AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, INC.

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21

PLEASE ADDRESS REPLY TO:

July 21, 1980

Statement of ACGIH, Inc. at the NIOSH Public Meeting on the NIOSH Role in Testing and Certifying Personal Protective Equipment and Hazard Meausring Instruments July 28-30, 1980.

I am William D. Kelley, Executive Secretary of the American Conference of Governmental Industrial Hygienists (ACGIH, Inc). The ACGIH is a professional society of occupational health and safety professionals employed by governmental units and universities in this country and over thirty other countries. Our sole goal is "worker health protection". This goal is achieved through the mechanisms of any professional society. We are here today to positively contribute to this NIOSH public meeting.

I have been employed in positions in Nuclear Safety, Radiological Health, and Occupational Health since 1962 and for NIOSH and its predecessor organization from 1967-1978. During my employment at NIOSH, I served as the Assistant Division Director for the Division of Laboratories and Criteria Development with specific responsibilities for the coordination of the Division's Quality Assurance efforts including the analytical laboratories at Cincinnati and Salt Lake City; the Chemical Reference Laboratory, and the Testing and Certification Laboratory.

I will not attempt to address the relative merits of 1) NIOSH or 2) NIOSH/MESA or 3) NIOSH and private laboratories or 4) industry self-certification programs. However, since 30 CFR Part 11 is only one of a family of some 18 sets of regulations used in underground coal mine a commonality of approach and requirements would seem to have merit for effective and efficient health protection. Would a testing and certification program without MSHA be accepted by MSHA, for instance in the area of instruments used in gaseous coal mines. I will attempt to focus on the elements of such a program as outlined in the Federal Register Notice of June 18, 1980 and the Consultants Report HEW (NIOSH) Publication No. 80-113.

Performance Specifications -

Performance specifications have been the goal of the program for years with some considerable sums of money and effort expended in this area, e.g. fit testing panels.

Performance requirements cannot be static but neither must they be changed for reasons that will not make significant improvements in "worker health protection". Otherwise resources which could be better used for other "worker health protection" activities will be spent on an "annual" new model respirator replacement program.

Quality Control -

No evidence was presented in the consultant's report or in the Federal Register notice to substantiate the statement "The detailed, in depth review and approval of applicant's quality control plans as presently specified in 30 CFR 11 needs to be eliminated."

Either from other input here or from a NIOSH followup investigation, it will become clear that the population of personal protective equipment and hazard measuring instrument manufacturers will show a wide diversity of experience and ability to establish a formal quality system. To assume that manufacturers can readily implement a self-certification program is fraught with danger.

I am shocked that NIOSH is now considering a field audit program. Such an off-the-shelf purchase plan was developed for NIOSH a number of years ago by its consultant, Mr. Thomas A. Ratliff, Jr.. The plan was based on work done by the NHTSA. An application involving detector tubes was first worked up. Three Reliability Cost Sampling plans of the same type were worked up for the 3 M White Cap and two other representative types of respirators. The basic approach was documented by Francis Armstrong of the NHTSA in the ASQC Transactions of 1972 (pages 225-236). Mr. Ratliff made a formal lecture presentation to the TCB staff and officials on the Reliability Cost Sampling Plans developed for NIOSH. I would suggest that the TCB records be studied or Mr. Ratliff be asked to refresh NIOSH's memory.

NIOSH needs to decide what NIOSH role in the personal protective equipment and hazard measuring instruments area would best insure "worker health protection". It may well be that NIOSH should assume the role that equipment purchasers and users would exercise if they could act together. The Generic Guidelines for Quality Systems is a new standard developed under the auspices of the American Society for Quality Control as ANSI/ASQC Z-1.15-1979. These guidelines would be useful in setting up any such systems. If it is NIOSH's intention that the level of product quality is to be determined at the manufacturer's site, then it could be advocating the proper use of AQL sampling plans with appropriate O.C. curves so that the proper protection for individual lots is present. ANSI/ASQC Standard A2-1978 Terms, Symbols and Definitions for Acceptance Sampling can be consulted.

Engineering Drawings with Dimensional Tolerances -

If a number of suppliers of personal protective equipment and hazard measuring instruments have great difficulty in developing and implementing a quality assurance system (as my knowledge would indicate) is it really feasible to expect these same people to "prepare a detailed engineering design (i.e., failure mode) analysis for each respirator submitted for approval"? I fear that NIOSH would be trading in one set of declining headaches for a new set that would make the former problems miniscule.

Changes to Approved Devices -

The intent of this section (to allow "nonsignificant" changes in respirators without modification of the certificates of approval) seems to counteract the intent of the Duration of Approval Section. It would be most informative to hear the quantitative definition of "insignificant changes", "nonsignificant changes" and "significant changes". The statement that ... "significant would be defined as any change that may place the performance ...." does not help because "may place" must then be quantitatively defined with the level of variance of the performance test involved included.

Product Quality Requirements -

It would be most informative for this meeting to see the documents or hear the rationale behind moving away from the AQL concept. Has NIOSH through a quality control expert reached these conclusions? The makeup of the panel of consultants charged by NIOSH to review the Testing and Certification program is distinguished by the competence of the members in their fields of expertise and in being without credentials in the field of product quality assurance per page 44 of their report publication. The discussion on pages 17-18 of the consultants report is not reassuring. How many plant quality control audits have the consultants performed? How much input to their report came from people knowledgeable in product quality assurance.

Witnessing of Approval Tests -

No Comment

Unpublished Test Requirements -

Unless priority is given to the publication of new "tested and proven and subjected by public scrutiny" test requirements improved worker health protection will be seriously jeopardized by freezing a state-of-the-art technology and stifling all innovation and research.

Testing of Prototype Respirators -

No Comment

Approval Tests -

Approval tests only on production samples on initial testing may be counterproductive. If a manufacturer has to gear up a production line, buy raw materials and subassembly materials in production sized lots, train production people, inspectors etc. to turn out a few devices for approval the financial risks will be greater which will stifle newer models with improved worker health protection. Should approval not be granted the costs will ultimately be borne by the worker in one form or another. Even if approval is granted the worker will pay for the plant, equipment and personnel costs of production capacity lying idle awaiting the receipt of an approval.

Perhaps a contingency approval pending the first production lot being submitted for formal approval could minimize risks and costs to the worker.

Group Testing of Respirators -

No comment

User and Maintenance Manuals -

Some balance between the intent of this section and the intent of the Changes to Approved Devices section must be achieved.

NIOSH Systems Manual -

Agreed.

Publication of Test Data -

Performance results reporting by NIOSH will require consideration of their advertising value by manufacturers of competitive devices. It would be hoped that insignificant differences in certain performance tests will not lead purchasers to less than optimum buying decisions. Of course, NIOSH will be able to replicate and validate any reported performance differences because they may be forced to do so.

Consultants Report -

It is unfortunate that the obvious dedication and many hours of work of the consultants was negated to a great extent by the lack of a professional quality assurance competence in the group.

The inconsistencies are exemplified by the statement on page 28 "an industry of this size is no longer an infant and does not require assistance for quality assurance (QA)". Yet on page 21, the report states "They must also teach manufacturers how to perform performance criteria tests, if the manufacturers desire such instruction". I would recommend that in subsequent deliberations NIOSH should provide some quality control in input into the process to better reflect the appropriate role of quality assurance.

Summary -

ACGIH wishes to work with NIOSH to strengthen and refine the Testing and Certification program. It will require a priority of resources, both staff and money, which heretofore has not been evident on a long term basis. We stand ready to assist in any way we can.

Thank you.