Overview of the National Institute for Occupational Safety and Health Respirator Approval Program and Post Market Activities

Jeffrey Peterson
Deputy Chief, Conformity Verification and Standards Development Branch

Jim Harris
Team Lead (Morgantown), Evaluation and Testing Branch

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An estimated 20 million workers use personal protective equipment on a regular basis to protect themselves from job hazards.

The **MISSION** of NIOSH NPPTL and the NIOSH PPT Program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).
Where Does NIOSH Get its Authority?

- NIOSH authority to approve respirators found in 42 CFR 84
  - Establishes procedures and requirements for requesting approval
  - Establishes a schedule of test fees
  - Describes the criteria for a quality assurance program for the manufacture of respirator systems
  - Provides criteria for the issuance of new approval as well as for modifications of existing approvals
What is NIOSH Approval?

- An approval is issued when a respirator system meets the minimum requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84)
What Can NIOSH Approve?

- NIOSH approves ‘individual, completely assembled respirators’
  - 42 CFR 84.30(a)

- NIOSH will not issue approval of ‘any respirator component or any respirator subassembly’
  - 42 CFR 84.30(b)

- Concept makes it easy to track actual configurations and identify critical performance characteristics
What Can NIOSH Approve?

**Air-Purifying:**
- Particulate
- Gas & Vapor
- Gas masks
- Powered Air-Purifying Combination

**Atmosphere-Supplying:**
- Self-Contained Breathing Apparatus
- Supplied-Air
- Self-Contained Self-Rescuer Combination
Air-Purifying Respirators

- Powered air-purifying respirator
- Filtering escape self-rescuer

Options:
- Full-face
- Half-face
- Filtering-facepiece
- Filtering-mouthpiece
Air-Supplying Respirators

- Self-contained breathing apparatus
- Supplied-air respirator
- Self-contained self-rescuer
Respirator Approval and Quality Assurance Program

98 approval holders
119 manufacturing sites
20 countries

Applications – ~400
Approvals – 250

US, Australia, Brazil, Canada, Chile, China, Colombia, Denmark, England, Finland, Germany, India, Italy, Japan, Korea, Mexico, New Zealand, Taiwan, Thailand, Sweden
What are the NIOSH Minimum Requirements for filtering facepiece respirators?

- Approvals follow the *Code of Federal Regulations* and the Standard Application Procedure for the Certification of Respirators

  - [http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c9c15fd462ffe5c4f4e85b73f161b2e0&r=PART&n=42y1.0.1.7.67](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c9c15fd462ffe5c4f4e85b73f161b2e0&r=PART&n=42y1.0.1.7.67)
  
Post Approval Activities involve both manufacturer sites and products

- **Site Audits**
  - Pre-qualification site audits
  - Post approval site audits – conducted every two years for each manufacturer site

- **New Product Audits**
- **Certified Product Investigation Process (CPIP)**
- **Long term field evaluation**
- **New efforts underway to evaluate stockpiled products**
NIOSH Site Audits

- NIOSH will audit the manufacturing site
  - At least every two years
  - Full compliance with configuration management and drawings
  - Full compliance with all quality plans
  - Compliance to 42 CFR 84
Product Audits

- Historic approach: ~40-50 models selected each year
- Products chosen from the Certified Equipment List using criteria such as:
  - Respirator type
  - Time since last tested
  - Problem history
- Product is requested from approval holder or purchased through commercial distribution system
- Tested to performance specifications of approval
- Failures will result in a Certified Product Investigation Process (CPIP)
Current Product Audit Approach

- Current approach: Audit a minimum of one product per year for each approval of product approved for conformity to requirements of standard.
- Any test failures resolved through a Certified Product Investigation Process (CPIP)
Additional Post Market Evaluation Activities

- Additional product audits and evaluations conducted based on emerging issues and stakeholder needs
  - increased FFR audits during outbreaks (e.g. H1N1)
  - SCBA evaluations to support Fire Fighter Fatality Program
  - Near-miss evaluations to support IAFF
  - Closed circuit escape respirator evaluations to support MSHA and Navy
  - Evaluation of stockpiled products
  - Other point of use evaluations being explored
Certified Product Investigation Process (CPIP)

- Purpose is to ensure the quality of NIOSH approved respiratory units by promptly investigating and resolving reports of product nonconformance issues.

- Failures of approved product to conform to approval requirements:
  - During customer use
  - During product audit
  - Based on manufacturer self report

- Examples of nonconformance issues:
  - Performance failure
  - Failure to maintain quality control requirements
  - Misleading advertising
  - Manufacturing under a private label without prior approval from NIOSH
When is a CPIP Needed?

- When an approved NIOSH respirator is in nonconformance with the specified requirements in Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).
- A nonconformance is a failure to comply with specified requirements – in this case, failure to comply with 42 CFR 84.
CPIP Goals

- Maintain quality of NIOSH approved units.
- Investigate potential nonconformance issues.
- Document findings of the approval holder’s investigation and their corrective actions.
- Address inventory units, field units and future production, when necessary:
  - Quarantine affected *inventory units*
  - Manufacturer or NIOSH issued notice for *field units*
  - Corrective actions to reduce likelihood of occurrence for *future production*
CPIP Process

- Contact the Approval Holder (manufacturer):
  - Provide test reports and photos, if applicable
  - Confirm NIOSH approval numbers affected
  - Request a full investigation including, reason for failure and extent of nonconformance

- For SCBA units, also contact SEI (Safety Equipment Institute)
  - Joint investigation

- Review investigation report from manufacturer

- Evaluate root cause and corrective actions

- Ensure actions are being taken to addresses inventory units, field units and future production
Possible Follow-Up Actions

- **User Notices**
  - Typically issued by manufacturer and reviewed by NIOSH
  - Link posted to NPPTL website
  - On occasion, NIOSH will issue a notice:
    - Covers multiple approval holders units
    - Agreement not reached that one is needed or the message

- **Stop Sales**
- **Recalls/ Retrofits**
- **NIOSH Application to make changes to:**
  - Quality Control Process
  - Production Process
  - Product Modifications

- In extreme cases, rescission of Approval Numbers, when resolution is not foreseeable.
CPIP Closing

- Has approval holder properly identified the cause of the nonconformance?
- Has approval holder developed effective corrective actions to resolve nonconformance?
- Has approval holder successfully addressed *inventory units, field units* and *future production*?
- When NIOSH determines investigation can be closed, Approval Holder receives closing letter.
Technical Assistance

- Many calls, letters, emails, faxes

- Variety of issues: selection, training, enforcement, verify approval, APF, interchanging parts, etc.

- Inquiries from organizations, labor, other government, contractors, general public
Information Dissemination

- Standard Test Procedures
- Letters to All Manufacturers
  - Policy Changes
  - Clarifications
- User Notices developed by NIOSH
  - Inform users of product failures or recalls
- User Notices developed by Approval Holders
  - Inform users of product failures or recalls
- Letters to all Interested Parties
  - Inform all customers of new initiatives at NIOSH
- Certified Equipment List and Trusted Source Page
  - Record of approved products
- Other corrective measures under development
Contact Information

Jeff Peterson, Deputy Branch Chief
Conformity Verification and Standards Development Branch
National Personal Protective Technology Laboratory
626 Cochrans Mill Road
Pittsburgh, PA 15236
Email: jap3@cdc.gov
Phone: 412-386-4014
Visit us at: http://www.cdc.gov/niosh(npptl)