July 19, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

RE: Comments
Respiratory Protective Devices

Dear Sir or Madam:

Enclosed are three copies of written comments from John Moran and myself regarding the proposed rule for certifying respiratory protective devices (particulate filters) as published in the Federal Register on May 24, 1994. We appreciate the opportunity to provide NIOSH with our perspective on this important matter for protecting worker safety and health.

Sincerely,

Bill Kojola
Associate Director
Occupational Health

cc: John Moran
Brian McQuade
Joe Fowler
COMMENTS OF

Bill Kojola
and
John B. Moran

Respiratory Protective Devices; Proposed Rule
42 CFR Part 84
NIOSH Docket Office

July 1994

Laborers’ Health & Safety Fund of North America
905 16th Street, NW
Washington, DC 20006
On behalf of the Laborers' Health & Safety Fund of North America (LHSFNA), we welcome the opportunity to comment on the NIOSH proposed rule regarding certification of particulate respirators in 42 CFR Part 84. The Fund is a jointly trusteed labor-management organization representing the Laborers' International Union of North America (LIUNA) and contractors who employ members of the union on construction sites. Respiratory protection is a vital concern to many of the 650,000 LIUNA members who must wear respirators as a means to protect their health, particularly for those workers engaged in asbestos abatement, hazardous waste remediation, and construction activities where lead-based coatings are disturbed. From a worker health perspective, it is essential that regulations for certifying respiratory protective devices keep pace with improvements in respirator design, effectiveness, and technological developments affecting the user community. In that regard, NIOSH serves a pivotal role with its responsibility for promulgating effective testing and certification requirements that ultimately are linked to those who must use and derive the protective benefits from the respirators they wear in the workplace.

The existing NIOSH testing and certification rules and procedures in 30 CFR Part II have not been revised in more than 20 years. During this interval, advances in respirator protection technology and concerns about respirator effectiveness have arisen that are not adequately addressed by current certification requirements which are two decades old. While NIOSH attempted to undertake a comprehensive revision to respirator approval requirements with its 42 CFR Part 84 proposal in 1987, the number diversity and complexity of comments it received brought the process to a standstill. It is our view however, that this current
proposed rule offers the opportunity to end regulatory grid-lock and to move the testing and certification process forward consistent with advances in and knowledge about respirator effectiveness.

MODULAR APPROACH

With this proposed rule, NIOSH is now intending to proceed to revise certification requirements in a series of modules. This approach is designed to prioritize subject matters that are expected to have the greatest impact on improving worker protection and to overcome the current regulation revision stalemate. We support this approach as proposed by NIOSH and view it as the mechanism that will accomplish these objectives.

In this proposed rule regarding particulate respirators, the first of a number of modules identified by subject matter to be addressed, the stage is being set for a sequence of events to achieve comprehensive revision of 30 CFR Part II. While we agree with this strategy and the modular subject area timetable, we must stress that NIOSH has to diligently hold to its schedule. The agency must maintain a committed time frame, especially for the subject area addressing Assigned Protection Factors. In using a modular approach, NIOSH must make a careful effort to insure that there is compatibility between the modules and that modules are fully integrated and consistent with each other. Maintenance of consistency between modules is essential in this process of achieving a comprehensive revision of the testing and certification requirements. The first module, that dealing with particulate respirators and
particulate filtering tests, will impact all other subsequent modules; NIOSH will thus need to carefully review the impact of modifications to this module as it applies to proposed changes to subsequent modules as well. It is our view that the issue of Assigned Protection Factors is central to accomplishing the overall objective of comprehensively revising the certification requirements. The APF values represent a critical factor for accomplishing protection of worker health and thus must be addressed upfront in the modular revision scheme that NIOSH has proposed. We strongly encourage the agency to move forward on the APF module as quickly as possible and that it follow next after this particulate respirator revision proposal as indicated in the notice.

PARTICULATE FILTER TESTING METHODOLOGY

This proposed rule plans to test and certify particulate filters for air purifying respirators by measuring the penetration efficiency against the most penetrating size of particulate. Filters which meet or exceed the capture efficiencies of the new classification system proposed by NIOSH in this rule will be certified. We agree with the approach of using the most penetrating size of particulates for filter testing. By using capture efficiencies of the most penetrating size of particulates as the criteria for passing a filter test, the agency is in effect insuring that capture efficiencies for other less penetrating particles are higher than that associated with the most penetrating size upon which testing, certification, and assignment to the capture efficiency classification system is based. However, because these filter testing procedures are different from that in 30 CFR Part II, NIOSH must be certain that, with
regards to the new penetration testing methods, it can document their accuracy, reliability, and repeatability. Furthermore, NIOSH must assume a technical assistance burden to assist respirator manufacturers by ensuring that in their hands the testing methodologies and results are compatible with that obtained by NIOSH when manufacturers submit their test data as part of the certification application.

CLASSIFICATION SYSTEM

With the updating of particulate filter test procedures, NIOSH is proposing a new classification scheme for particulate respirators based upon the capture efficiency of the most penetrating particles. The proposed scheme would establish three types of particulate filters based on percent efficiencies that are labeled as Type A (99.97% efficiency); Type B (99% efficiency); and Type C (95% efficiency). These various types will also be certified for use against only solid particulates (labeled S) or for use against both liquid and solid particulates (labeled L & S) within each of these three types for a total of six combinations of particulate filters available depending on efficiency rating and the physical state of the contaminant (solid only or liquid & solid).

NIOSH contends that the new classification system will permit the user (and selector) of particulate filters to "easily discern the level of protection that can be expected when using a particular respirator." However, it is our view that rather than simplifying selection and making the level of protection easily discernable to the wearer and selector, this scheme will
add confusion and complexity to the selection process affecting both selectors and wearers of particulate filtering respirators.

Under the current certification regulations for particulate respirators in 30 CFR Part II, the bulk of filters are certified for intended use to dusts and mists (DM); dusts, fumes and mists (DFM); and high efficiency (HEPA for use against dusts, fumes, and mists or both liquid and solid). This constitutes essentially three types of particulate filtering respirators that are available for selection. Under the NIOSH proposal, the types of filters available for selection will be doubled making it difficult for us to conclude that discerning the level of protection will be easier for wearers. To genuinely simplify the selection process, we strongly recommend that particulate filters only be certified for use against liquids and solids (L&S) rather than establishing a distinction between solid only and the liquid/solid combination. By doing this, selectors of particulate filtering respirators will be assured of selecting a filter that is intended for exposure to both liquids and solids where adequate characterization of exposures is not performed or where changes in the nature of exposures occur as they often can on construction sites. Currently the high efficiency or HEPA filters can be used for exposures to liquids and solids while under the newly proposed scheme, two choices of high efficiency filters will now be available for selection, one for solids only and the other for both liquid and solid exposures. We fail to see the rationale for concluding that such a scheme that doubles the types of HEPA filters available will make the level of protection more easily discernable to wearers. We are also concerned that cost of the filters will be the driving force in the selection process, rather than appropriate protection under
NIOSH's new classification system. The lower costs of solid only versus liquid/solid filters could play an unintended (but unfortunate) influence on the person responsible for selecting respirators for workers to wear at the ultimate expense of the protection of the wearer. Asbestos abatement activities may be a case in point. It is certainly plausible for lower cost HEPA Filters intended for solids only to be selected over more costly HEPA's certified for use with liquid/solid in asbestos abatement where liquid exposures from the spraying of amended water is being conducted. We are convinced that such cost considerations will play a role in the "real world" in inappropriate circumstances and that wearers will generally not be aware of this distinction or the level of protection they are to be receiving.

As an alternative to the proposed NIOSH classification, we would propose the following to be adopted:

1. **Certify particulate filters for both liquid/solid and eliminate the filters only intended for use with solids.** By providing particulate filters intended for use with both liquids and solids, it simplifies the selection process to include both physical states of a particulate to which workers may be exposed, eliminating the potential for inappropriate filter selection, removing cost considerations in selecting filters of the solid type only where liquid/solid filters ought to have been selected, and ensures the wearer that he will be protected against both physical states of the particulate.

2. **Include the high efficiency filter (99.97%) intended for use against both liquid and solid particulates with the magenta color code.** This recommendation maintains the
current situation with which workers and selectors have familiarity. The NIOSH proposal to add a high efficiency filter intended for solids only is unnecessary, adds additional complexity to the selection process, and would not guarantee that users would easily discern the level of protection being provided.

3. Include the 95% efficiency filter intended for use against both liquid and solid particulates. The capture efficiency of these filters would be sufficient for many workplace circumstances and would permit it to be selected, in lieu of a HEPA Filter, in health care settings where workers are potentially exposed to tuberculosis in compliance with the draft Centers for Disease Control recommendations for preventing transmission of TB.

4. Eliminate the 99% efficiency classification type altogether. To include this type only adds complexity to the range of particulate filters available for selection and does not offer any significant improvements in the level of protection over that of the 95% efficiency filter classification.

5. Revise the proposed A, B and C type classification nomenclature. We make this recommendation for two reasons. First, a number of the instructors who teach the hazardous waste worker course to laborers in conformity with 1910.120 have expressed to us their concern that trainees will become confused with the A, B, C particulate filter efficiency classifications and the A, B, C levels of protection.
assigned to the protective equipment ensembles for conducting hazardous waste remediation. This confusion may occur because the letter designations for particulate filters are the same as those used for the equipment ensembles but they are not compatible with each other in terms of the degree of respiratory protection the particulate filter type and equipment ensemble are to offer. Secondly, to the extent that it is now possible, NIOSH should attempt to provide some general harmonization with international classification designations of particulate respirator types. This proposed rule offers NIOSH the opportunity to do so at this juncture and it is our view that our recommendation is in order at this time.

**USER GUIDE**

We strongly support NIOSH's intention to develop a user guide that will accompany final rule changes to the certification requirements for particulate filtering respirators. The user guide is an essential element for those who have the responsibility for selecting proper respiratory protection and for the users who must wear such devices. In addition, the guide will assist trainees of workers to fully explain and make comprehensible the changes that are occurring with the promulgation of this new regulation. The users guide will inform the regulated community of the new requirements and help to minimize confusion with any new rules. The user guide, in addition to explaining the new rules, should also provide recommended training materials to assist wearers and selectors in comprehending the changes that have occurred.
It is our view that the development of the user guide would be best accomplished by the establishment of a diverse national technical workshop. Participants would include workers and their representatives, employers, manufacturers, and government officials (NIOSH, OSHA, DOE, etc.) who will have the responsibility to prepare the user guide. The guide must also cross interpret every OSHA standard that requires the use of particulate respirators. We would recommend that the cross interpretation of these standards be accomplished by a national interagency task force.

FIT TESTING

The NIOSH proposal provides for isoamyl acetate "tightness" testing for particulate filtering respirators in 84.181 and 84.182. However, the language in each of these sections provides scant detail as to the detailed procedures and protocol for conducting the fit testing itself nor does it describe the characteristics of individuals that would constitute a fit testing panel for such purposes. We would recommend that NIOSH develop a detailed and extensive protocol for conducting fit testing of air purifying respirators. Secondly, we recommend that this protocol be included in the Assigned Protection Factor module that is to be developed next in NIOSH's time table for respirator certification regulations and not in this proposed rule as it pertains only to particulate filters and not respirators as an integral unit. The fit testing protocol also needs to be included in a written user guide. The determination of an adequate fit on the wearer is essential in order to be assured that the respirator is achieving its APF.
A NIOSH protocol will assist the regulated community that wearers can achieve an adequate fit.

CONCLUSION

We applaud NIOSH’s effort to revise its certification requirements for respiratory protection. Such an effort is long overdue. By moving forward using the modular approach, we believe that NIOSH will accomplish this objective and provide improvements in the level of protection to workers. We trust that NIOSH will find our comments helpful in carrying out this endeavor.