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From:

Heinz Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

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: 412-386-4000
Fax: 412-386-4051

Subject: Extended Testing (Default to Test) Policy

Letter to All Respirator Manufacturers

The following is in response to requests for clarification of the NPPTL procedure for selecting tests for extension of approval requests.

Testing required under 42 CFR 84.35 (d)

Air Purifying

Any changes to the material or design of the approved respirator configuration under an existing air purifying approval. These changes include but are not limited to:

Changes to facepiece, facepiece harness, mouthpiece or respirator inlet covering.

Changes to the breathing circuit including canisters, cartridges, breathing tubes, valves, blower and/or filters.

Changes to or addition of accessories that make physical contact to the respirator facepiece or head harness.

Changes to donning instructions and/or user seal check instructions.

Substituting a part previously approved under another approved configuration into a configuration where that part has not yet been approved is considered a change in configuration requiring testing.

Atmosphere Supplying

Any changes to the material or design of the approved respirator configuration under an existing air supplying approval. These changes include but are not limited to:

Changes to facepiece, facepiece harness, mouthpiece or respirator inlet covering.

Changes to backframe.

Changes to the breathing circuit including: respirable breathing gas container, gas pressure or line pressure, regulators, valves, airlines, hand operated valves, breathing bags or gas filters.

Changes to donning instructions and/or user seal check instructions.

Changes to or addition of accessories that make physical contact to the respirator facepiece or head harness.

Changes to or addition of accessories that are in or contiguous to the breathing circuit.

Substituting a part previously approved under another approved configuration into a configuration where that part has not yet been approved is considered a change in configuration requiring testing.

Extended Testing under 42 CFR 84.35

All respirator types

Changes not affecting the material or design of the approved respirator configuration which are submitted within the time frames specified below will not be testing. Changes outside of those timeframes will default to testing. Changes not affecting the material or design of the approved respirator configuration include:

Changes in labels.

Changes in user instructions that do not affect the user seal check or donning instructions that were used for initial evaluation.

Modification to accessories listed on the matrix that are not in or contiguous to functional respirator components.

Processing Protocol for Extended Testing

Upon receipt of an application for modification of approval not affecting the material or design of the respirator, the application will be processed in two stages:

Stage 1: Process paperwork update for approval extension. Modification of the approval will be granted on completion of paperwork.

Stage 2: For approvals that have not been tested in the time frames specified below, from the date of receipt of the request for modification to the completion of the last approval action requiring testing, extended testing will be performed as follows:

A TN number will be assigned by TEB to the testing project.

TEB will transfer the necessary information from the request for modification of approval to the standard application form for the testing project.

All certification tests may be performed.

NPPTL will indicate respirator hardware required for testing.

Respirator hardware requested is to be provided by the manufacturer within reasonable time not to exceed 4 weeks.

****If equipment is not delivered on time, or if there is a sense of deliberate delay, the next approval or extension of approval request from the manufacturer will not be processed until extended testing is performed.**

TEB will perform tests and process the extended testing TN.

TEB will issue a test passing report. This report will start a new time period.

Failures will result in a Certified Product Investigation Process (CPIP).

Test Selection for Testing

NIOSH maintains the right to require all certification tests on extensions of approval that effect the material or design of an existing respirator approval. Tests performed will evaluate design change and specifically component level performance and systems level performance.

Factors that NIOSH will consider in selecting tests are:

Pretest data submitted by manufacturer.

Time lapse since last full system tests: less than 24 months from the date of the granting of the last approval action under this approval involving a full battery of applicable tests may result in full testing.

Failure mode effect analysis submitted by manufacturer.

Changes that will not result in testing without regard to the time since the last approval action requiring testing.

All respirator types:

Updates to drawing revision levels that do not involve material changes, design changes or major product quality plan (PQP) changes.

Updates to NIOSH matrices or exploded view drawings to reflect revision level changes that do not affect the material or design of the respirator.

Manufacturer voluntary submission for testing

The manufacturer may submit samples for testing to establish a start date for the testing interval. Upon successful completion of testing, a new testing interval will start on the date the testing report is issued. Failures will result in a CPIP. The manufacturer will work voluntarily with TEB to submit product for testing independent of extensions of approval actions. Manufacturers will provide as part of voluntary submission pre-approval test data and technical rationale for selecting the tests.

TEB will review manufacturer application including data submitted.

-Review data and manufacturers rationale for selecting tests.

-Determine what tests TEB will perform.

Extended Test Schedules

Approval Type	Interval Requiring Extended Testing
Filtering Facepiece	1 Year
CBRN SCBA	Not Required
All Others	2 Years

If you have any questions, please call 412-386-4000.