for an application that does not require testing is $1,000.

Applications may be made following the standards application procedures available through the NPPTL web site:
http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/sap-0101.pdf

NIOSH may request additional documentation or test samples from the manufacturer if it determines that such documentation or samples are necessary to evaluate the CBRN APR retrofit kit process application. If a CBRN APR retrofit kit fails testing, the extension of approval is denied.

Note:
Comments on the topics presented in this posting should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513-533–8285. Comments may also be submitted by e-mail to niocindocket@cdc.gov. E-mail attachments should be formatted in Microsoft Word. Comments should be submitted to NIOSH no later than December 23, 2004. Comments regarding CBRN APR Retrofit concept should reference Docket Number NIOSH-002 in the subject heading.