

COMMENTS TO PUBLIC NOTICE
JUNE 18, 1980

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The most significant changes from the Bureau of Mines' certification program to the NIOSH controlled certification program were the requirements for a quality control system and the submissions of modifications to the product.

These changes were important for the users and inherently helped the manufacturers for liability protection. There were also some test criteria that were updated at that time to attempt to cover the state of the art.

The conflicting fears between NIOSH and the manufacturers caused the regulations to be written to protect the actions of the regulators and the manufacturers to rebel at any indication of over regulation or interference by the Federal Government. This conflict between the two factions caused the pendulum to swing to an overkill position for each side.

People of NIOSH became vulnerable to attacks by both users and manufacturers. Actual vendettas began to arise between certain user groups and certain manufacturers and TCB was caught in the middle.

TCB's reaction was to use less and less judgement for which they had the capability, reduced their voluntary assistance to expedite better products reaching the users, and as a matter of pure self preservation the so called "Black Hole" was created. This resulted in increased time lags between submission and approval.

Now, it appears evident that a change in procedure is necessary to maintain user protection and simultaneously calm down the various factions.

The solutions we see proposed in the June 18, 1980 notice are reactionary in nature and treat, for the most part, only the symptom rather than the disease. The problem areas listed are:

- (a) Performance Specifications
- (b) Quality Control

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- (c) Engineering Drawings with Dimensional Tolerances
- (d) Changes to Approved Devices
- (e) Witnessing of Approval Tests
- (f) Duration of Approval
- (g) Product Quality Requirements
- (h) Unpublished Test Requirements
- (i) Testing of Prototype Respirators
- (j) Approval Testing
- (k) Group testing of Respirators
- (l) User and Maintenance Manuals
- (m) NIOSH Systems Manual
- (n) Publication of test Data

A. Performance Specifications

The current performance specifications were established on what was required to use a unit and survive or remain healthy. Has the human body changed its requirements to fit the state of the art? NO!!

What is needed is new categories to allow new concepts and designs that ^{Permit} comfort and safety beyond basic survival, thus allowing basic economical survival units as well as more expensive models with extra features. Why burden the user to pay for regulated luxuries they may not need or cannot afford. These new proposed dynamic rather than static requirements might be met with less opposition by manufacturers if the manufacturers were not forced into expensive revisions of products already deemed as reliable life saving devices.

B. Quality Control

The detailed Quality Control plans submitted to NIOSH were never any guarantee that a Quality Control System existed at the manufacturer's plant. Usually, however, "on site" inspections revealed that the system was either being followed or that the system being followed was equally or more effective than the one submitted.

In this industry, to operate without a complete documented Quality Control system is suicidal. The cost of losing a liability lawsuit far outweighs the cost of an effective Quality Control system. Quality is not free! But once the decision is made to be

a Quality Producer, the most economical way to do so is with an effective defect prevention oriented Quality Control program. Maybe the need for the regulatory agency to be as deeply involved as it has been in the past in the structure of the manufacturer's system has been reduced but the need for the manufacturer to have a system has not in any way decreased. If the proposed field audit has any chance at all of detecting what is representative of what a manufacturer is producing, then the manufacturers must have a system to produce products that are consistent.

The starting of purchasing products that have been used appears to be somebody's idea of measuring reliability of certified products. While the need for reliability requirements for respirators has been discussed for at least six years, TCB has not had either the budget or time for its employees to properly study what the requirements should be. Now, with no proposed accelerated life tests, with reduced emphasis of design specifics, and with Quality Control to be on the honor system, a used (or abused) unit will be picked up from the field and tested. Based on these results all such units by that manufacturer is subject to recall, stop sale or continued approval. This puts the manufacturer in a position of just waiting for the axe to fall. We completely agree with the idea of introducing the reliability concept to the respirator industry but this proposed approach is like shooting somebody to show that guns can be dangerous.

C. Engineering Drawings and Dimensional Tolerances

When the submission of a 12 lb unit requires 27 lbs. of paperwork, it is evident that the reduced staff of TCB could never review every dimension. We would believe, however that a complete elimination of all drawings would be a handicap to TCB. We believe that one set of drawings of the manufactured parts and sub-assemblies including a top assembly drawing would be helpful in the certification process. These drawings would appear to us to help identify the unit components, and analysis by the TCB personnel would be easier.

D. Changes to approved Devices

We would question the necessity of using the time required by TCB for a new approval just for one major modification as the suggested solution proposes.

E. Witnessing of Approval Tests

The presented solution sounds appropriate.

F. Duration of Approval

Unless the user can pay the manufacturer a reasonable fee to refurbish the units in their possession after five years, this proposed regulated antiquety regardless of condition or circumstance could be prohibitively expensive for large users or limited budgets.

G. Product Quality Requirements

AQL's are not guidelines for establishing the allowable percent of defective units as the notice mistakenly suggests. AQL or Acceptable Quality Levels are the foundation for sampling plans which are scaled up and down according to the seriousness of the defect and the risk of making an error in the sample measurement. The effort of any manufacturer is to have no defective units. The use of AQL's have proven to be the most effective way to accomplish this. The suggested alternative of an allowable percent defective works from the other end of the Operating Characteristic Curve. Any realistic criteria of an allowable limit would be a basis for excuses for failures and a criteria impossible to measure by the regulatory agency from the standpoint of logistics and budget. This alternative is completely incompatible with the proposed field audit.

H. Unpublished Test Requirements

This problem and solution is a prime example of reactionary thinking. In spite of the generally friendly rapport of the various manufacturers with each other, they are serious competitors and dislike any loophole which may allow a competitive edge to their competition. The proposed solution appears to be the result of such pressures.

When 30CFR11 was written there were types of respirators both self-contained and Air-purifying that were not invented yet but were subsequently presented to NIOSH for certification. Some of them were good and deserved special consideration to serve the public and a market the company had the foresight to accomodate. Let us not lose sight of the fact that the only reason for the existance of any regulatory agency is to protect the public from harm and not to stifle original thinking and competition. We are not suggesting an uncontrolled free hand by the testers "whim for the day" but the solution must allow room for inovative designs for unique industrial applications that cannot wait a year for the proven test requirement.

I. Testing of Prototype Respirators

The use of NIOSH laboratories as an extension to the research and development arm of the manufacturer was never the intention of prototype testing allowed in 30CFR11.

J. Approval Testing

The ability of TCB to test a pretested prototype made in every way like the production model with the exception of using machined parts in stead of moldings or castings has permitted manufacturers to bring a variety of respirators to the public at affordable prices. If these molds and castings were made before the certification and a problem should arise during the process, thousands of dollars would be wasted in revising molds and tens of thousands of investment dollars would be tied up for an excessive period of time. Large companies would pass this cost to the users and small companies would simply go out of the business. In either case the public loses. We totally agree that a retest of the crucial characteristics should be made on the production model and after all NIOSH can revoke a certification if it did not perform satisfactorily.

K. Group Testing of Respirators

The notice states that this procedure would be more responsive to the user's and applicant's needs. There is no way to respond to this statement since the frequency of the acceptance periods is not stated. We cannot know the status of our competitors but as near as we can calculate the waiting time costs about \$30,000 a month per model in lost engineering time and allocated overhead.

What we would like to see is a bigger portion of our tax dollars allocated to increase the qualified staffing sufficient to handle the overload that has existed for years and appears to be getting progressively worse. In fact, it is our opinion that had the Government properly funded the certification program with sufficient personnel and travel money instead of trying to fit the program into a mold suited for research Doctors and technicians, we would not be meeting here today.

L. User and Maintenance Manuals

We agree with the proposed solution.

M. NIOSH Systems Manual

We agree with the proposal.

N. Publication of Test Data

NIOSH already has the power to pass, fail, instgate recalls, stop sales etc. and now they want to bring back the public whipping post. This psychology is sick. Submissions to NIOSH are simply nobody's business but the applicant and NIOSH. When the unit is certified then the test data is available through the freedom of information act if it is so important to someone.

The publication of the field audit data will show the failure of TCB's ability to do enough field testing to have statistical confidence in their sample data. This would not be true because of their lack of ability to run the tests well, but because there is not enough money in the whole NIOSH budget to properly conduct such a program. The program of field audit is valuable to detect problem areas and works quite effectively as long as it is kept at a low profile for quick response.

We believe that better communication between NIOSH and the manufacturers that it regulates would be the best way to serve the public. The barriers of distrust on both sides of the fence has been the precipitating factor for most of the things listed as problems in the notice. We have never believed that the purpose of TCB is to pot shot and punish but to try to serve the industry in getting to the respirator users the best protection possible in the most effecient and economical manner.

James D. Powers
President
Portable Air Supply Systems Corp.