



Centers for Disease Control and Prevention
National Institute for Occupational
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February 16, 2011

National Institute of Standards and Technology
100 Bureau Drive
Stop 1060
Gaithersburg, MD 20899-1060

Docket Number 0909100442-1012-03

Dear Sir/Madam:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the National Institute of Standards and Technology (NIST) request for information on *Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization* published in the *Federal Register* on December 8, 2010 [75 FR 76397]. Our comments and references are enclosed.

Please do not hesitate to contact me at 513/533-8302 if I can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Paul A. Schulte".

Paul A. Schulte, Ph.D.
Director
Education and Information Division

3 Enclosures



Comments to NIST

**Comments of the National Institute for Occupational Safety and Health on the
National Institute of Standards and Technology
Request for Information
Effectiveness of Federal Agency Participation in Standardization in
Select Technology Sectors for
National Science and Technology Council's Sub-Committee on Standardization**

Docket No. 0909100442-0563-02

**Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Cincinnati, Ohio**

2/16/11

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the National Institute of Standards and Technology (NIST) request for information (RFI) *Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization* published in the *Federal Register* (FR) on December 8, 2010 [75 FR 76397]. The following comments regarding NIOSH engagement in standard-setting activities are intended to assist NIST in examining the effectiveness of Federal agency participation in standards-setting efforts led by the private sector. Our responses correspond to the RFI questions.

Standards-Setting Processes, Reasons for Participation and the Benefits of Standardization

Q. Who participates in standards-setting activities?

Response: NIOSH researchers, scientists, and engineers recognized as subject matter experts (SMEs) participate on an array of technical committees of numerous national and international standards development organizations (SDOs). Involvement of some researchers in American Society for Testing and Materials (ASTM International) and International Organization for Standardization (ISO) work was initiated by former division directors who saw the value of these activities in technology transfer, collaboration, and generation of new research ideas.

Q. What are the most important reasons for participation?

Response: Participation in standards setting activities supports the NIOSH mission to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the betterment of workers. NIOSH conducts scientific research to address knowledge gaps and disseminates scientific knowledge to aid in the development of standards, guidance, and authoritative recommendations. For example, the mission of NIOSH includes supporting the development of personal protective equipment (PPE) performance standards to enhance worker safety. NIOSH research data are used by private standards development organizations to update existing protective clothing and equipment standards and develop new standards.

Addressing the recommendations of the Institute of Medicine (IOM) report, *Certifying Personal Protective Technologies: Improving Worker Safety* (2010), to establish risk-based conformity assessment processes for non-respiratory PPE may initiate a number of additional standards-development committees to initiate or upgrade certification standards. If this occurs, stakeholder interest in participation would likely increase with the expanded number of standards-setting activities. The report can be accessed at (http://www.nap.edu/catalog.php?record_id=12962).

Q. What are the benefits of developing standards for this sector?

Response: Employers and workers depend on consensus-based standards developed by private organizations to insure the availability and use of PPE with appropriate levels of protection against dermal, inhalation, and physical exposure hazards. PPE is used when engineering controls are not adequate to reduce exposure hazards to acceptable levels. Involvement in standards development helps NIOSH maintain awareness of new developments and the state of the art in the field.

Examples of NIOSH products emanating from standards development activities are listed in subsequent responses.

Q. How do the standards impact organizations and their competitiveness?

Response: Organizations could include Federal agencies, their partners, and their stakeholders. For NIOSH, standard-setting activities help identify research opportunities and emerging health and safety issues. For manufacturers, they provide performance and design requirements for their products and a minimum level of quality and performance for competing products. Consumers (employers and workers) receive assurance in expectations of product quality, level of safety, and performance commensurate with certification of conformance to the standard.

Q. How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?

Response: There are many examples in NIOSH. In the case of worker protective clothing and equipment, the activities of standards development organizations is vital to enhancing the protective performance of PPE and the development of new performance criteria in product certification standards. Revisions to current standards and the development of new standards encourages product manufacturers to develop PPE with improved worker protection levels and drives research into improved products offering enhanced protection. Good examples are the National Fire Protection Association (NFPA) fire and emergency services protective clothing and equipment standards and the ASTM International protective clothing and equipment standards.

NIOSH researchers also participate in developing national and international consensus standards on the measurement of workplace toxins. Those standards are used for health-related research, the support of implementation of control measures, or decision-making regarding compliance with good air quality. The national body engaged in their development is ASTM International. NIOSH researchers obtain Institute permission to become members of ASTM International as an official duty and may vote according to ASTM International procedures.

The International Standards Organization (ISO) is engaged in similar work. NIOSH researchers obtain Institute permission to join the U.S. delegation as an official duty and may make technical contributions to the U.S. position and national vote. Both ASTM International and ISO committees include sub-committees (SC) specific to standards in workplace atmospheres (i.e., ASTM D22.04 and ISO TC 146 SC 2); NIOSH researchers participate in sub-committee activities and their respective working groups (WGs). The active WGs in ISO TC 146, SC 2 are the following:

- WG 1 Particle Size-Selective Sampling and Analysis
- WG 2 Inorganic Particulate Matter
- WG 4 Organic Vapors
- WG 5 Inorganic Fibers
- WG 7 Silica
- WG 8 Assessment of Contamination of Skin and Surfaces from Airborne Chemicals
- WG 9 Sampling Pump performance

For more information about the work and relevance of ASTM D22.04 and ISO TC 146 SC 2, see Ashley and Harper [2004, 2005].

Q. What is the current phase of the standards development process for this technology?

Response: Regarding air sampling and analysis, Ashley and Harper [2004, 2005] address advancements in sampling methods, analytical protocols, and instrumentation. Many examples can be given for other NIOSH research and development activities; some are included in this response.

Most standards development activities with NIOSH participation have established revision cycles. A typical periodicity for technical revision is five years, and the cycles vary according to the SDO responsible for the standard and the date of its last revision.

Q. How has the process worked so far?

Response: Participation in consensus standards development activities has proved to be an effective use of NIOSH resources for the transfer of technology developed in NIOSH research. For air sampling and analysis, see Ashley and Harper [2004, 2005]. Many examples exist for other NIOSH research and development activities.

Q. When developing standards, how are the standards-setting processes managed and coordinated?

Response: Ashley and Harper [2004, 2005] address the processes for air sampling and analysis. The consensus standards organizations (i.e., ASTM International and ISO) have their own well-developed and well-managed processes.

NIOSH helps prevent work-related injury, illness, and death by advancing the state of knowledge and application of PPT through relevant and timely PPT research, training, and evaluation. NIOSH activities include the following:

- Respirator certification and technology development
- Policy, standards, and guidance development
- Technology research
- Surveillance and communications

PPT in this context is defined as the technical methods, processes, techniques, tools, and materials supporting development and use of PPE worn by individuals to reduce the effects of their exposure to a hazard. NIOSH standards development activities fall under Item 6 (page 76397): "Other technologies involving significant Federal agency participation in standards setting" and include performance criteria, certification standards, and selection, care, and maintenance standards for PPE and protective clothing.

Q. Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?

Response: Organizations such as ASTM International and ISO have established strategic plans. NIOSH does not define standards needs and standards development life cycles. However, the NIOSH Strategic Plan recognizes that improvements in personal protective technology are realized through better standards and regulations and subsequent availability of PPE that complies with standards and regulations.

Commitment to continuous improvement of PPE is reflected in program actions such as (1) conducting research projects addressing technology gaps and providing research data used by SDOs in their standards development activities; (2) establishing Memoranda of Understanding with NFPA, ASTM, and ISEA to define cooperative partnerships that include standards development activities; (3) sponsoring active participation of program scientists in SDO committee meetings and associated activities; and (4) establishing annual performance plans for staff defining their SDO activities.

Commitment also is demonstrated through research emphasis areas in Chemical, Biological, Radiological and Nuclear (CBRN) protection requirements and in national protective clothing standards.

NIOSH actively participates in standards development activities with the ISO, American National Standards Institute (ANSI), NFPA, ASTM, Canadian Standards Association International (CSA), and the International Safety Equipment Association (ISEA) in the areas of respiratory protection, hearing protection, eye and face protection, fall protection, industrial head protection, and protective clothing. These standard writing activities address PPT performance, use, and maintenance. User involvement in SDO activities helps improve comfort, utility, and wearability.

Q. Are there barriers to developing high level strategies for standard-setting activities?

Response: Indifference, unfamiliarity with the National Technology Transfer and Advancement Act of 1995 (NTTAA), and lack of resources, funding, and support can be barriers.

Perspectives on Government's Approach to Standards Activities

Q. What methods of engagement are used by Federal agencies to participate in private sector led standards development?

Response: Ashley and Harper [2004, 2005] address the engagement methods for air sampling and analysis. Other examples are given elsewhere in this response. NIOSH makes an effort to support in-person attendance of researchers at meetings so they may actively participate in standards development activities.

Q. How transparent is each method?

Response: For air sampling and analysis, this matter is addressed in Ashley and Harper [2004, 2005]. The ASTM International process is one of the best methods; it is open and due process is

exemplary and laudable. There can be challenges in the ISO process if some countries act as a bloc and publish standards against the wishes of other national representatives.

Q. How could the methods be improved?

Response: Consensus standards activities are well established in ASTM International and ISO. In ASTM International standards development, every member has a vote. In the ISO process, it is one vote per country which occasionally results in bloc voting (as stated above).

Q. What other methods should the Federal agencies explore?

Response: Consider education of agency leadership regarding requirements of the NTTAA.

Q. What impact have Federal agencies had on standards activities?

Response: NIOSH impact has been extensive. Participation allows NIOSH experts to provide an impartial contribution to the process that may not be feasible in the private sector. Many published international standards promulgated by ASTM International and ISO had NIOSH authorship/co-authorship.

Additional consensus standards-setting organizations with NIOSH collaboration include:

1) National Fire Protection Association (NFPA) Technical Committees on:

- Fire and Emergency Services Protective Clothing and Equipment (FAE-ACC)
- Electronic Safety Equipment (FAE-ELS)
- Emergency Medical Services Protective Clothing and Equipment (FAE-EMS)
- Hazardous Materials Protective Clothing and Equipment (FAE-HAZ)
- Respiratory Protective Clothing and Equipment (FAE-RPE)
- Special Operations Protective Clothing and Equipment (FAE-SCE)
- Structural and Proximity Protective Clothing and Equipment (FAE-SPF)
- Wildland Fire Fighting Protective Clothing and Equipment (FAE-WFF)

NIOSH chairs the overarching Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment and the Technical Committee on Emergency Medical Services Protective Clothing and Equipment, and the Principal and Alternate members on all NFPA Technical Committees listed above. The following are examples of NIOSH leadership roles and research leading to revisions to NFPA protective clothing and equipment standards:

- Development and incorporation of optional CBRN protective ensemble performance requirements into NFPA 1971 Standard on Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting, 2007 Edition.
- Development and incorporation of mandatory CBRN performance requirements into NFPA 1981 Standard on Open-Circuit Self-Contained Breathing Apparatus (SCBA) for Emergency Services, 2007 Edition.

- Revision of NFPA 1982 Standard on Personal Alert Safety Systems (PASS), 2007 Edition with new testing procedures and performance criteria to overcome high temperature performance failures.
- Development of NFPA 1994 Standard on Protective Ensembles for First Responders to CBRN Terrorism Incidents, 2007 Edition.
- Development of additional performance requirements based on NIOSH research into NFPA 1999 Standard on Protective Clothing for Emergency Medical Operations, 2008 Edition.

2) ASTM International:

- E54 Homeland Security Applications Committee
- E54.04 Personal Protective Equipment
- F23 Protective Clothing and Equipment Committee
- F23.20 Physical Hazards
- F23.30 Chemical Hazards
- F23.40 Biological Hazards
- F23.60 Human Factors
- F23.70 Radiological Hazards
- F23.80 Thermal Hazards
- F23.95 Planning
- F23.97 Sub-committee on Liaisons
- F23.96 ISO Technical Advisory Committee
- E56 Nanotechnology Committee

NIOSH personnel had committee leadership roles and provided supporting research that led to the development and release of the following ASTM standards:

- ASTM F2588-07 Standard Test Method for Man-In-Simulant Test (MIST) for protective ensembles
- ASTM F2704-10 Standard Specification for Air-Fed protective ensembles
- ASTM F2668-07 Standard Practice for Determining the Physiological Response of the Wearer to protective clothing ensembles
- ASTM F2731-10 Standard Test Method for measuring the transmitted and stored energy of firefighter protective clothing systems

3) U.S. Department of Justice (DOJ) and National Institute of Justice (NIJ):

NIOSH scientists served on the Special Technical Committee established by DOJ and NIJ that developed the "CBRN Protective Ensemble Standard for Law Enforcement, NIJ Standard-006.00" released in November 2010.

4) ANSI:

- ANSI Z88 ASC – Respiratory Protection
- ANSI Z88.2 Respiratory Selection and use
- ANSI Z88.6 Medical Qualifications for Respirator Wearers
- ANSI Z88.7 Color Coding for Cartridge and Canisters
- ANSI Z88.10 Fit Test Methods
- ANSI Z88.12 Respirator Selection for Biohazards
- ANSI Z88.14 CBRN Respirator Selection and Use

5) ISEA:

- ISEA-ANSI Z87.1 Eye and Face Protection
- ISEA-ANSI Z89.1 Head Protection
- ISEA-ANSI 103 Classification and Performance Requirements for Chemical Protective Clothing
- ISEA-ANSI 110 Smoke Hoods

6) CSA:

- CSA Z94.4 Respirator Selection and use
- CSA Z180.1 Breathing Air Systems

7) ISO:

- ISO TC94/SC6 Eye Protection
- ISO TC94/SC13 Protective Clothing
- ISO TC94/SC15 Respiratory Protective Devices

NIOSH scientists also participate in non-government organizations developing consensus guidance for selection, care, and maintenance of PPE. Examples include the American Industrial Hygiene Association (AIHA) Protective Clothing and Equipment Committee and Respiratory Protection Committee.

Q. When Federal agencies have been involved in standards setting efforts in a technology sector, how has the progress of standards setting efforts in this technology sector changed after Federal agencies became involved?

Response: Federal regulatory responsibilities, such as NIOSH respirator certification requirements, often are strong motivators for standards-setting efforts.

Adequacy of Resources

Q. What resources are needed to successfully complete the efforts?

Response: Assuring dedicated time for staff to work on the standards to which they have been approved as NIOSH representatives is very important. Support for travel to committee meetings and similar events is also needed. Currently, many standards development activities are accomplished through electronic exchange of information and web-based meetings to reduce the need and expense of travel. However, face-to-face participation is important for frank and open discussion.

Q. What resource constraints impact the successful completion of the standards efforts?

Response: There has been no specific Institute barrier to the participation of NIOSH researchers. However, resources necessary for participation, particularly for meeting attendance, compete with other budget priorities. Support for consensus standards activities within Agency structures is needed to positively impact the success of standards development. A strong commitment to budgetary support coupled with recognition and appreciation for continued participation would provide direct, positive motivation for participation.

Process Review and Improvement Metrics

Q. How has this information been documented or disseminated, and implemented?

Response: In the field of air sampling and analysis, much of this is covered in Ashley and Harper [2004, 2005]. Collaboration with national and international researchers in standards-setting activities has led to valuable research studies and numerous peer-reviewed publications.

Q. What kinds of performance metrics are appropriate to measure the effectiveness of the standards-setting process?

Response: Useful performance metrics are: the standards promulgated, peer-reviewed articles published, and agency compliance with the NTTAA.

Q. If any such performance metrics have been used, what are the results?

Response: In air sampling and analysis, there are many scientific products generated in addition to the standards themselves, notably peer-reviewed scientific papers and publications, and numerous intangible benefits.

References

Ashley K, Harper M [2004]. ASTM Standards for monitoring chemical hazards in the workplace. *Standardization News* 32(4):22–25.

Ashley K, Harper M [2005]. ASTM International Standards for monitoring chemical hazards in workplaces. *J Occup Environ Hyg* 2:D44–47.