

A New Direction for the National Institute for Occupational Safety and Health Respirator Certification Program*

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Background

The National Institute for Occupational Safety and Health (NIOSH) is mandated by Federal Law to establish and administer an occupational respiratory protective equipment certification program.

To ensure that respirators perform as intended by design, additional rules addressing respirator performance and manufacturing requirements were added to the United States code. The Institute is authorized by Title 30, Code of Federal Regulations, Part 11 to certify and audit respirator performance, and manufacturing quality systems.

Respirator use at the worksite is regulated by the Federal Occupational Safety and Health Administration (OSHA) under Title 29, Code of Federal Regulations, Part 1910.134. This regulation includes requirements specifying when a respirator is required, details of a written respiratory protection program, respirator maintenance,

selection, instruction criteria, and training in the proper use of respirators.

The origins of the Federal respirator certification program go back to 1919 when the Bureau of Mines (BOM) established performance requirements for self-contained breathing apparatus (SCBA) and gas masks. These respirators were primarily for protection of rescue workers following a mine disaster. The certification requirements underwent several expansions and revisions in the decades that followed. For example, in 1934 the Bureau introduced performance requirements for particulate respirators. These certification requirements addressed respirators that were used in mines, but did not cover manufacturing processes or other occupations.

The respirator certification program's origins can also be traced to the Bureau of Entomology and Plant Quarantine. In 1949 this department invited respirator manufacturers to submit products for evaluation against pesticides. This led to the listing of gas masks and chemical cartridge respirators that passed their evaluation. In 1969, at the request of the Department of Agriculture,

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the Bureau of Mines assumed the task of evaluating pesticide respirators.

In 1970, the Occupational Safety and Health Act was legislated that required all respirators used in the workplace to be NIOSH Certified. Each Bureau was still permitted to certify their occupational respirators but OSHA would only accept NIOSH certification for regulatory and enforcement actions. In 1972, the BOM transferred their respirator certification program (including those duties inherited from the Department of Agriculture) to NIOSH.

Another significant regulatory legislation was passed in 1977 that had an impact upon the certification program. It was the promulgation of the Mine Safety and Health Act. This Act requires the joint approval of respirators used in mining by the Mine Safety and Health Administration (MSHA) and NIOSH.

Today's certification program is a hybrid collection of governmental regulations. These were established by different departments within the federal government that spanned more than 70 years. The respirator certification standards were developed to address specific occupational needs and respirator performance concerns. While many revisions have been made throughout the years, many standards are technically obsolete and must be substantially upgraded. If nothing else, this history of fragmented technical requirements and diverse program administration, demonstrates the need for contemporary certification standards. Technological innovation is restricted, and workers are denied vastly improved protection that could be made more readily available by a new certification concept.

Current Certification Program

The respirator certification program is mandated in the Code of Federal Regulations Title 30, Part 11. The program consists of five primary functions: respirator certification; quality assurance of the respirator manufacturing or production processes; investigation of complaints concerning certified respirators; technical assistance to users, manufacturers, and other safety professionals; and standards development for the improvement of certification standards. This program services 6 to 7 million workers, and processes 500 manufacturer applications annually. Approximately 80% of the applications received are granted certification status. Seventy-five percent of the applications received are for air-purifying respirators.

The certification process requires the manufacturer to submit an application stating the type and intended protection of the respirator, samples of respirators, test data, a written quality program, and engineering drawings. The Institute reviews these applications, conducts performance tests, evaluates the respirator design, evaluates the manufacturer's quality program, and then approves or denies the application.

The Institute's certification duties comprise a diverse range of technical responsibilities, including performance testing, audit testing, product

evaluation, drawing comparisons and archiving, quality system evaluations, manufacturing-site quality assurance auditing, product reliability assessments, standards development, investigations of nonconforming certified respirators, and technical assistance.

This process is resource intensive. Therefore, staff size and budget directly affects accomplishments and progress. A new process is needed, one that broadens the influence of the certification program without requiring proportionally more resources. A vision and a transition process have been formulated that will create substantial benefits to workers, respirator manufacturers, business operators, and governmental regulatory agencies. The benefits include:

- (1) enhanced respiratory protection for workers by making technically improved respirators readily available;
- (2) improved quality of the certification program by having it congruent with international standards; and
- (3) stimulus for manufacturers to invest in innovative respirator development.

Internationally Integrated Certification Program

The five-year vision of NIOSH is to achieve an internationally integrated certification program. The primary elements of this vision include

- The integration of NIOSH-certification requirements with international performance, reliability, and quality system standards.
- A regulatory reform program that permits continuous improvements to the certification requirements through a modular approach to rulemaking.
- An electronic information system that permits worldwide, electronic communications with NIOSH via computer technology.

Each of these elements is described below.

International Standards Integration

Performance standards for respirator certification are currently described in 30 CFR 11. The Part 11 standards have not been revised since 1972 and many are much older. Some of these standards represent obsolete technology. For example, the silica dust and silica mist tests of Part 11 have remained virtually unchanged for 60 years. Today, science and technology provide vastly improved methods and instruments for evaluating respirator filter efficiency.

The most recent published proposed revision of the respirator certification standards is represented by the 1987 draft of 42 CFR 84. These requirements have not yet been promulgated. The recommendations in this regulatory proposal were started 10 to 15 years ago. Our scientific and technical knowledge has greatly improved since that time. Our administrative and program knowledge has improved, as evidenced by concepts such as total quality management and continuous improvement philosophies. Even our partnerships have improved. While many of these earlier standards are still appropriate today, the promulgation efforts of 1993 provide a unique opportunity that just was not available then. New regulatory reform efforts offer an opportunity to seriously consider international standards. The trend towards multinational common markets, free trade agreements and international standardization or

harmonization make this unique opportunity a possibility.

Quality system standards are a special part of the international harmonization activities. The ISO-9000 quality system standards provide a rare opportunity for the establishment of a novel certification program. ISO-9000 establishes, for the first time, uniform quality system standards for manufacturers and a qualification program for quality system auditors. These standards are gaining global acceptance. They provide a tool that NIOSH can use to expand and improve its certification program with minimal increases in governmental resources. The Institute is considering acceptance of ISO-certified QA systems and auditors. The quality of both the product and the audits conducted will improve.

The current NIOSH audit program is severely limited. The number of both product and manufacturing-site audits are limited by governmental resources available to conduct the audits. The Institute is considering the use of certified auditors and accredited laboratories to remove this limitation. The Institute is also considering the use of accredited laboratories to conduct certification tests. Prior to the establishment of ISO-9000 quality system standards, there were no universally accepted QA standards or auditor qualifications. ISO standards provide a vehicle for NIOSH to adopt unique certification philosophies that empower the talents and resources within the private sector, but retain its leadership role and the integrity that the Institute brings to the program.

Reliability standards are not contained in 30 CFR 11. Part 11 specifies respirator performance criteria and quality assurance requirements, but does not contain reliability engineering standards.

In the mid to late 1980s, several reports were received from within the mining industry that identified performance failures with a number of different self-rescuers. These reports prompted investigations that were jointly conducted by experts of NIOSH, MSHA, and BOM. The investigations provided governmental decision makers with information indicating that the performance and quality assurance standards of Part 11 were insufficient to assure the reliable performance of

field-deployed respirators. Although the product designs were in conformance to standards and specifications, and the quality systems of the manufacturers appeared to be adequate, many of the performance failures were determined to be related to reliability issues. These issues were associated with product design and performance, conditions of use and storage, and duration of use or product age. New regulatory reform efforts provide an opportunity to add reliability standards to the certification requirements.

Regulatory Reform

Over a decade of effort has failed to produce a single regulatory enhancement to the Part 11 standards. A movement to reform the regulatory process has begun. Under the new approach, the standards would be upgraded in a series of steps or modules rather than a comprehensive, "all or nothing" approach. Each regulatory module would address a particular needed improvement.

The modular approach has many potential advantages:

- It would allow the Institute to organize rulemaking in order to promulgate regulation changes in priority order. Those affecting the greatest number of workers and those most important to health and safety would be implemented first.
- It would facilitate and encourage public participation by dividing the 1987 regulatory proposal into separable constituent

parts, each of which is more manageable than the whole.

- It would provide the Institute the opportunity to integrate international standards that are not considered in the present proposal.
- It would enable the Institute to establish and redirect resources to implement the new certification program incrementally on a priority basis.

Electronic Information System

An electronic information system is the communications vehicle and information-management component of the vision. It will provide the following capabilities: an electronic records archive of certification information; integrated databases; incorporated automated test results; an administrative tracking system; and a communications method for sharing information both nationally and internationally in real-time. Both audio and visual communications through the computer are possible. An electronic-based information system allows certification-related information to be available to the public in the form of databases. It allows the integration of specific databases and makes the information instantly available to those who need it and have the computer equipment to access the system. It provides NIOSH with a communications method that is much superior to the current methods of writing letters or placing telephone calls.

Transition Philosophy

The process for achieving the vision involves the unique integration of four philosophies: continuous improvement, industry empowerment, matrix management, and goal champions.

Continuous improvement embodies the spirit of total quality management (TQM). Employees are encouraged to participate in the decision-making associated within their area of work. Standard operating and test procedures are constantly evaluated for improvement opportunities. Performance measures of effectiveness and performance assessment tools are used to improve organizational quality and productivity. The primary areas

of work that are subject to continuous improvements from suggestions by employees include: processing applications for NIOSH certification; performing both pre-assessment and post-assessment of the manufacturing site and product; investigating product complaints; providing technical assistance; and developing improved technical standards, tools, and programs.

Empowering industry entails the philosophy that the Institute could greatly expand resources and expertise by establishing partnerships with industry. An empowered industry expands both the amount and qualifications of the resource base

that could be applied to improve worker safety and health. For example, the Institute could authorize qualified laboratories to perform standardized certification tests, thus increasing the resources available for conducting certification testing. Another example of enabling industry and effectively expanding the Institute's resource base is the use of ISO-certified quality auditors to conduct manufacturing site audits. The current certification program is obviously limited by funding, facilities, staff, and laboratory equipment. These limitations are greatly reduced when the pool of resources is drawn from an empowered industry.

Matrix management principles are used to integrate Program Managers into the conventional product (functional) structure. The functional or product structure consists of two sections organized by class of respirator: the Air-Purifying Respirator Section and the Air-Supplied Respirator Section. These Sections are supervised and managed by a Section Chief. The Section staff provides the expertise to perform all of the Branch projects and assignments.

Three program managers have been appointed who have authority and responsibility for a specific program area. The program areas include the quality assurance system, Part 84 regulatory

reform, and the electronic information system. These program areas support the components of the vision. The Program Managers administer a program; they do not directly supervise staff. This relieves them from time-consuming supervisory duties and permits them to focus on achieving program goals and objectives.

Within this matrix structure the ongoing projects and activities of the certification program are addressed by the Section Chiefs, while the programs crucial to achieving the vision are directed by the Program Managers.

Goal champions are established to lead Branch programs and projects in achieving specific goals and objectives. Each Program Manager or Project Manager, the "champion," provides technical leadership, energy, and enthusiasm while coordinating activities within a program area or on a project. Goal champions are also established for special projects that require a high degree of focus and specialization. Developing an audit decision logic, compiling of international respirator performance standards, conducting bio-aerosol respirator research, and organizing a protective technology workshop are examples of efforts where goal champions have been utilized on projects.

Conclusion

The five-year vision of NIOSH is to achieve an internationally integrated certification program. The primary elements of this vision include: the integration of NIOSH certification requirements with international performance, reliability, and quality system standards; a regulatory reform program that permits continuous improvements to the certification requirements through a modular approach to **rulemaking**; and, an electronic information system that permits worldwide, electronic

communications with NIOSH via computer technology. The transition to this new certification philosophy will maintain the integrity that the current program enjoys, continue Institute leadership while empowering the private sector, and provide a certification system that continuously improves itself and the products that receive certification. As a result, NIOSH will ensure that the best respiratory protection available is provided to workers.