

National Personal Protective Technology Laboratory

Respirator Certification Fees Workshop/Webinar

March 18, 2015

Meeting Agenda

Topic

Presenter

Welcome / Opening Remarks

Maryann D'Alessandro

Combination Unit Respirator

Frank Palya

PPE-PROS Database

Tim Rehak

Respirator Fees Rule Review

David Chirdon

Fees Administration/Use of PAY.GOV

Jeff Peterson

Lunch

SAP / ISEA Workgroup

Tom Pouchot

Questions

Panel

National Personal Protective Technology Laboratory

Combination Unit Respirator Webinar and Institute of Medicine Workshop

Frank Palya

March 18, 2015

Discussion Topics

- **Why NPPTL is revisiting the Combination Unit Respirator (CUR) Concept**
- **NIOSH Historical Perspective**
- **2015 NIOSH CUR Webinar (postponed) Objective**
- **National Academies of Science, Institute of Medicine (IOM) Workshop**

NPPTL is revisiting the Combination Unit Respirator (CUR) Concept (*previously Combination Respirator Unit*) in Response to FY15 Omnibus

A combination respirator is a multi-functional unit that employs the technology of two or more different types of respiratory protective devices.



Photos courtesy of Avon Protection and MSA Safety. Use of these photos does not constitute product endorsement.

Report due to Congress December 2015

Outline: NIOSH Historical Perspective

- **Overview** of current NIOSH regulations regarding combination respirators
- **Summary** of previous public meetings

Combination respirator unit = Combination unit respirator

CRU = CUR

Overview of Current NIOSH and OSHA Regulations Related to CUR

NIOSH

- 42 CFR §84.63(b) Test requirements; general
- 42 CFR §84.70(c) Self-contained breathing apparatus; description

OSHA

- 29 CFR 1910.134(d)(2)(i) Respirators for IDLH atmospheres
- 29 CFR 1910.134(d)(3)(i)(A)

NIOSH Public Meetings

- October 2006
- December 2010



Photos courtesy of Avon Protection and MSA Safety. Use of photos does not constitute product endorsement.

2006 CUR Public Meeting Summary

- **NIOSH October 2006 public meeting to introduce**
“Concept for Open Circuit CBRN SCBA in combination with Non-Powered CBRN Air-Purifying Tight-Fitting respirators and/or Powered Air-Purifying Tight-Fitting respirators”

- **Established NIOSH Docket 82; Combination Units - SCBA/PAPR/APR**

<http://www.cdc.gov/niosh/docket/archive/docket082.html>

- NIOSH received one set of comments from one manufacturing stakeholder

2010 Public Meeting Summary

- **December 2010 Public Meeting as request for information forum to solicit information from stakeholders on combination unit respirators**
 - Well-attended meeting, two users and one manufacturer presented at the meeting
- **Established: NIOSH Docket 82A; Chemical Biological Radiological and Nuclear (CBRN) Combination Respirator Unit (CRU)**

<http://www.cdc.gov/niosh/docket/archive/docket082A.html>

- NIOSH received four sets of comments from stakeholders
 - One manufacturing stakeholder
 - Three others including one user group and two private citizens

2015 NIOSH CUR Webinar

The objective of the NIOSH CUR webinar:

- Summarize the NIOSH CUR historical perspective
- Solicit input from stakeholders to better address the needs of the CUR stakeholder community and the resources required to address those needs at the April 30, 2015 IOM Workshop on matters such as:
 - Research needs
 - Regulatory considerations
 - Training needs

Proposed IOM Questions and Topics

- What combination unit respirator technology is currently available in the U.S.?
- Describe the unique features of the manufactured devices and according to the RPD types included in the combination(s)
- What are the primary user groups interested in using NIOSH-certified CURs?
- What are the anticipated hazardous atmospheres/conditions that each user group is expected to encounter and how are they assessed?

Proposed IOM Questions and Topics (Cont'd)

- Identify new features not currently available in combination unit respirators and the user group needing the new features
- Identify potential performance standards or requirements to be used or developed to include the identified (new and existing) features in certified CUR
- Liability issue if a CUR is used in the wrong mode in the given dangerous atmosphere
- Should a regulation be established to regulate the liability?

Proposed IOM Questions and Topics (Cont'd)

- Will the deployment of CUR improve workplace or worker safety and health?
- Could CUR use detrimentally impact worker safety and health? Would there be no change?
- Should user switch modes while in hazardous atmosphere or before entering?
- Is a unit desired so the wearer can have a SCBA for firefighting and switch to AP for fire overhaul
 - How will this potentially impact the user?

Proposed IOM Questions and Topics (Cont'd)

- How rapidly could conditions change (for better or worse)?
 - How fast do you have to switch over?
- What information do users need to have on hand to make the switch over?
- Identify potential research including (sensor technology) needed to validate or develop the performance standard for use by NIOSH
- Estimate timelines and resources needed to complete the required research

Proposed IOM Questions and Topics (Cont'd)

- Are there current regulations limiting the use of CUR by the identified user groups?
- How do they limit use?
- What regulatory options should NIOSH consider related to developing and adopting a NIOSH CUR certification performance standard

Proposed IOM Questions and Topics (Cont'd)

- Are there other questions that should be presented at the workshop? From the following perspectives:
 - Manufacturer
 - User
 - Regulator
 - Industrial Hygienist and Occupational Safety Specialist
 - Researcher
 - Other

Overview NIOSH Path Forward

- **NPPTL is currently revisiting this priority to determine the path forward and address the congressional language included in the FY15 appropriation**
 - NIOSH Respirator Policy Group, March 3, 2015
 - Webinar to re-engage stakeholder community TBD
 - IOM workshop April 30, 2015
 - **Examine the technical, operational, and regulatory needs from an objective perspective**
 - **Workshop-in-brief report provided by June 30, 2015 as input to NIOSH report to Congress**

IOM CUR Workshop Information

- **Date - April 30, 2015**
- **Keck Center, 500 Fifth ST NW, Washington, DC 20001**
- **Information at:**
 - www.iom.edu/CURworkshop

Questions?

National Personal Protective Technology Laboratory

PPE-PROS Database

Tim Rehak

March 18, 2015

Overview of Presentation

- **Background**
- **Demonstration of Database**

Background of PPE-PROS Database

- **November 2010 - National Academies [and its Institute of Medicine (IOM)] publishes “*Certifying Personal Protective Technologies: Improving Worker Safety*”**
 - Among other recommendations in the document, NPPTL is charged to “expand its efforts to become a national clearinghouse for information on all types of PPT.”

Background of PPE-PROS Database

- **2011 - The NIOSH Personal Protective Technology Conformity Assessment Working Group (PCAWG) is established**
 - Among other goals, the Products and Standards Subgroup (PASS), is charged with *developing an inventory of product and performance standards*
- **2011 to 2012 - Members of the Products and Standards Subgroup research current OSHA regulations and PPE performance and testing standards**

Background of PPE-PROS Database

- **2012 - Resulting data were subsequently integrated into an interactive, searchable, prototype database for non-respiratory PPE Standards**
- **2012 to 2013 - This prototype database was unveiled to key stakeholders. Feedback on it was positive and plans were made to develop a web-based searchable database**

Background of PPE-PROS Database

- **2013 – Emergint Technologies was contracted to develop a beta-version of the database for review by key stakeholders**
 - The database was based on the original input from PASS subgroup
 - Several standards were updated to show a wider range of possibilities than was present in the original prototype version
 - Database was fully searchable in a wide variety of ways, with links to other standards incorporated by reference

Background of PPE-PROS Database

- **2014 – Three Focus Group Meetings were held on the beta version of the database to receive input regarding its utility and possible improvements to the database**
 - January 16, 2014
 - February 12, 2014
 - March 27, 2014

PPE-PROS Demo

<http://wwwn.cdc.gov/ppepros>

PPE-PROS

The PPE-PROS database is intended to serve as a compendium of regulations and standards regarding Personal Protective Equipment (PPE). Data in the current beta application focus on non-respiratory technologies and have been shared by members of the [PPT Conformity Assessment Working Group](#).

The slides following will demonstrate some of the functionality that the PPE-PROS database has to offer.

Personal Protective Equipment Products Standards (PPE-PROS)

BASIC SEARCH
Search standards by Title, Standard Number, or by Full Text.

ADVANCED SEARCH
Enhanced search capabilities with filters to create precise queries.

HELP
An in depth look at the terminology and functions of PPE-PROS.

What is PPE-PROS?

The PPE-PROS Database is intended to serve as a compendium of Federal regulations and consensus standards regarding Personal Protective Equipment (PPE). Data in the current beta application focus on non-respiratory technologies.

Currently the PPE-PROS database is comprised of regulations and standards about non-respiratory occupational personal protective equipment (PPE). Standards in the database are believed to be current, except when superseded standards are still permissible by regulation. The standards included in this database are only from the International Standards Organization (ISO), the US Government, and SDOs accredited by the American National Standards Institute (ANSI).

Future plans for the database include the following:

- ◆ Refining the application with assistance from stakeholders in the PPE community
- ◆ Completing/updating data with the input of Standards Development Organizations (SDOs)
- ◆ Including respiratory protective device information
- ◆ Developing information about PPE products that claim to comply with the regulations and standards in this database
- ◆ Serving as a clearinghouse of information regarding conformity assessment activities (e.g. certification, testing, inspection, quality management) for PPE

Feedback

In order to better serve the public, as well as the scientific and educational communities, all comments and suggestions to improve this site are welcomed. E-mail us at PPEPROSFeedback@cdc.gov.

Searching

A search can be performed in three ways:

- **Full Text** - search against all fields in the database
- **Title** – search against the title of standards
- **Standard Number** – search against the standard number, for example NFPA 1992

By default Full Text is used. The search engine will separate search terms by white space unless a phrase is enclosed in quotation marks.

The search results are ordered in several ways:

- Standard Organization
- Standard Number
- Occurrences of search terms

Personal Protective Equipment Products Standards (PPE-PROS)

- This form will generate a query of applicable standards and regulations related to various types of PPE. Leaving the search box empty will return all possible results.
- To search for phrases, enclose search terms in quotation marks.
- For more detailed information click the question mark button.

Advanced Search

NFPA

Search By Full Text

?

31 Results Found | Page 1 of 4

NFPA 1999 National Fire Protection Association (NFPA) ☰

"Standard on protective clothing for emergency medical operations", 2013

This standard specifies requirements for EMS protective clothing to protect personnel performing patient care during emergency medical operations from contact with blood and body fluid-borne pathogens. It also includes additional requirements that provide limited protection from specified CBRN terrorism agents.

- **Status:** Current
- **Standard Type(s):** Specification , Test Method
- **Hazard Type(s):** Biological , Chemical , Biohazards , Radiological , Nuclear Particulate
- **PPE Type(s):** Medical gloves , Medical protective clothing , Medical protective footwear , CBRN protective ensembles
- **SOC Occupation(s):** 29-2041 Emergency Medical Technicians
- **Reference(s):**
 - ◆ **Referenced Standard:** [ANSI/ISEA Z87.1](#) , [NFPA 1994](#) , [ASTM D5151 - 06 \(2011\)](#) , [ASTM D5712 - 10](#) , [ASTM F2010/ F2010M - 10](#) , [NIJ Test protocol 99-114](#) , [ASTM F2100 - 11](#) , [29 CFR 1910.132](#) , [ANSI/ISEA Z89.1](#) , [ANSI/ISEA 107](#) , [ASTM F1154 - 11](#) , [ASTM F 1342](#) , [ASTM F 1359](#) , [ASTM F 1868](#)
- **Conformity Assessment:** Third party certification required

NFPA 1983 National Fire Protection Association (NFPA) ☰

"Standard on Life Safety Rope and Equipment for Emergency Services", 2012

This standard specifies requirements for life safety rope and associated equipment used to support emergency services personnel and civilians during rescue, fire fighting, or other emergency operations, or during training.

- **Status:** Current
- **Standard Type(s):** Test Method , Specification
- **Hazard Type(s):** Mechanical Hazards
- **PPE Type(s):** Safety belts, harnesses, lanyards and lifelines
- **SOC Occupation(s):** 29-2040 Emergency Medical Technicians and Paramedics , 33-2010 Firefighters
- **Reference(s):**
- **Conformity Assessment:** Third party certification required

Search Result Options

- Each result will have three icons beneath the Standard Organization. These icons represents the options a user has for each result.

 **Standard Details** – Takes the user to the standard details page for that particular standard.

 **Email Link** – Opens an email template to send the link to the standard details page for that particular standard. This icon has been temporarily removed.

 **Provide Feedback** – Opens an email template to send feedback to the monitored mailbox for that particular standard.

Personal Protective Equipment Products Standards (PPE-PROS)

[Home](#)
[Search](#)
[Advanced Search](#)
[Help](#)

- ◆ This form will generate a query of applicable standards and regulations related to various types of PPE. Leaving the search box empty will return all possible results.
- ◆ To search for phrases, enclose search terms in quotation marks.
- ◆ **For more detailed information click the question mark button.**

Search By Full Text

46 Results Found | Page 1 of 5

NFPA 1999

"Standard on protective clothing for emergency medical operations", 2013

This standard specifies requirements for EMS protective clothing to protect personnel performing patient care during emergency medical operations from contact with blood and body fluid-borne pathogens. It also includes additional requirements that provide limited protection from specified CBRN terrorism agents.

- **Status:** Current
- **Standard Type(s):** Specification , Test Method
- **Hazard Type(s):** Biological , Chemical , Biohazards , Radiological , Nuclear Particulate
- **PPE Type(s):** Medical gloves , Medical protective clothing , Medical protective footwear , CBRN protective ensembles
- **SOC Occupation(s):** 29-2041Emergency Medical Technicians
- **Reference(s):**
 - ◆ **Referenced Standard:** [ANSI/ISEA Z87.1-2010](#) , [NFPA 1994](#) , [ASTM D5151 - 06 \(2011\)](#) , [ASTM D5712 - 10](#) , [ASTM F2010/ F2010M - 10](#) , [NIJ Test protocol 99-114](#) , [ANSI/ISEA Z89.1-2014](#) , [ANSI/ISEA 107-2010](#) , [ASTM F1154 - 11](#) , [ASTM F1342 / F1342M - 05\(2013\)je1](#) , [ASTM F1359 / F1359M - 13](#) , [ASTM F1868 - 14](#) , [ASTM F2100 - 11](#) , [29 CFR 1910.132](#)
- **Conformity Assessment:** Third party certification required
- **Testing Lab(s):** Intertek - Personal Protective Equipment - PPE Cortland

National Fire Protection Association (NFPA)




NFPA 1983

"Standard on Life Safety Rope and Equipment for Emergency Services", 2012

This standard specifies requirements for life safety rope and associated equipment used to support emergency services personnel and civilians during rescue, fire fighting, or other emergency operations, or during training.

- **Status:** Current

National Fire Protection Association (NFPA)




Standard Details

This page shows a more detailed view of a standard in a print-friendly layout

A user or entity may leverage this page to link directly to details of a particular standard by using the following format:

<http://wwwn.cdc.gov/ppepros/Standards/Info/<Standard Number>>.

Example:

<http://wwwn.cdc.gov/ppepros/Standards/Info/NFPA 1992>

Personal Protective Equipment Products Standards (PPE-PROS)

[← Return to Search Results](#) [Print](#)

[NFPA 1992](#)

National Fire Protection Association (NFPA)

Title

"Standard on Liquid Splash-Protective Ensembles and Clothing for Hazardous Materials Emergencies", 2012 (Current)

Description

This standard shall specify minimum design, performance, certification, and documentation requirements; test methods for liquid splash-protective ensembles and liquid splash-protective clothing; and additional optional criteria for chemical flash fire protection.

Standard Type(s)

Test Method

A definitive procedure that produces a test result: Examples of test methods include, but are not limited to: identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method.

Personal Protective Equipment

Body Protection

All items of clothing and/or accessories (whether or not detachable) designed and manufactured to provide specific protection. This includes bullet-proof clothing, general protective clothing and full body ensembles that protect from cuts, radiation, temperature extremes, hot splashes from molten metals and other hot liquids, potential impacts from tools, machinery and materials and hazardous chemicals. Examples of body protection include laboratory coats, coveralls, vests, jackets, aprons, surgical gowns and full body suits

- ◆ Chemical protective clothing

Foot and Leg Protection

All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the foot and/or the leg and to provide anti-slip protection. This category includes protection against static electricity, risk of explosion, falling or rolling objects, crushing or penetrating, protection from exposure to hot substances and/or corrosive or poisonous materials

- ◆ Chemical protective footwear

Hand and Arm Protection

All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the arm and/or the hand this includes all garments protecting the hand or part of the hand, including gloves, fingerless gloves, mittens, garments protecting the fingers only or the palm only, etc. Potential hazards include skin absorption of harmful substances, chemical or thermal burns, electrical dangers, bruises, abrasions, cuts, punctures, fractures and amputations.

- ◆ Chemical protective gloves

Hazards

Chemical

An element or mixture of elements or synthetic substances that are considered harmful to employees.

- ◆ Chemical
- ◆ Chemical Reactions

Thermal

Thermal hazards are objects or substances that transfer energy as heats, such as an open flame. In addition, some cold substances will absorb so much heat that they can be thermal hazards such as dry ice and liquid nitrogen. Substances or materials that absorb heat are only contact hazards.

- ◆ Flammability and Fires

Advanced Search

The advanced search offers all the functionality of the standard search with the addition of five filters that can be used to refine a query

- PPE Category
- Hazard Category
- Standard Organization
- Standard Type
- Standard Status
- SOC Code

By leaving the filters blank, all possible results will be displayed. As more filter values are added, the search will become more refined

Personal Protective Equipment Products Standards (PPE-PROS)

Filter by Personal Protective Equipment Category

Filter by Standard Organization

Filter by SOC Code

Filter by Hazard Category

Filter by Standard Type

Filter by Standard Status

- ◆ This form will generate a query of applicable standards and regulations related to various types of PPE. Leaving the search box empty will return all possible results.
- ◆ The query fields are joined by "AND", meaning that choosing more options will narrow the search. Not choosing any filter values will return all possible results.
- ◆ To search for phrases, enclose search terms in quotation marks.
- ◆ For more detailed information click the help button.

[Search](#)

Search By Full Text ▼

17 Results Found | Page 1 of 2

NFPA 1971
National Fire Protection Association (NFPA) ☰

"Standard on Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting", 2013

NFPA 1971 protects fire fighting personnel by establishing minimum levels of protection from thermal, physical, environmental, and bloodborne pathogen hazards encountered during structural and proximity fire fighting operations.

- **Status:** Current
- **Standard Type(s):** Test Method , Specification
- **Hazard Type(s):** Biological , Chemical , Flame and Thermal , Physical , Radiological , Nuclear Particulate
- **PPE Type(s):** Firefighter protective clothing , CBRN protective ensembles
- **SOC Occupation(s):** 33-2010 Firefighters
- **Reference(s):**
 - ◆ **Referenced Standard:** [ANSI/ISEA Z87.1](#) , [NFPA 1983](#) , [ASTM F 2412 - 11](#) , [ASTM F 2413 - 11](#) , [ISO 17249](#) , [ASTM F2010/ F2010M - 10](#) , [ASTM F1060 - 08](#) , [ASTM F 1342](#) , [ASTM F 1359](#) , [ASTM F 1671](#) , [ASTM F 1790](#) , [ASTM F 1868](#) , [ASTM F903 - 10](#) , [ASTM F2731 - 11](#) , [29 CFR 1910.132](#)
- **Conformity Assessment:** Third party certification required

PPE-PROS Recap

- **A search can be performed in three ways**
- **The search results are ordered in several ways:**
 - Occurrences of search terms, Standard Organization, Standard Number
- **Advanced search capabilities with filters to refine search queries**
 - PPE Type, Hazard Type, Standard Organization, Standard Type, and Standard Status
 - By leaving the filters blank, all possible results will be displayed. As more filter values are added, the search will become more refined
- **A print-friendly standard details page**
 - This page may be leveraged by users to link directly to a standard
 - By Full Text , By Title, or By Standard Number (e.g. NFPA 1992)

PPE-PROS Database

Questions?

National Personal Protective Technology Laboratory

Revised Fees Rule

David Chirdon

March 18, 2015

History of Fees

- **U.S. Bureau of Mines**

- Authorized to test mining equipment submitted
- Began testing in 1910
- Established approval schedules, e.g.:
 - Schedule 13 – Self-Contained Breathing Apparatus
 - Schedule 14 – Gas Masks

History of Fees

- **Coal Mine Health and Safety Act 1969**
- **Occupational Safety and Health Act 1970**
 - Requires testing of safety equipment
 - Requirements incorporated into 30 CFR 11
 - Bureau of Mines approvals schedules incorporated 1972
 - Schedule 13 F– Self-Contained Breathing Apparatus
 - Schedule 14G – Gas Masks

History of Fees

- **42 CFR 84, Respiratory Protective Devices finalized in 1995**
 - Incorporated 30 CFR 11 fees without change
 - Rule administration moved from Mine Safety and Health Administration to National Institute for Occupational Safety and Health

History of Fees

- **OMB Circular A-25 was revised in 1993**

When a service (or privilege) provides special benefits to an identifiable recipient beyond those that accrue to the general public, a charge will be imposed (to recover the full cost to the Federal Government for providing the special benefit...)

Approaches to Creating Revised Fees Rule

- **Recover all costs (OMB Circular A-25)**
- **Do not disadvantage small businesses (Small Business Regulatory Enforcement Fairness Act)**
- **Create the minimum burden to all parties (Executive Orders 12866 and 13563)**
- **Fees should reflect actual request or usage**
- **Phase-in new fees over a reasonable time**

Two Categories of Fees

- **Administrative and Maintenance Fees**

- New
- Will include applications, modifications, maintenance, product and site audits

- **Testing Fees**

- Modified
- Will be based on associated tests rather than respirator type

Administrative fees

- New applications
- New approvals
- Approval modification
- Records maintenance
- Site qualification [new production sites]
- Site audits
 - Quality assurance maintenance
- Product audits
 - Maintenance of product performance

Administrative fees

Estimated recovery under revised regulation - Applications

- Applications \$ 87,000
- New approvals \$ 70,000
- Modifications \$ 41,000
- Maintenance fee, records \$340,000
- Site qualification \$ 30,000
- Total fees \$568,000
- Percent recovery 97.1%

Administrative - Audit fees

Estimated recovery under revised regulation - Audits

- Product audit fees \$123,000
- Site audit fees \$578,000
- Total audit fees \$701,000
- Percent Recovery 99.0%

Fixed Fees

- **Maintenance of NIOSH Testing and Approval Facilities**
- **Maintenance of NIOSH Test Equipment**

Additional Costs - Fixed fees

Fixed Fee Recovery Estimates

Facility maintenance

- 2009 Actual Cost\$233,156
- Proposed Fee\$231,200
- Percent Recovery99.2%

Test equipment depreciation

- 2009 Depreciation\$251,000
- Proposed Fee\$249,600
- Percent Recovery99.4%

Testing fees

- Includes all laboratory tests on Air-Purifying Respirators, Air-Supplied Respirators, and respirators for Chemical, Biological, Radiological and Nuclear protection
- Fees set for each specific test

Currently, Department of Defense costs associated with CBRN live agent testing are invoiced by NIOSH but paid directly to the U.S. Army

Timing of Fee Implementation

- **Public meeting, April 30, 2013**
- **Public comment period ended May 28, 2013**
- **Final rule published January 26, 2015**
- **Revised fees go into effect May 26, 2015**

National Personal Protective Technology Laboratory

Fee Administration and Use of PAY.GOV

Jeff Peterson

March 18, 2015

Revised Fees Rule

- **Final Rule can be found at**

<http://www.cdc.gov/niosh/npptl/respcertfee.html>

- **Effective date is May 26, 2015**

– All approval requests received on or after May 26 will be billed in accordance with revised fee structure

Fee Administration

- **Effective date is May 26, 2015**
 - Requests to become a new approval holder received on or after May 26 will need to undergo a site qualification visit prior to being issued a manufacturer's code
 - New production sites added by an existing approval holder on or after May 26 will be billed in accordance with revised fee structure

Fee Administration

- **Effective date is May 26, 2015**
 - Annual fees (Schedule A) will become effective and will be invoiced, yearly, in September
 - Estimate of yearly fees will be provided to each approval holder no later than July 1, 2015
 - Year 1 only
 - Reconciliation period will be between July 1 and September 1

Annual Fees (Schedule A)

Maintenance of Product Performance (Product Audits) 42 CFR 84.20(b)(5)

-Annual flat fee of \$761 per approval holder
-Variable fee based on respirator chosen and testing required

Quality Assurance Maintenance (Site Audits) 42 CFR 84.20(b)(4)

-Annual flat fee of \$3000 per each manufacturing facility on file with NIOSH on July 1 of applicable year
-Variable fee based on location and time spent at facility

1 day domestic audit	\$2,500/site
2 day domestic audit -	\$5,000/site
1 day international audit -	\$7,500/site
2 day international audit -	\$10,000/site

Records Maintenance 42 CFR 84.20(b)(1)

-Annual flat fee of \$50 per every approval listed in the CEL on July 1 of applicable year

Facility Maintenance 42 CFR 84.20(b)(2)

-Annual flat fee of \$34 per every approval listed in the CEL on July 1 of applicable year

Test Equipment Maintenance 42 CFR 84.20(b)(2)

-Annual flat fee of \$36 per every active approval listed in the CEL on July 1 of applicable year

Annual Fees (Schedule A)

- **First year in effect**

- Estimate will be provided to each approval holder by July 1
 - Provides opportunity to resolve discrepancies
- Final invoice will be provided by September 30
 - Payment due by October 30
 - Based on listed approvals

- **Subsequent years**

- Final invoice will be provided by September 30
 - Payment due by October 30

Annual Fees (Schedule A)

- **Sanctions for missed payments**
 - Penalties administered will include
 - 30 days late - Refusal to accept future applications
 - 60 days late - Stop-sale of all approved product
 - 90 days late - Initiate debt collection procedures

Application and Test Fees (Schedule B)

Application Fee 42 CFR 84.20(b)(1)

- \$200 per application submitted
- Due with submission of SAF

Site Qualification Fee 42 CFR 84.20(b)(3)

- Existing approval holder adds mfr. site via submitting SAF
 - Paper Review
 - \$400 per each new facility
- Request to become an approval holder
 - Required site visit
 - Domestic site - \$2,500/site
 - International site - \$7,500/site

Approval Fee 42 CFR 84.20(b)(1)

- \$100 for each new approval issued
- Upon issuance of approval

Approval Modification Fee 42 CFR 84.20(b)(1)

- \$50 for each approval modified
- Upon issuance of approval

Testing Fees 42 CFR 84.20(b)(1)

- Cost based on tests identified
- Upon issuance of approval

Application, Approval, and Test Fees (Schedule B)

- **Application Fee**

- \$200 per application

- Due upon submission of an approval request (SAF)

- Must be received within 2 weeks of first item received

Application, Approval, and Test Fees (Schedule B)

- **Approval Modification Fee**

- \$50 per modification of approval

- Estimate will be provided during Initial Review

- If the estimate is exceeded, a re-estimate request will be sent for approval

- Final invoice will be sent upon initiation of Final Review

- Fee due upon issuance of approval

Application, Approval, and Test Fees (Schedule B)

- **New Approval Fee**

- \$100 per approval issued

- Estimate will be provided during Initial Review

- If the estimate is exceeded, a re-estimate request will be sent for approval

- Final invoice will be sent upon initiation of Final Review

- Fee due upon issuance of approval

Application, Approval, and Test Fees (Schedule B)

- **Site Qualification Fee - Existing Approval Holder**
 - \$400 for each new site
 - Extension of Approval for all affected approvals
 - All relevant documentation
 - Estimate will be provided during Initial Review
 - If the estimate is exceeded, a re-estimate request will be sent for approval
 - Final invoice will be sent upon initiation of Final Review with
 - Fee due upon issuance of approval

Application, Approval, and Test Fees (Schedule B)

• **Site Qualification Fee - New Approval Holder**

- Submit questionnaire describing product, quality system, and location of sites
- Coordinate/schedule a date for site visit
 - Verify location of facility
 - Verify that a quality system is in place
 - Evidence that a documented quality system exists
 - Evidence that quality system is being followed
 - Fee due upon agreement of assessment date

Application, Approval, and Test Fees (Schedule B)

- **Testing Fees**

- Itemized for each test conducted

- Estimate will be provided during Initial Review

- Required by 42 CFR 84.21

- Final invoice will be sent upon initiation of Final Review

- Fee due upon issuance of approval

Testing Fees

- **Testing fees found within Appendix B**
 - Tests not listed in Schedule B or special and/or additional tests required under 84.24 will be billed in accordance with New and Unspecified Tests costs
 - \$500/day
 - Costs of non-NPPTL staff
 - Medical coverage for man tests
 - Test subject costs
 - Currently pertains to CCER, EBSS and Wildland Fire Fighting Respirator testing
 - CBRN LAT fees are not controlled by NIOSH
 - Actual LAT fees are \$9,142 per test
 - Will potentially change on an annual basis
 - Published as a LTAM

Payment Methods

- **Preferred payment method**

- Paper check until further notice
- Must have Applicant Assigned Reference # (AAR) and tax identification # on check

- **Optional payment method**

- PAY.GOV
- Available to domestic approval holders only at this time
- Will phase into primary payment method

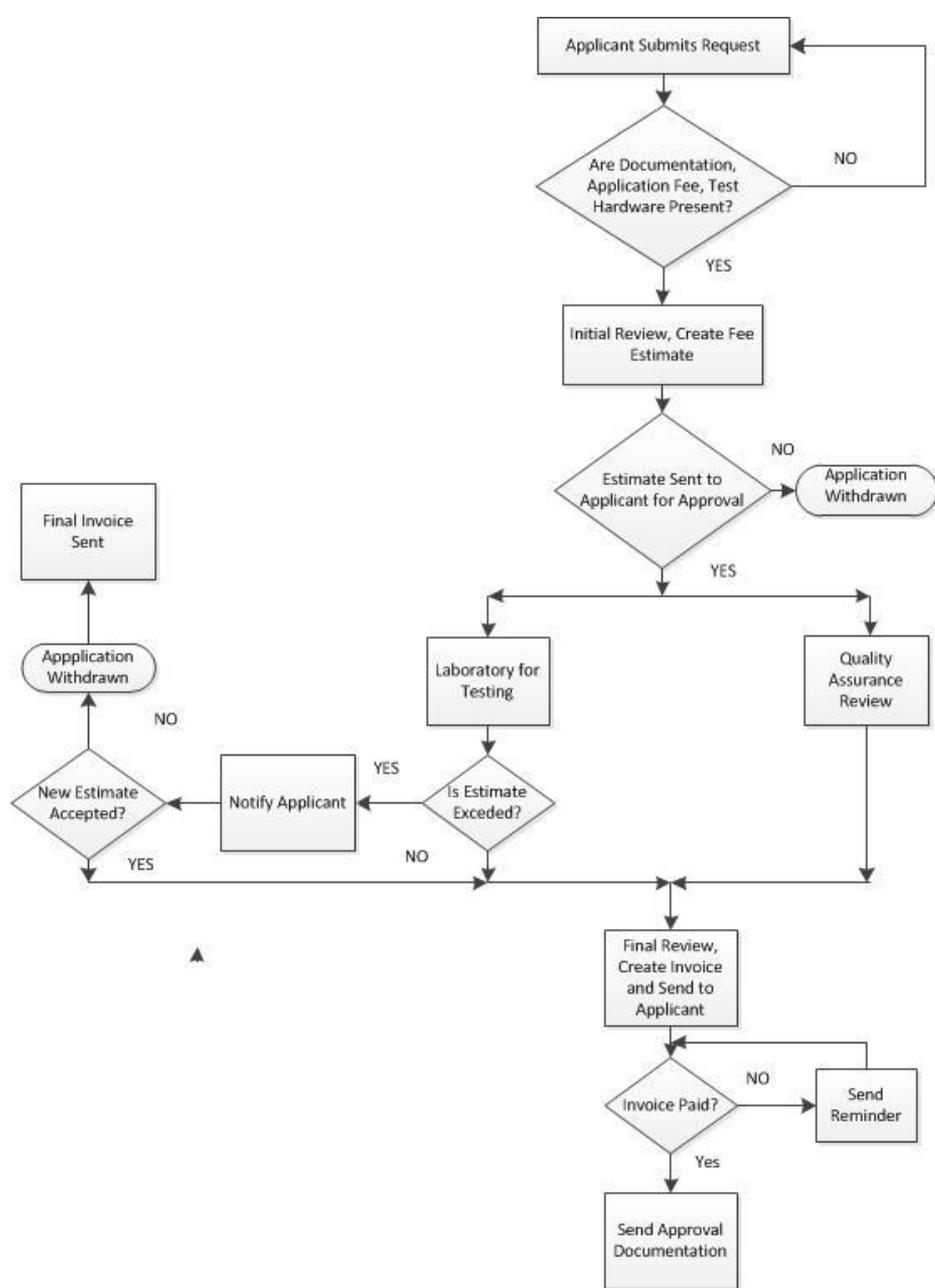
Payment Methods

- **PAY.GOV is available for use**
 - Offers the Federal government an electronic method for collecting debts owed via Automated Clearing House (ACH) and credit card processing
 - One time or recurring payments
 - Free service
 - Payment limit of \$200,000 maximum per transaction

Payment Methods

- **PAY.GOV Registration Process**

- Prior to making any payment of fees manufacturer must establish an account on <https://pay.gov/paygov/accounts/selfEnrollmentRob.html>
- Instructions will be added to the SAP and posted on the NPPTL website
 - Can be obtained from jap3@cdc.gov



Typical Examples

Description	Old	Revised
New Filtering Facepiece w/exhalation valve – one new approval issued	\$1,250	\$2,100
New OV cartridge added to 5 models of full facepiece respirators – 5 new approvals issued	\$1,150	\$1,450
New multi-gas (AM/CD/CL/FM/HC/HF/P100) canister approved with 1 full facepiece – one new approval issued	\$1,150	\$6,050
New 4500 PSI SCBA (45 Minute)/Part 84 Evaluation – One new approval issued	\$2,750	\$6,675
Change in filtering media of an approved filtering facepiece w/o exhalation valve – Modification of 1 Approval	\$650	\$1,750
Addition of an alternate OV carbon in a cartridge utilized on five approvals	\$600	\$1,000

Fee Updates

- **Fee schedule in effect for at least 2 years**
 - Changes published as an NPRM in the **Federal Register**
 - Exception is ECBC costs (revised annually and posted on NPPTL website)
- **Revisions to fee schedules will reflect adjustments based on data**
 - Time spent during technical review process
 - Equipment depreciation/replacement
 - Lab supplies

National Personal Protective Technology Laboratory

Standard Application Procedure Update

Tom Pouchot

March 18, 2015

Standard Application Procedure (SAP) Update

- **Current SAP issued July 2005**
 - Still valid
- **Current plan**
 - Phased program
 - Will solicit stakeholder input
 - Completion and publication of the update, all phases, end of 2015

SAP Update Phase I

- **Update fees as listed in the fees module**
- **Corrections to the current procedures**
 - Mailing address change
 - No longer use P.O. Box 18070 for U.S. Mail Service
 - New mailing address is 626 Cochrans Mill Road, Pittsburgh, PA 15236-0070
 - Policy changes
 - Add application check list
- **Phase I Publication Date**
 - Mid May 2015

SAP Update Phase II

- **Add CBRN information**
 - Add test requirements
- **Add CCER information**
 - Add test requirements

SAP Update Phase II

- **Add other respirator examples**
 - Examples specific to types of respirators
 - Filtering facepiece
 - PAPR and others
- **Policy Items**
 - Filtering facepiece labeling
 - Private label identification
- **Will solicit stakeholder input**
- **Phase II publication**
 - August 2015

SAP Update Phase III

- **Reorganization of SAP based on respirator type**
 - Filtering facepiece section
 - PAPR section
 - SCBA section

SAP Update Phase III

- **Other items as identified**
- **Based on input from stakeholders**
- **Phase III publication**
 - December 2015
- **5 year revision cycle**

ISEA Response to Certification Working Group Meeting

- **Work group establish through ISEA meeting
December 2, 2014**
 - Manufacturer input to improve NIOSH certification process
- **6 topic areas discussed concerning the NIOSH respirator certification process**

ISEA Response to Certification Working Group Meeting

- **Topics as discussed:**

- Rejection criteria in the Standard Application Procedure (SAP)
- Linked applications
- Identifying alternate applicant contacts to reduce waiting times
- Prioritization of applications based on national needs (FFR, CCER, CBRN SCBA)

ISEA Response to Certification Working Group Meeting

- **Topics as discussed continued:**
 - Identifying applicable Product Quality Plans (PQPs) associated with each approval
 - Exploring opportunities for utilizing alternative test laboratories

ISEA Response to Certification Working Group Meeting

- **Response to the discussion points and suggestions issued through ISEA**
 - Received by NIOSH January 30, 2015
- **NIOSH responded on **March 15, 2015****

Improving the Certification Process

- Next work group meeting is tentatively scheduled for **April 22, 2015**

**This concludes the presentations.
We'll now be happy to address your
questions.**