

PRESENTATION

To the NIOSH Public Meeting on the Testing and Certification Program

Made By K. V. Vaughan, General Manager of Racal Airstream, Inc.

1. Racal Airstream, Inc. is a manufacturer of powered air-purifying helmets, products which are approved by NIOSH as permissible respirators.
2. These comments are offered in a constructive and considered way, as a direct reaction to the remarkable process that has brought about this public meeting. It was a wise and courageous decision to commission the independent consultants' report, and to make the report positively public. It was also wise and necessary to offer this public forum as a means of obtaining relevant inputs. This whole process is a commendable example of responsive, responsible and open government.
3. I welcome, too, the supplementary information published in the Federal Register on June 18th. This is a professional and generally successful, objective identification of the options available to the Institute. In fact, NIOSH has brought its management options to its constituents in a way which is clear, precise, and understandable.
4. Any restructuring of the NIOSH test and certification program that is to be done, must be guided by one firm principle: the need to protect the end-users of our equipment. I believe that this is the principle that has led NIOSH to bring about this re-evaluation procedure, because after having studied the proposals and the options presented by NIOSH it is clear to me that these are guided by the principle that the end-user is the most important person in this complex interaction between government, manufacturer, employers, and users. I also perceive from these proposals that NIOSH wishes to be consistent in its approach. Therefore, although I have some disagreements with some of the options presented, I strongly support those aspects of the proposals that are the most important and the most significant.
5. There are three basic, fundamental statements of philosophy before us. These three are much more important, in my view than some of the incidental

detail contained in the proposal.

- (a) Should there be a NIOSH test and certification program? My answer is a definite yes. Further, I support "alternative two", that NIOSH develop a new testing and certification program, making major revisions to the existing program, leading to regulations where NIOSH alone would test and certify respirators. I would support NIOSH being able to contract certification testing to other laboratories, provided that the laboratories concerned were independent and non-captive. I do not support a program that would allow other laboratories to approve respirators. I do not support a program that would allow manufacturers to self-certify products.
- (b) Should the tests be replaced with performance specifications? My answer is, again, a definite yes. This change in emphasis is vital, because it relates to use in the worker's environment. Technology is improving, applications are changing, requirements are tougher, and users are becoming more aware of their needs. All these factors lead to a requirement for increased end-use assurance, which will be achieved by a move to performance specifications and away from engineering specifications.
- (c) Should a field audit program be a major part of the NIOSH involvement in product monitoring? Again, my answer is a definite yes. An audit test program could provide real, continuing assurance of performance in the real world, where the end-user lives.

I support these three major principles. However, the procedures and the details must be worked out and must be technically sound, practical and effective. It will not be easy to define performance tests. Performance at the end-user level is a function of filtration efficiency, face-fit efficiency, wearability and comfort. All these product characteristics need to be considered in performance specifications, and in a revision of NIOSH certification procedures.

Field audit results are a function of outgoing quality, reliability, main-

tenance, use (or misuse) and environmental stresses. The audit program must consider all these aspects in a statistically meaningful way. Perhaps NIOSH should stratify its audit effort, placing a much greater emphasis on equipment whose failure would cause death or injury than on other items.

The concepts and formats to be used should be arrived at by enlisting specialists and consultants, and must be open to public comment before being adopted.

6. I would offer the following comments on some of the other proposals.

- (a) I welcome the requirement that the applicant should certify that an effective Q.C. plan exists.
- (b) I agree that NIOSH do not need and should not require detailed, dimensioned drawings. A parts lists and an outline drawing will serve to control the configuration.
- (c) I agree that non-significant changes do not need NIOSH review, but that redesigned items should be resubmitted.
- (d) I believe that applicants must have the right to witness certification testing, but that this right must not affect the correct conduct or the scheduling of the test.
- (e) I have some difficulty with the concept of approvals being for a fixed period of time only. If the field audit program is effective, and regular acceptable tests are being performed by NIOSH, the sunset requirement is not necessary. Again, perhaps NIOSH should require resubmission of life-supporting or life-preserving devices, while relying on the audit program to control other types of respirators. The NIOSH requirement would have to be for a re-submission date, not an re-approval date, since the NIOSH workload should not be allowed to penalize an applicant.
- (f) I agree that AQLs (acceptable quality levels), are not good guidelines for quality control. A sampling plan for inspecting a lot to an

AQL of 1.0% is statistically arranged so that if the lot is 1.0% defective, it will almost certainly be accepted, and not be rejected! However, the AQL tables are widely used. A more precise guide to the use of AQL would help to improve the theoretical outgoing quality. We have 100% test and inspection activities at various points, including the final stages.

(g) I believe that prototype testing is an important activity. Some of the NIOSH test procedures are very difficult to duplicate, and manufacturers are reluctant to invest very large sums of money in tooling and processing equipment without the final assurance of success in the NIOSH laboratory. It is likely that those products that need prototype testing are the very ones that might bring new benefits to end-users. Prototype testing should be scheduled as if it were a normal application requirement.

(h) I find the proposal for group testing of respirators to be commercially unacceptable, technologically inhibiting, and possibly discriminatory.

7. Several aspects of the present program were not covered by the report or by the proposals.

(a) I believe that communication and interaction between NIOSH and its constituency is important, both at the management level and at the technical level. I would support regular conferences to develop understanding and technical cooperation.

(b) The progress of applications is a concern to manufacturers. I believe the manufacturer is entitled to regular progress reports from NIOSH. I believe applications must not be bumped to the bottom of piles for minor non-conformities. I also believe that NIOSH should have a fixed time from the date of application for its evaluation.

I thank you for this opportunity to provide my perspectives to this meeting.