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NIOSH

23 December 1987

NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road, NE
Atlanta, GA 30333

Subject: 42 CFR Part 84

Dear Mr. Moran:

The following comments and suggestions as provided for the proposed rules of 42 CFR Part 84.

1. Regulatory Impact Analysis--The proposed rules limiting the use of pure oxygen rebreathers in firefighting are likely to cause a major increase in the cost of rebreathers for government agencies. Specifically, both the USAF and USN are planning large procurements of rebreathers for firefighting applications. The proposed rule will significantly increase costs of these units for the government.
2. In general the proposed rules are often too specific in areas where there is little or no need to be specific. Conversely, the rule is far too broad and ill-defined in critical areas, such as safety, where specific levels of safety should be quantified to provide guidance for equipment designers. There are several sections in the proposed rules that are written in such a manner that NIOSH will have great latitude in accepting or rejecting respirators or in imposing additional requirements on the respirators.

Paragraphs numbered: 83.30.d, 84.30.e.3, 84.32.c.1, 84.33.d.2, 84.20.h, 84.20.c, and 84.220 are all related to "evidence that the respirator is free from defects or characteristics which may make it unsafe for its anticipated use" or to requirements that the respirator be "designed and constructed to ensure against creation off any hazard to the wearer."

As the complexity of any device increases there is usually an increase in the number of potential failure modes for the device. Obviously, redundancy and override features can be added to increase the probability of completing a mission, however, this adds cost and may even decrease the overall benefit that the device offers on a system wide basis. (i.e. it becomes too heavy with extra features to be man portable).

The requirement for a device "free" from characteristics which may make it unsafe is so vaguely worded as to be open to a wide range of interpretations which arguably could prevent any respirator from ever being certified. A realistic measure of the level of safety of the device must be provided for design engineers to design to. Some form of Mean Time Between Failure (MTBF), MTBF resulting in an injury or accident, availability, Mission Completion Probability or Safety Index should be provided..

3. Paragraph 84.31.c

States that "the applicant shall provide for testing of applicant's respirator by experts qualified by training and experience to evaluate the effectiveness and safety of the respirator." How will NIOSH determine the qualifications of an expert? What will NIOSH accept as an expert and how will the expert be certified? How will conflict of interest be eliminated if the expert is being paid by the applicant to evaluate the applicants equipment? NIOSH must provide a design standard for this critical factor; safety. Without a standard to design to, there will only be wavering and subjective judgements that will change as frequently as the individual in the job who determines what safety is.

4. Paragraph 84.40.a.9

This should be clarified for certain SCBA to differentiate between breathing rigs and the breathing cannisters. Different weights will occur by mixing different rigs with different cannisters.

5. Paragraph 84.41.b

What constitutes a major respirator component? This requires some definition.

6. Paragraph 84.2.10.b.iii and 84.211

NIOSH should be aware of the potential for applications for certification based on alternative technologies such as:

semi-closed circuit, diverters, rebreathers with out scrubbers, etc., etc.

7. Paragraph 54.220.f and 85.220.h

Please define "adequate vision".
Please define "minimal fogging".
What is an acceptable level of visibility and fogging?

8. Paragraph 84.220.j

This needs to be defined as to time duration, operating conditions, and test subjects or else provide a list of approved materials.

9. Paragraph 84.223.c

What is the rationale for this requirement?

10. Paragraph 84.225

Requiring an even distribution of pressure over the entire area in contact with the face may prove difficult in design, practice and testing. In some cases this may not be the preferred design for a mask.

11. Paragraph 84.229.a

"Target population" should be defined to eliminate ambiguity about the applicability of the device to user groups.

12. Paragraph 84.240

NIOSH should be aware of the potential for applications based on technologies which are not addressed in this section.

How would NIOSH define a mixed-gas, semi-closed circuit device?

13. Paragraph 84.242.a

Will applications be permitted using mixed-gas as a breathing medium?

14. Paragraph 84.242.b and Appendix A part (j)

Limitation on the use of pure oxygen respirators should be considered in the light of the operational history of pure oxygen rebreather use in fire fighting situations. The U.S. Navy has used the oxygen breathing apparatus (OBA) for more than 40 years as its primary breathing system for firefighters on ships. These units are used at the training commands in actual fires at a yearly rate of several hundred thousand uses per year. The historical accident/injury rate for the use of OBA's should be investigated and considered prior to creation of any rule limiting the use of pure oxygen systems in firefighting situations. If the demonstrated experience of large number of uses of these types of rebreathers in fires shows a very small or zero incidence of accidents caused by the 100% oxygen atmosphere then the rationale for a 30% maximum oxygen concentration should be carefully reassessed.

15. Paragraph 84.243.c

This requirement should be optional since gauges exist on the rig and designs can be built where a gauge on the bottle would be of no value and only create one additional failure mode for the system.

16. Paragraph 84.244.a

Is this requirement for gauges to be "marked in force per unit area" or for gauges to be marked in units of force per unit area?

17. Paragraph 84.224.c

There are other satisfactory methods of displaying information such as pictographic representations of bottles. These presentation methods should be permitted.

18. Paragraph 84.224.g

Over what time period is "Z" permitted to occur?

19. Paragraph 84.245.h

This should read that the "remaining service life indicator alarms shall be clearly and distinctly ...".

20. Paragraph 84.245.f

Allowance should be given for use of alarms that provide a warning that can be set at variable points rather than a standard 20-30% or full cylinder pressure since many users will wish to remain in an environment for a longer percentage of time. The timer should be set so the user will immediately start to exit upon hearing the alarm.

21. Paragraph 84.246.d and e

The requirements are ill defined and may actually reduce the overall safety and reliability of a rebreather.

NIOSH should specify an acceptable level of safety or reliability for the unit and permit the designer to meet the constraint.

22. Paragraph 84.247.a

If the requirement for bag size is to be incorporated in the rules, it should be provided as a set number (say 5 liters of compliant volume). Failing to specify a volume leaves the designer in a position where he might be forced to design for a worst case which is open to discussion.

23. Paragraph 84.243-3

What is the breathing mixture used in the bags during this test?

24. Paragraph 84.248-.b

Oxygen concentration in the mask should be set at some realistic percentage below %19.5.

25. Paragraph 248-6.b.2 and 3

Does this requirement apply to chemically generated oxygen systems.

Why is this required?

26. Paragraph 84.248-16.b

An objective test or specification is required to determine what is obscured vision.

27. Paragraph 84.248-16.c

Please define "after correction for deviation from 24° C".

28. Paragraph 84.248-17.c

Where in the flame is the temperature measured?

29. Appendix A, (j), 3

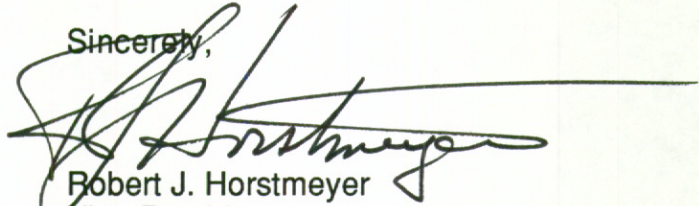
There should not be a constraint on using 100% oxygen cylinders

30. OTHER COMMENTS

Waivers and/or exemptions should be available from these rules. Methods for obtaining waivers and exemptions should be described. The technology available for meeting the requirements is changing: this fact, in addition to the occurrence of special situations require that a procedure should be available to

allow NIOSH to certify equipment with an exemption from certain aspects of the rules and for certain specific users.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Horstmeyer', with a long horizontal line extending to the right.

Robert J. Horstmeyer
Vice President
Business Development

RJH:lk