

National Personal Protective Technology Laboratory

Workshop on Personal Protective Equipment for Healthcare Workers in the Event of Pandemic Influenza: Next Steps and Research Directions

Institute of Medicine

Panel 5 Identifying and Certifying Effective PPE-Next Steps

February 22, 2007



Presentation Topics

- **Respirator Program Overview**
- **Particulate Respirator Descriptions**
- **Research Initiatives**
- **Respirator and Surgical Mask Comparison**

NIOSH Respirator Approval Program

More than 8,500 approvals issued

- **84 approval holders**
- **102 manufacturing sites**
- **18 countries**



U.S., Australia, Brazil, Canada, Chile, China, Denmark, England, Finland, Germany, Italy, Japan, Korea, Mexico, New Zealand, Taiwan, Thailand, Sweden



Workplace
Safety and Health



NPPTL *Research to Practice
through Partnerships*

Final 11-01-05

NIOSH Respirator Approval Program

- **Respirator Testing and Certification (non-CBRN)**
 - **Documentation Review**
 - **Design Evaluation**
 - **Quality Control System**
 - **Performance Verification**
- **Quality System Assessment and Records**
 - **Manufacturing Site Audits**
 - **Product Audits**
- **Certified Product Investigation Procedure (CPIP)**
 - **Initiation**
 - **Approval Program Activities**
 - **User Reported Incidents**
 - **Other Agency and NIOSH Divisions Inquiries and Reported Incidents**
 - **Resolution**
 - **Product Retrofit**
 - **Product Recall**
 - **Approval Revocation**

CPIP Activities Involving N95 Respirators (2006)

- **94 Revoked Respirator Approvals**
 - No Revocations Involving N95 Respirators
- **16 User Notices Issued**
 - 3 User Notices Involving N95 Respirators
- **11 Active recall/retrofits**
 - 2 Open Investigations Involving N95 Respirators



NIOSH RESPIRATOR USERS' NOTICE

Subject: Mislabeling representation of the Three Guard Particulate Respirator as a NIOSH Approved N95 Respirator

It has been brought to the attention of the National Institute for Occupational Safety and Health (NIOSH) through the process of a product recall that 3M/Chicoma is representing and selling a Particulate Respirator model Three Guard as a NIOSH approved respirator.

The Three Guard respirator is a substantially packaged and packaged labeled with the NIOSH and Department of Health and Human Services logo. Additionally, the label contains a NIOSH approval number, TC 844-471, which was not issued to 3M/Chicoma. The Three Guard package label is illustrated below.

A NIOSH approval is issued to a respirator only after it has been evaluated in the laboratory and found to comply with all the requirements of Title 42, Code of Federal Regulations, Part 84, including a review of the manufacturer's quality plan. The Three Guard 100 Particulate Respirator is not certified and approved by NIOSH.

Sincerely yours,

Shane W. Allen
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory



NIOSH RESPIRATOR USER NOTICE

Subject: Mislabeling Representation of the Mako-Protec Respirator as a NIOSH Approved P95 Respirator

It has been brought to the attention of the National Institute for Occupational Safety and Health (NIOSH) through the process of a product recall that 3M/Chicoma is representing and selling a Particulate Respirator (RPPR) as a NIOSH approved respirator. These respirators are being sold in the United States.

The Mako-Protec Respirator (RPPR) is a substantially packaged and packaged labeled with the NIOSH logo on the top of the respirator package label.

A NIOSH approval is issued to a respirator only after it has been evaluated in the laboratory and found to comply with all the requirements of Title 42, Code of Federal Regulations, Part 84, including a review of the manufacturer's quality plan. The Mako-Protec RPPR Particulate Respirator is not certified and approved by NIOSH.

Sincerely yours,

Shane W. Allen
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclure



CORRECTED USERS NOTICE
REVISED 10/19/06
(Changes from original in bold.)
(Original enclosures are not included.)

RESPIRATOR USERS NOTICE

Subject: Cores, Inc. Models RPP011 and RPP012 Mining Respirator

NIOSH certificates of approval, TC 844-472 and TC 844-473, for the Models RPP011 and RPP012 Mining Respirator respirator are null and void.

NIOSH is making these certificates of approval because there were false and material statements in the applications submitted to NIOSH for the approval of these respirators and these approvals should not have been issued.

Models RPP011 and RPP012 Mining Respirator do not have a NIOSH certificate of approval and should not be used in workplaces requiring NIOSH approved or NIOSH certified respirators. Employees wearing these respirators may no longer be considered, awarded, paid or benefited.

If you have questions regarding any of these respirators that you purchased please contact Cores, Inc. For more information regarding the Cores Respirators, please call the Technology Evaluation Branch at 617-235-2000.

Sincerely,

Shane W. Allen
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

42 CFR 84 Particulate Filter Respirators

- **Non-Powered**

- 9 Classifications
 - 3 Efficiency Levels – 95%, 99%, 99.97%
 - 3 Degradation Levels – N , R, P
 - N for **Not** resistant to oil,
 - R for **Resistant** to oil
 - P for oil **Proof**
- ½ Mask, Full Facepiece
- Disposable or Reusable

- **Powered**

- HEPA Efficiency (99.97%)
- ½ Mask, Full Facepiece, Hood, Helmet



Research Initiatives

- Reusability of Filtering Facepiece Respirators
- Metabolic Evaluation of N95 Respirator Use With Surgical Masks
- Frequency of Fit Testing
- Improved Criteria for Emergency Medical Protective Clothing



Comparison of Respirators and Surgical Masks

	N-95 Filtering Facepiece Respirator	Surgical N-95 Respirator	Surgical mask or Procedure mask
Intended use	Occupational use Reduce wearer's exposure to certain airborne particles < 100 μ	Occupational use Reduce wearer's exposure to certain airborne particles < 100 μ To protect both the surgical patient and the operating personnel from transfer of microorganisms, body fluids, and particulate materials	To protect both the surgical patient and the operating personnel from transfer of microorganisms, body fluids, and particulate materials
Use limitations	Subject only to considerations of hygiene, damage, and increased breathing resistance - 8 hour use in dirty workplaces - extend beyond 8 hours only if - demonstrate extended use will not degrade filter efficiency - total mass loading of filter is less than 200 mg	Subject only to considerations of hygiene, damage, and increased breathing resistance - 8 hour use in dirty workplaces - extend beyond 8 hours only if - demonstrate extended use will not degrade filter efficiency - total mass loading of filter is less than 200 mg One time use when fulfilling the role of a surgical mask.	One time use



Comparison of Respirators and Surgical Masks

	N-95 Filtering Facepiece Respirator	Surgical N-95 Respirator	Surgical mask or Procedure mask
Certification requirements	Certified by NIOSH under 42 CFR 84	Certified by NIOSH under 42 CFR 84 FDA reviews 510(K) submission and clears for marketing	FDA reviews 510(K) submission and clears for marketing
Filter elements	nonreplacable	nonreplacable	nonreplacable
Filter efficiency Testing	95%	95% bacterial filtration efficiency quality indicator	Particle and bacterial filtration efficiency quality indicator
Particle size	Sodium chloride test aerosol with a mass median aerodynamic diameter particle of about 0.3 μ	Sodium chloride test aerosol with a mass median aerodynamic diameter particle of about 0.3 μ Staph. aureus filtration test, per ASTM standard (PFE)	Polystyrene latex sphere test aerosol approx 0.1 μ and staph. aureus filtration test, per ASTM standard (PFE)
Airflow	Airflow rate of 85 L/min	Airflow rate of 85 L/min Airflow rate of 28 L/min	Airflow rate of 28 L/min
Test aerosol	charge neutralized test aerosol	charge neutralized test aerosol	unneutralized test aerosol
Preconditioning	preconditioning at 85% relative humidity and 38°C for 24 hrs	preconditioning at 85% relative humidity and 38°C for 24 hrs	no preconditioning

Comparison of Respirators and Surgical Masks

	N-95 Filtering Facepiece Respirator	Surgical N-95 Respirator	Surgical mask or Procedure mask
Face seal fit	Designed to fit tightly to face	Designed to fit tightly to face	Not designed to fit tightly to face
User Seal check requirement	Required with each use	Required with each use	Not designed for user seal check
Available sizes	Some models available in three sizes	Some models available in three sizes	Only one facepiece size is generally available, tends to produce more leakage on small facial sizes
Approximate cost	\$0.50 ea - \$2.75 ea	\$0.70 ea - \$1.25 ea	approx. 0.15 each

Quality Partnerships Enhance Worker Safety & Health



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Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

Thank you