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SAFETY EQUIPMENT INSTITUTE

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August 13, 1996

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, OH 45226

Re: NIOSH *Federal Register* Notice 61 FR 24740, Request for Public
Comments: Changes to Administration of Respirator Certification and
Establishing Priorities for Future Rulemaking

Dear Sir/Madam,

The Safety Equipment Institute (SEI) is pleased to provide the following response to the May 16, 1996 *Federal Register* Notice requesting comments on revisions to current NIOSH procedures for certifying respiratory devices used to protect workers in hazardous environments.

SEI is a private, non-profit organization established in 1980 to administer the first non-governmental, independent certification programs to certify a broad range of safety and protective equipment used by American workers. SEI's certification Programs are accredited by the American National Standards Institute (ANSI) to the standard ANSI Z34.1-1993, *Third Party Certification Programs for Products, Processes and Services*. SEI's accreditation was accomplished through a rigorous one-year application and auditing process conducted in accordance with ANSI policies and demonstrates SEI's compliance with ten ISO Guides pertaining to product testing, inspection and certification.

The purpose of SEI's certification program is to assist government agencies, along with users and manufacturers of safety equipment in meeting their mutual goal of protecting those who use safety equipment from workplace hazards. SEI currently operates certification programs for 45 types of safety products used by millions of workers. Over 70 manufacturers participate in SEI's third party certification programs that include annual testing of products to national consensus standards and ongoing quality assurance audits of each manufacturer's facility. SEI's certification programs rely on the scrutiny of an independent laboratory for product testing and an independent quality assurance auditor who performs an audit on site at the manufacturing facilities.

SEI is an objective organization as is reflected by the wide cross-section of interests represented on its Board of Directors. The Board represents corporate users of safety equipment representatives from organized labor, the insurance industry, the fire service and one safety equipment manufacturer.

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A. Priority of Technical Modules

Issue 1.

(1) What criteria should be used to rank the priority of each module?

It is SEI's suggestion that the priority of the various modules should be primarily based on the safety of the user of the particular product involved. This would include consideration of levels of risk, which may be quantified by the severity of the hazards involved and the frequency/extent of exposure to the hazards. Of next importance is the role of the user for the safety of others who may be exposed to the hazards. Respirator equipment for the fire service is cited as an example of a module deserving a high priority. The fire fighters expose themselves to the hazards of fire and perform a vital service in rescuing others.

Issue 2.

(1) What changes to current respirator certification requirements are needed in the modules identified in this notice?

Current NIOSH requirements for positive pressure self-contained breathing apparatus (SCBA) contain a weight limit of 35 pounds. This limit is endorsed and quoted in the National Fire Protection Association standard for the apparatus (NFPA 1981). Recent advances in the integration of equipment for fire fighters, however, are demonstrating the potential for achieving reductions in the total weight of the equipment by integrating some items with the SCBA. It is recommended that the NIOSH requirements be revised to permit an Integrated SCBA to weigh more than 35 pounds, provided it can be demonstrated that the unit's weight is less than the net weight of the individual parts.

The NFPA Technical Committee responsible for drafting the *Report on Proposals* for the upcoming 1997 Edition of NFPA 1981 is proposing to revise the standard to permit such a weight increase, up to 40 pounds. It is timely now for NIOSH to address this subject, and to indicate its concurrence to the weight increase as qualified above.

(2) Are there existing national standards that could be adopted by NIOSH to replace current certification requirements pertaining to a given module?

The NFPA 1981 Standard mentioned above is nationally recognized as the pre-eminent standard for SCBA for the fire service. As to be discussed later, it includes requirements for third-party certification based on pre-testing, as well as requirements for annual re-certification and for evaluation and semi-annual audits of the manufacturer's quality assurance program. However, in its present form it could not replace the NIOSH standard, as it is intended to augment the NIOSH standard by requiring that SCBA be NIOSH approved. It would require additional provisions in order to maintain the present level of protection which has been achieved by the combined standards.

B. Administrative/Quality Assurance Module

Issue 1.

(1) Are private sector testing laboratories capable of conducting the respirator testing currently performed by NIOSH?

Absolutely. SEI has a proven track record with fifteen years' experience in administering certification programs for safety and protective equipment. Since its inception, as SEI certification programs expanded and new standards were developed, SEI has secured laboratories with the necessary professional expertise and testing capabilities. SEI requires all of its testing laboratories to maintain compliance with ISO Guide 25:1990 - *General Requirements for the Competence of Calibration and Testing Laboratories*. Additionally, the competence of SEI, as the third-party certification organization, and Inchcape Testing Services- ETL Testing Laboratories (ETL), as the testing laboratory, to conduct respirator testing and certification have been well demonstrated during the four years since the NFPA standard instituted the requirements for third-party certification (the 1992 Edition of NFPA 1981). The SEI SCBA certification program has been effective in the certification of approximately 17 different models of SCBA (by nine different manufacturers) to the requirements of the standard which, as stated above, also requires confirmation of NIOSH approval. In a continual process, new variants and accessories to the certified models are pre-tested before certification. All models are annually tested for recertification through a program of random sampling by SEI's quality assurance auditor during the semi-annual audits of all manufacturing facilities.

Use of a private, third-party certification organization and testing laboratory would present a significant advantage to NIOSH, in that it would allow the NIOSH resources to be focused on other than pre-approval testing activities. NIOSH would be better able to accomplish important functions such as research to support standards development, investigation of accidents and field reports of malperformance, monitoring of market

practices, etc. The NIOSH letter of May 23, 1996, regarding the use of unapproved supplied-air respirators in the paint spray and automotive refinishing industries, is a good example of the important role to which NIOSH could give greater emphasis if its pre-testing resources could be re-directed.

(2) What qualification requirements should NIOSH require of private laboratories who perform certification and product testing under NIOSH guidance?

As mentioned above, SEI, as the administrator of the certification program, complies with ANSI - Z34.1-1993. As part of that accreditation, SEI's laboratories must comply with ISO Guide 25. To ensure continued compliance, SEI conducts audits of its laboratories annually for compliance to the ISO Guide 25. Additionally, once SEI received its accreditation by ANSI, SEI agreed to periodic monitoring, audits and surveillance of the SEI certification programs, at least annually to maintain the ANSI accreditation.

As evidence of the reliance on accreditation of certification program administrators or sponsors, the *Report on Proposals* for the upcoming 1997 Edition of NFPA 1981 includes new requirements that the third-party certification organization shall be accredited for personal protective equipment by the American National Standards Institute (ANSI) in accordance with ANSI Z34.1-1993. It is the intention of the NFPA Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment to include this requirement in all NFPA standards within its jurisdiction.

(3) Should NIOSH assign the testing of a manufacturer's respirators to laboratories approved by NIOSH or should the manufacturer be permitted to use the laboratory of choice among approved laboratories?

SEI, as an accredited certification organization, is in a position to select laboratories with the appropriate capabilities for the particular product involved. Use of a third-party certification organization such as SEI by NIOSH would obviate the need for use of resources to maintain lists of approved laboratories or to assign testing to specific laboratories, and would prevent potential problems arising from maintenance of such a list. Additionally, a program such as SEI's guarantees a level of consistency and uniformity of testing for all participating manufacturers that we do not believe is possible in a more loosely structured arrangement, such as a list of labs to be self-selected by the manufacturer. The advantage of this system for the testing lab is that the lab maintains its independence; SEI, not the manufacturer is the client. The advantage of this system for the manufacturer is the enhanced marketplace value of the resulting certification.

(4) What type of monitoring should NIOSH perform to assure that private sector laboratories continue to provide quality service?

Requiring the use of a certification organization which is accredited to ANSI Z34.1 - 1993 assures continued monitoring by ANSI to meet the accreditation requirements. As mentioned above, SEI is subject to annual audits by ANSI personnel to ensure continued compliance to the ten ISO Guides. As part of this program, ANSI audits: (1) SEI headquarters, (2) SEI's contract testing laboratories to ISO Guide 25, (3) SEI Quality Assurance auditors to ISO Guide 30:1988 -E, *General Requirements for the Acceptance of Inspection Bodies*, and (4) onsite audits conducted by SEI QA auditors at participating manufacturer's facilities. This comprehensive program conducted by ANSI is another advantage of using a third-party certification organization over individual testing laboratories. The entire program falls under one umbrella and every component of the certification process is accountable to the administrator, SEI, who is monitored by ANSI.

On a daily operational level, SEI's internal procedures mandate continual oversight of all laboratory testing. No testing can commence without SEI authorization. If a retest of any product is necessary, the company involved must report to SEI the results of its investigation of the noncompliance that occurred and its corrective action taken. This information is supplied to SEI's Quality Assurance Auditors who, when applicable, take steps to ascertain during the next audit that the corrective procedures have been correctly implemented and documented.

Issue 2.

Utilization of SEI's certification program would again allow NIOSH to focus its resources on research and other monitoring areas in the field. SEI's two-pronged approach to product certification is a time-tested approach that has worked for 15 years. Independent testing is only one requirement for SEI certification. Before permission to use the SEI label is granted, the manufacturing plant must also pass a quality assurance audit. These audits are conducted on location at a manufacturer's facility by SEI's independent auditor who has appropriate engineering and product expertise. The purpose of the audit is to establish that the manufacturer is capable of producing quality products consistently, and that all product variations are fully documented. In order to meet this goal, the supplier of critical components may also be audited on a periodic basis. Quality assurance audits are conducted on a semi-annual basis for all products certified to NFPA standards, and annually (after the three semi annual audits and subject to the SEI Quality Assurance Auditor's approval) for programs where products are certified to ANSI and ASTM standards.

The SEI audit is a combination product/system audit. Because of the critical nature of the products certified by SEI, an ISO certification audit cannot be substituted for SEI's full audit requirements. ISO is strictly a system standard and only refers to product in a general sense in design, production, and test, etc. Typically audits for registration in ISO are for pre-assessment, assessment, follow-up assessment, and periodic (usually semi-annual) assessment purposes. This differs from SEI audits in that they do not start until the products pass laboratory testing, which prompts initial semi-annual and anniversary audits the first year. On the anniversary audit, the SEI auditor selects random samples which are packaged in his presence and shipped for annual recertification testing. SEI audits go beyond the ISO system audit and include requirements such as: provisions for a stringent recall system, appropriate traceability, and SEI requirements for demonstrating compliance to the product standard, sampling requirements, stock rotation, process development and the ultimate recall of products.

To address the issue of redundancy in quality assurance audits by various certification organizations, in January 1996, the SEI Board of Directors approved Criteria which allows SEI to integrate the SEI audits with the ISO 9000 audits. With the initiation of SEI's procedure to recognize ISO 9000 audits of manufacturers who certify products to NFPA standards, SEI will recognize one ISO 9000 audit as one of the two required audits for the NFPA programs. Once a manufacturer has met SEI's recognition Criteria, SEI considers the ISO audit as the systems-based audit and the SEI audit goes beyond systems and focuses on product. The SEI auditor is responsible for sample selection at the anniversary audit. It is SEI's goal to maintain effective control of the SEI quality assurance requirements and to reduce overlapping requirements. Attached is the program Criteria and the *SEI Procedure for Recognition of ISO 9000 for Companies Certifying Products to NFPA Standards*.

Issue 3.

(1) How should certification fees be structured and calculated to recoup the cost of the certification process?

SEI has an established fee schedule for its certification programs. Each manufacturer pays an annual participation fee ranging from \$300.00 to \$2400.00 based on annual company sales for those products for which SEI offers certification programs. A manufacturer will pay a one-time application fee of \$175.00 per model and a certification fee of \$390.00 per model on a yearly basis. Laboratory testing fees vary according to the particular product category involved. Since testing is conducted by a laboratory under contract to SEI, a 10% surcharge is added to the testing fees. As SEI is non-profit, SEI strives to keep fees at the level necessary to cover operating expenses of the program.

Issue 4.

(1) Should NIOSH allow replacement parts for respirators by manufacturers other than the original manufacturer?

SEI does not advocate the replacement of parts for respirators if manufactured by other than the original manufacturer. A certification method such as this cannot assure system performance as the original manufacturer would not have the ability to control the manufacturing process. Additionally, there may be problems arising from liability considerations, as no manufacturer would accept responsibility for another's product and, rightly or wrongly, could attempt to blame any malperformance on the other's product. In addition, there would be significant administrative expense involved in the testing and certification of such replacement parts.

(2) How should the effectiveness of replacement parts be assured?

The SEI Certification Program for SCBA has effectively handled the testing and certification of new variants to certified SCBA by a system for evaluating all such submittals to determine the appropriate tests as required by the NFPA 1981 standard for the particular component. Authorization to submit the component to the testing laboratory is given only when the required tests are determined by SEI and are agreed upon by the manufacturer.

(3) Would NIOSH need to adopt or develop component-specific certification requirements to allow alternate supplier for replacement parts?

Replacement parts by other than the original equipment manufacturer should not be permitted, as explained above. Avoiding the necessity for component-specific requirements is one significant advantage of not permitting alternate replacement parts.

(4) Should NIOSH consider certifying respirator components in addition to, or instead of complete respirators?

NIOSH should certify only the complete, functional respirator. Once a model is so certified, however, variants and accessories for that particular model may properly be submitted by that manufacturer for testing and certification. Such testing must be conducted on that specific model, and the variant must be certified only for use on that model. The NFPA 1981 Standard specifically requires that the inspection and testing for determining compliance with the requirements of the standard shall be performed on a complete SCBA unless otherwise specified within the standard.

(5) Do other certifying agencies or standards organizations allow suppliers other than the original manufacturer to provide replacement parts for certified units?

SEI is not aware of any certification organization which does so. In fact, in the SEI certification program, it would be considered as voiding the certification if any such change is made in a certified product.

(6) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor these alternate suppliers?

If it is necessary to permit this, monitoring should first include receipt by NIOSH of documented acceptance of the alternate supplier part by the manufacturer of the original manufacturer, along with specific identification and description of the part as well as the product for which it is intended. NIOSH should require testing of the part on the specific product for which it is intended, with resulting certification limited to use only with that product, by specific model name and identification. The complete program for quality assurance evaluation and audit should be assured for the manufacturer of the replacement part.

(7) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor those parts?

The answer to (6) above includes requirements for monitoring the parts as a portion of monitoring the supplier.

(8) Would NIOSH need to adopt design specifications to ensure that interchangeability of parts is safe?

This is another reason for not permitting alternate suppliers of replacement parts. The administration of such a program, adopting component specifications, monitoring compliance, resolving disputes, etc., could be very wasteful of resources. NIOSH should not be involved in evaluating or monitoring design features beyond the performance aspects necessary to ensure compliance with performance standards.

Issue 5.

The sample selection process for annual recertification testing utilized by SEI's SCBA auditor has proved to be successful in achieving a random sampling of the products. It is SEI's goal to achieve a random sampling of whatever is being produced at the time of the SEI audit. As stated in the SEI SCBA Certification Program Manual, "It shall be permissible for the timing of the sample selection audit only to be jointly agreed upon in

order to coincide with production schedules. It shall be acceptable for the manufacturer to produce extra SCBA at the time of the audit, for a minimum lot size of twelve units, and the auditor shall randomly select four identical SCBA from the total production run." They are packaged and shipped at that time.

There would be no expense to NIOSH or to the certification organization with recognition of such a system through SEI's certification program. In addition, it may be of interest to note that the NFPA Technical Correlating Committee mentioned above also is requiring the inclusion of requirements for annual recertification in each standard within its jurisdiction. The SEI experience with annual recertification testing has demonstrated the value and importance of such testing for revealing performance-denigrating conditions of which the manufacturer may not even be aware, such as unreported changes in vendor-supplied components which may affect performance.

Issue 6.

Response to the several questions on this issue are best answered through a description of the requirements SEI follows in its annual recertification of SCBA to the NFPA 1981 standard. Within 12 months from previous tests, SEI requires that compliant SCBA shall meet the requirements of one test series of Categories A, B, C, D and E outlined in the standard. Every fifth year, the complete recertification of all products, including full testing is required. Inasmuch as NFPA standards are revised every five years, this coincides with the timing for the issuance of the next Edition of the standard, and assures that on-going production of the SCBA will be upgraded as necessary for compliance with the new Edition. There may be a question as to whether a Federal agency could time-limit the validity of a certification, could require reporting of changes in production status, or could advise purchasers and users of the expiration of certification. These actions may not be within NIOSH's authority. Even if so, they could involve significant use of resources. SEI can, and does, control notice of expiration by removing a product from the annually updated SEI Certified Product List. Other certification organizations have similar listings of their certified products, which are updated periodically. This is another example of the advantage to NIOSH from using a private sector certification organization.

SEI believes that it stands as an exemplary model for the type of third-party certification program that NIOSH can utilize for the testing and certification of respirators. When NIOSH terminated its certification program for Gas Detector Tube Units, SEI was in a position to initiate a program that continues to remain successful with 20 substances certified and four participating manufacturers. The SEI Gas Detector Tube Unit certification program exceeds NIOSH's former program in that SEI also requires periodic quality assurance audits of the manufacturer's facility. In 1995, SEI's gas detector tube

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certification program achieved recognition by OSHA. OSHA maintains a Chemical Information File containing substances encountered by compliance officers in their workplace audits. SEI certified tube units are now listed in this File as a recommended screening device for compliance officers. Previously, only OSHA verified tube units were permissible.

In addition to this recognition, since an announcement by Donald D. Ballard, Chief, General Engineering Group, General Services Administration, on August 8, 1989, for Commercial Item Descriptions for purchasing personal protective equipment. SEI certification is acceptable as evidence that the product is in conformance with the requirements of the appropriate industry standard.

At present, SEI maintains a cooperative relationship with NIOSH through an informal sharing of information to assist the industry. It is SEI's suggestion that a relationship be formalized to include a Memorandum of Understanding to allow for SEI to broaden its respirator certification program to include the testing and certification currently conducted by NIOSH. Through such a cooperative effort, SEI would encourage an approach to phase-in these programs to ensure that the NIOSH staff provide the technical oversight deemed necessary. SEI will make its resources fully available to accomplish this task. All documentation on the SEI certification program such as the following would be made available for NIOSH review: SEI Certification Program Manual, SEI Open-Circuit SCBA Program Manual, SEI Certified Product List, SEI Quality and Operational Procedures Manual, and the American National Standards Institute, Application for Accreditation of Certification Program for the Safety Equipment Institute.

SEI stands ready to assist NIOSH in providing the safest workplace possible for American workers.

Sincerely,



Patricia A. Gleason
President

Enclosures

Assurance Auditor retains oversight authority for all "local" audits.

- C. The initial audit is performed jointly by the SEI Quality Assurance Auditor and the Local Auditor.
- D. Subsequent audits are performed independently by the Local Auditor except that the SEI Quality Assurance Auditor again performs a joint audit with the Local Auditor every five years.
- E. The Local Auditor keeps the SEI Quality Assurance Auditor fully informed on independent audits, supplying full copies of his/her report to the company. The Local Auditor recommends a "pass" or "fail" rating to the SEI Quality Assurance Auditor who must concur before the rating becomes final. The SEI Quality Assurance Auditor then notifies SEI of the final determination.
- F. During the annual recertification audit or the NFPA anniversary audit, the Local Auditor will select the appropriate samples.

8.4 Recognition of ISO 9000 Audits for Companies Certifying Products to NFPA Standards

It is SEI's goal to maintain effective control of the SEI quality assurance requirements and to reduce overlapping requirements of various organizations. SEI will recognize one ISO 9000 audit as one of the two audits required for SEI's NFPA program. Participants must meet the overall program Criteria approved by the SEI Board of Directors.

8.4.1 Criteria for SEI ISO 9000 (ANSI ASQC Q 9000) Audit Recognition Program for Companies Certifying Products to NFPA Standards

8.4.1.1 The ISO Quality Assurance Auditor used by an SEI participant must be accredited through a recognized accreditation program for quality system registrars.

8.4.1.2 The ISO 9000 Auditor must agree to work with SEI to meet the requirements set forth in the SEI quality assurance auditing program.

8.4.1.3 SEI may require the first ISO 9000 audit to be conducted on a joint basis with the SEI Quality Assurance Auditor.

8.4.1.4 Since NFPA Standards require two quality audits per year, SEI will recognize the ISO audit as the systems audit and the SEI Auditor will conduct SEI's product oriented audit. Sample selection for annual recertification audits will be handled by the SEI Auditor.

8.4.1.5 The company will be required to submit an audit report to the SEI Auditor within two weeks of the ISO audit. If the report is in compliance with SEI quality assurance program requirements, SEI may accept the audit.

8.4.1.6 The SEI Auditor will notify SEI of a pass or fail of a manufacturer's quality assurance program.

8.4.1.7 The SEI Auditor may conduct a joint audit with the ISO Auditor every five years.

**8.4.2 SEI Procedure for Recognition of ISO 9000 Certification
for Companies Certifying Products to NFPA Standards.**

**8.4.2.1 Requirements for Initiating the Procedure to
Recognize the ISO Audit**

A. Manufacturer must have the following QA elements in place:

1. 100% "Acceptable" rating on all questions in the SEI Quality Assurance Audit Questionnaire (re-audit relative to the questionnaire required just prior to initiating the procedure).
2. Certification of 100% compliance with all line-items requirements of the NFPA Standard.
3. A product quality control plan appropriate for certified products(s), documented and implemented.
4. A supplier quality assurance plan appropriate for certified product(s), documented and implemented.
5. A Closed-loop corrective action system that also requires preventive action, verification of action effectiveness by QA, and which includes problems found at the SEI testing laboratory.

6. Measures of quality performance suitable for trend analysis, coupled with a program for continuous improvement.
- B. Evidence from quality measure trend lines that indicates ongoing improvement.
- C. Samples for each annual recertification must be selected by the SEI QA Auditor. (SCBA manufacturers: random selection by the Auditor from lots 3 x the sample size.)
- D. Must have a history of no major performance related problems.
- E. The manufacturer's quality assurance manual is acceptable to the SEI QA Auditor.
- F. The SEI QA Auditor would require a copy of each ISO 9000 audit report.

8.4.2.2 Conditions Leading to Reinstatement of the Two-Audits Per year Requirement

- A. Loss of ISO 9000 certification.
- B. The company does not provide QA auditor with copies of audit reports.
- C. Problems at annual recertification testing that lead to product recall.
- D. Repeat of the same problems of lesser magnitude during annual recertification testing.
- E. Changes in company ownership where the new owner has not formally committed to maintain the same or greater level of quality.

- F. Evidence from quality measures which indicates that quality is trending in the wrong direction.
- G. Failure to act on a timely basis to fix problems associated with the product, the process, or the quality system.

8.4.2.3 Request to Initiate Recognition Process

Participants must submit documentation to the SEI Quality Assurance Auditor evidencing compliance to all SEI requirements. The attached form should be used for the format.

