846-454

ICS
INC. REGULATORY COMPLIANCE AND STANDARDS CERTIFICATION SERVICES - INTERNATIONAL

July 7, 1996

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

Re: FR May 16, 1996 Vol. 61, No. 96; Request for comment on proposed revisions of NIOSH procedures for certifying respiratory protective devices.

Dear Sir / Madam:

International Certification Services (ICS) is pleased to submit the attached written comments in response to the Federal Register notice of May 16, 1996 Vol. 61, No. 96. The opportunity to participate and present our comments in the NIOSH public meeting in Washington on June 6th and 7th was appreciated, as is the opportunity to submit these written comments. We applaud and support the initiative of NIOSH, working in accord with private sector empowerment policy toward the privatization of respiratory protective device certification. We believe this process to be viable and hold many advantages to NIOSH, respirator manufacturers and the user community. NIOSH will have a greater availability of resources to devote to research and standards development. Manufacturers will have access to qualified and competent laboratories, market driven in pricing and turn-around time – getting products certified and to market faster. End users will benefit from increased research and improved standards from NIOSH and retain their confidence in product through a qualified comfority assessment process. In addition to these, the adoption of globally accepted conformity assessment protocols provide the basis for future advances in global trade in crossing yet another hurdle in the continued work on mutual recognition agreement (MRA) negotiations.

ICS is a provider of services in regulatory compliance, product testing and certification to international standards. Although not limited, our services focus on health and safety and personal protective equipment (PPE). We are a recognized agency of the Canadian Standards Association (CSA), providing turn-key product certification to CSA standards. Beyond North America we have formed key alliances with a select group of competent laboratories and notified bodies within European community. We are active participants in US and Canadian product standards development, and the ANSI committee on International Conformity Assessment Activities (ICAC) - US delegate committee to ISO CASCO activities.

Respectfully submitted,

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President

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ICS believes that NIOSH resources would be more effectively utilized in the primary role of research and standards development. NIOSH was not intended to act as a product testing agency or enforcement authority. MSHA, the FCC, the FDA and EPA all rely on private sector product testing and in the case of OSHA product safety compliance, the entire certification process has been privatized.

(1)
The capability of private sector laboratories to conduct respirator testing is without question. The concept, as presented during the public meeting that only NIOSH and manufacturers have the required expertise to carry on testing is unfounded. ICS personnel have both knowledge and experience in performing NIOSH testing. We do believe however, that in order to establish programs capable of ISO guide 28 and 25 conformity that further refinement of standards, test protocols and procedures are necessary. The adequate documentation of test protocols and procedures is essential for accurate and reproducible test results.

(2)
Performance of respiratory protective equipment is crucial to the health and safety of the American worker. When of decisions of the worthiness of a products effectiveness and resultant certification and sales are reliant on the results of laboratory test data, the reliability and accuracy of the test data is crucial. The measurement technology employed must be of high quality and derived from competent processes. Test data from different laboratories must be equivalent. ICS believes this overall statute of competency should hold true weather addressing the current NIOSH laboratory or multiple private sector laboratories. ISO Guide 25 *General Requirements for the Competence of Calibration and Testing Laboratories* serves as an internationally recognized and mandated criteria document used to determine the competence of testing laboratories. This global standard has been used as the basis of accreditation for over 8,000 laboratories around the world.

ICS recommends that any private laboratory be accredited to the requirements of ISO Guide 25, as assessed to competence in testing to criteria specified in NIOSH test procedures and protocols. The NIST / NVLAP and the A2LA programs are internationally recognized accrediting bodies to this standard. The OSHA NRTL and the ANSI Z34.1 program go beyond the scope of laboratory accreditation to accredit complete product certification programs. If NIOSH should only considering the privatization of laboratory functions, these programs will not be applicable. Laboratories accredited in accord with ISO Guide 25 will stand ready to accommodate future MRA's and the possibility to demonstrate testing competence and receive accreditation in testing to EN an other national standards. These possibilities represent a significant advantage to US manufacturers in an increasing global market.

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(3)
ICS believes that NIOSH should mandate ISO Guide 25 accreditation (in accord with NIOSH criteria) for laboratories performing certification testing on respiratory protection equipment. In this, the manufacturer should be able to utilize the laboratory of their choice for initial submittal / approval of product. The competence of these approved laboratories being qualified and equivalent, provides the manufacturer with a time to market option - dependent on price and lead time of the available laboratories. These are additional benefits realized in a private sector environment. In the case of routine product audits NIOSH could schedule and specify random selected laboratories which auditor selected product are sent for re-testing. This would further the competence of the entire program.

(4)
If NIOSH adopts laboratory accreditation by NVLAP or A2LA, these organizations will monitor laboratory performance as part of the scheme. NIOSH, may in turn evaluate accrediting agency records directly with copies of laboratory audits sent to NIOSH administrators.

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ICS is well versed in the ISO 9000 series of standards and well aware of the advantages and benefits a globally adopted outline for quality programs brings. But as important, we are aware of the short comings, and ill-perceived capabilities of this set of standards. It has become a growing fallacy that the ISO 9000 series of quality documents and third party certification to same guarantee conformity in products and services. Those companies who gain accreditation, although well deserved for in the effort made toward improving their quality systems within an international scheme, and utilize the accreditation to decorate the conformity of product in the market, misuse the real nature and intent of the standards. The ISO 9000 standards govern the way an organization conduct itself in pursuit of its own quality goals – and no more. It does not govern the quality or conformance of the product or service.

In addition to our reservation of employing the ISO 9000 series of documents for ensuring the quality of products, we are additionally concerned as to the mandate of third party ISO 9000 compliance to small manufacturers and those with multiple sites. The costs imposed to manufactures in obtaining ISO 9000 certification, is escalating in support an industry of consultants, seminar producers and third party assessors -- all for a standard which does not address the intent of NIOSH – the conformity of product.

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(1 - 3)
We do believe a third party quality assessment scheme is needed in the product certification program. ISO 9000 does not fulfill all the necessary requirements to insure product conformance and the system can not be readily adapted to assess these additional criteria. We suggest that such a scheme and its criteria be custom designed by NIOSH to insure that applicable criteria is imposed. In accord with ISO Guide 28, such a scheme could then be carried by private sector compliance auditors. These auditors should, in addition to having RAB or similar ISO 9000 lead-assessor ability, be trained and certified in the additional and special assessment requirements involved in product related quality assurance assessment as specified in the NIOSH scheme.

(3)
ICS would recommend a frequency of one quality audit annually. The audit would involve both product (testing) and site procedures.

(4)
Following a product conformity scheme in accord with ANSI / ISO criteria, we feel at initial audit of product is necessary prior to product sale.

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