

# National Personal Protective Technology Laboratory

NIOSH Regulatory Agenda for  
updating 42 CFR Part 84

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# Presentation Outline

- “Rules of the Road”
- “Path Forward”
- Comments and questions



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# Background

- Under 42 CFR Part 84, “Approval of Respiratory Protective Devices” (“Part 84”) NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres
- The Mine Safety and Health Administration (“MSHA”) and the Occupational Safety and Health Administration (“OSHA”) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of respirators



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# Background

- The Federal Rulemaking Process --  
The process of creating and enacting federal regulations is generally referred to as the “rulemaking” process.
- The “Rules” of Rulemaking  
Regulatory agencies create regulations according to rules and processes defined by another law known as the Administration Procedure Act (APA).



## Background

- The APA defines a "rule" or "regulation" as...  
“*[T]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.*”



## Background

- The APA defines “rulemaking” as...  
*“[A]gency action which regulates the future conduct of either groups of persons or a single person; it is essentially legislative in nature, not only because it operates in the future but because it is primarily concerned with policy considerations.”*



# Background

- Under the APA, the agencies must publish all proposed new regulations in the Federal Register at least 30 days before they take effect, and they must provide a way for interested parties to comment, offer amendments, or to object to the regulation.



## Background

New regulations or amendments to existing regulations are known as "proposed rules."

Notices of public hearings or requests for comments on proposed rules are published in the Federal Register; on the National Archives and Records Administration website; Regulations.gov; on the Web sites of the regulatory agencies; and in many newspapers and other publications.

The notices will include information on how to submit comments, or participate in public hearings on the proposed rule.



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## Background

Once a regulation is published in the Federal Register and takes effect, it becomes a “Final Rule” and is printed in the next edition of the CFR, and usually posted on the Web site of the regulatory agency.



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# Background

- Federal regulations created by the regulatory agencies are subject to review by both the president and Congress under Executive Order 12866
- Steps in the regulatory process can be found via these links:
  - <http://www.whitehouse.gov/omb/inforeg/default>
  - [http://www.whitehouse.gov/omb/inforeg/oira\\_review\\_process/](http://www.whitehouse.gov/omb/inforeg/oira_review_process/)
  - <http://www.whitehouse.gov/omb/inforeg/regmatters>



# Background

- Executive Order 12866 also requires all regulatory agencies to prepare and submit to OMB annual plans to establish regulatory priorities and improve coordination of the Administration's regulatory program
- NIOSH Unified Agenda:

<http://www.cdc.gov/niosh/regulatory.html>



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# Informal Rulemaking

“Notice and Comment Rulemaking”



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# Informal Rulemaking

- **Advanced Notice of Proposed Rulemaking (ANPRM)**
  - An Agency requests comments and data on specific issues. No proposed regulatory language.
- **Interim Final Rule**
  - A rule is promulgated without the proposal stage; comments on the rule are accepted after promulgation and the rule is revised if needed.
- **Direct Final Rule**
  - A rule is promulgated without the proposal stage; the rule is rescinded if adverse comments are received after promulgation





# Advance Notice of Proposed Rulemaking

- Published in the Federal Register
- No time requirements
- Receive public comments
  - Electronically
  - Mail
- Public meetings an option



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# Informal Rulemaking

- **Notice of Proposed Rulemaking (NPRM)**
  - An Agency proposes the regulatory text
  - States its authority
  - Explains the basis of the proposed rule
  - Discusses the impacts
  - Provides a time period for public comment
- **Final Rule**
  - Finalizes the regulatory text
  - Responds to public comments
  - Explains any changes from the proposed regulatory text
  - Specify an effective date



# Notice of Proposed Rulemaking

- Docket identified in the Federal Register
- Minimum 30 day comment period
- Public meeting an option
  - Notice Published in the Federal Register
  - Government in the Sunshine Act (5 U.S.C. § 552b)
- Complies with regulatory analysis and review requirements
- Agency, Departmental, and Executive Department clearance



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# Final Rule

- Docket identified in the Federal Register
- Analyze and respond to public comments
  - Changes in regulatory text may be based on a public comment
  - Has to be within the scope of the original rulemaking
  - Otherwise provision has be re-proposed
- Specify an effective date
- Comply with regulatory analysis and review requirements
- Agency, Department, and Executive Departmental clearance



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# IOM Certification Report

- *"NIOSH certification of respirators has had a significant positive impact on the quality of respirators available in the workplace."*

from *The PPT Program at NIOSH: Review of Research Programs of NIOSH, IOM and NRC (2008)*, page 119



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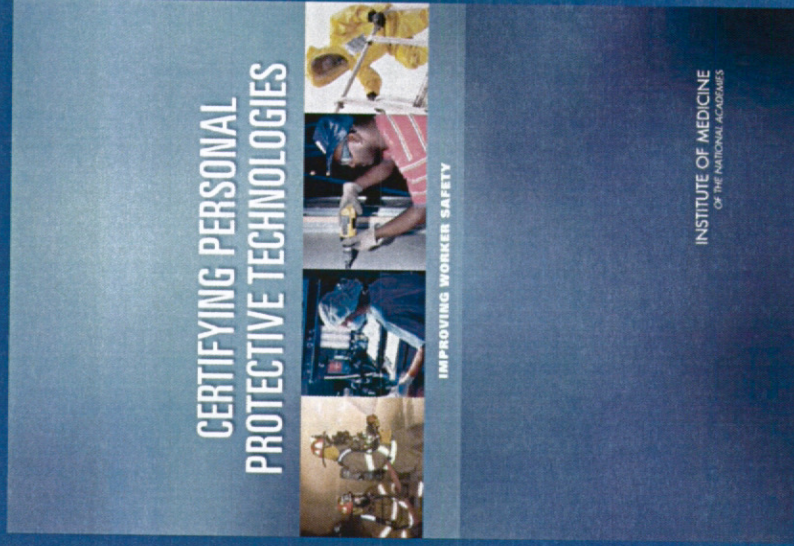


# **Certifying Personal Protective Technologies**

## **IOM Report released Nov 11, 2010**

Report is available via:  
National Academies Press  
website: [www.nap.edu](http://www.nap.edu)

Free PDF file of the report and 4-  
page report brief will be available





# Standard Development Organization Support

- National Fire Protection Association (NFPA)
- American Standard for Testing (ASTM)
- American National Standards Institute (ANSI)
- International Standards Organization (ISO)



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# 42 CFR Module Development Strategy

## Respirator Standards Timeline



### NOTES:

#### Docket Comment Period Closed:

- CCER (June 19, 2009)
- QA Module (October 9, 2009)
- TIL (half-masks & FFR) (September 30, 2010)

- PAPR/SAR - Powered Air-Purifying Respirator/Supplied Air Respirator
- EOSTI - End of Service Time Indicator
- CCSBA - Closed Circuit Self-Contained Breathing Apparatus
- CBRN CRU - CBRN Combination Respirator Unit
- AFE - Air Fed Ensemble
- ANPRM - Advance Notice of Proposed Rulemaking
- NPRM - Notice of Proposed Rulemaking



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## Summary

- Federal movement to use National and International Consensus standards
- Regulation gives NIOSH the tools to test and certify respirators
- NIOSH should define the content of the regulation through:
  - the definition of the standards necessary to provide respiratory protection
  - the rulemaking process



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## **Input Sought from Stakeholders**

- What classes of Respiratory protection should be addressed next in the regulatory agenda?
- What aspects of National and International Standards should be considered in updates to 42 CFR Part 84?
- Should NIOSH consider removing specific performance criteria from the regulation?
- Should NIOSH consider identifying sector specific performance capability assessments?
- Other perspectives?



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# **Information Docket**

## **NIOSH Regulatory Agenda for updating 42 CFR Part 84**

- **Mail:**  
NIOSH Docket Office  
Robert A. Taft Laboratories, M/S C 34  
NIOSH Docket **221**  
4676 Columbia Parkway  
Cincinnati, OH 45226
- **Email:** [niocindocket@cdc.gov](mailto:niocindocket@cdc.gov)
- **Fax:** (513) 533-8285
- **Phone:** (513) 533-8611
- **NPPTL Web Site:** <http://www.cdc.gov/niosh/npptl>



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