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August 17, 1998

OFFICE OF  
RULEMAKING  
ADJUDICATION

Secretary  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**DOCKET NUMBER**  
**PROPOSED RULE** **PR 20**  
**(63FR38511)**

**Attention:** Rulemakings and Adjudications Staff

**Subject:** Integrated Environmental Management, Inc.; Maryland Department of the Environment License No. MD-31-281-01; Comments on "Respiratory Protection and Controls to Restrict Internal Exposures", 10 CFR Part 20.

**Reference:** Federal Register, 63 FR 38511, July 17, 1998, Proposed Rule.

Integrated Environmental Management, Inc. (**IEM**) is licensed by the Maryland Department of the Environment (MDE), a U. S. Nuclear Regulatory Commission (USNRC) Agreement State. In addition, **IEM** is a small business that meets the USNRC's size standards in 10 CFR 2.810. Based on our review of the referenced proposed rule, we have concluded that, if implemented in its present form, the proposed revision to 10 CFR 20, Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposures", would have potentially negative ramifications from both a compliance standpoint as an Agreement State licensee, and from a business standpoint. The purpose of this letter is to provide **IEM**'s comments on those aspects (delineated below) of the proposed rule that are of concern to us.

**Operability Testing**

In §20.1703(c)(3), there is a requirement that respirators be tested for operability (e.g., fit check, functional tests) prior to each use. Such tests are typically not documented, and there is no quantitative means of determining whether the respirator "passed the test" or not. Therefore, licensees will be unable to demonstrate compliance with this requirement. On the other hand, §20.1703(c)(4) already requires that operability tests be included in written procedures, rendering the specific requirement of §20.1703(c)(3) moot.

**Bioassays**

Certain chemical and physical forms of the heavy elements (i.e., W- and Y-class forms of thorium, and Y-class forms of uranium and some transuranics) are relatively insoluble in body fluids. In addition, conventional bioassay methods (i.e., whole body and organ counting, urine bioassay, and fecal bioassay) are not sensitive enough for routine exposure monitoring for these elements. Under these circumstances, the only option open to a licensee is to sample the air in the breathing zone of the worker, and then make assumptions about intake rates, patterns, and metabolism in order to estimate the worker's dose of record.

In spite of these circumstances, section 20.1703(c)(2) of the proposed rule requires the use of bioassays during respirator use in order to evaluate actual intakes. Such a requirement places an

undue burden on licensees who work with the aforementioned materials. They would be either unable to comply with the regulation, or forced to implement a bioassay program that, because of inadequate sensitivity, is unable to provide any useful data. It may, in fact, place the licensee in a perpetual state of noncompliance since minimum detectable activities are larger than the annual limit on intake (ALI).

### **Permitted but Unassigned Uses of Respiratory Protection**

Under certain circumstances, a licensee may evaluate a work environment for its potential radiological hazards and make a determination that neither individual exposure monitoring nor respirators are necessary for dose control purposes. However, employees in those environments may choose, for reasons of their own, to wear respirators anyway. (**IEM** does not preclude the use of respirators by its employees or subcontractors.) Under the proposed regulations, the simple act of providing a respirator to an employee upon request results in licensees having to establish a respiratory protection program pursuant to section 20.1703 of the proposed rule. The result is the unnecessary dedication of resources even though no dose of record will ever be recorded.

### **Disposable Respirators**

No Assigned Protection Factors (APFs) for disposable respirators are given in the proposed rule, thus no credit may be taken for their use even though their use is encouraged.<sup>1</sup> However, the programmatic requirements of §20.1703 are activated if *any* form of respiratory protection is required or permitted. OSHA requires employers to provide respiratory protection to employees if it is so requested. To accommodate this request by offering the use of disposable respirators, if the licensee does not have an approved respiratory protection program incorporated into its license, would subject the licensee to enforcement action unless a costly program is implemented.

### **Emergency Response**

If a licensee is authorized to possess, handle or use sealed sources only, its radiation protection program must still address response actions in the event of a breach in a source's integrity (e.g., detection of a leak, damage to the source, etc.). If a required response action might, under certain circumstances, involve respirator use or consideration for respirator use, the proposed rule implies that the licensee must maintain a respiratory protection program pursuant to 10 CFR 20.1703. In other words, the proposed rule implies that *all* licensees incorporate a respiratory protection program into their license unless it can be demonstrated that respirator usage will *never* be required - even under emergency considerations. This implication imposes an undue burden on licensees that deal with only non-dispersible radioactivity under the provisions of their license.

### **Recommendations**

In light of the aforementioned comments, **IEM** offers the following recommendations to the USNRC in regard to the proposed rule.

- The §20.1703(c)(3) requirement that respirators be tested for operability prior to each use should be deleted.

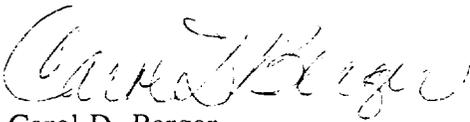
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<sup>1</sup> 63 FR 38515, July 17, 1998.

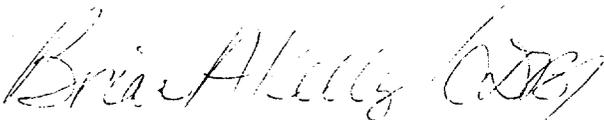
- Because conventional bioassay for certain radionuclides does not provide data useful for confirming the effectiveness of a respiratory protection program, and because the requirements in 10 CFR 1703 are costly and, under certain circumstances, provide no radiation protection benefit if no "credit" is taken for respirator use in the dose assessment process, section 20.1703(c)(2) should be modified to read as follows (modification shown in *italics*): "If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, the licensee shall implement and maintain a respiratory protection program that includes surveys and bioassays, *if appropriate and if protection factors are used for dose assessment*, to evaluate actual intakes."
- The use of disposable respirators or any other form of respiratory protection that does not have an APF should be exempt from the requirements of 10 CFR 20 unless they are mandated by the licensee for control of radionuclide intakes and/or an appropriate airborne protection factor has been approved pursuant to 10 CFR 20.1705.
- The proposed rule should establish the extent to which emergency planning efforts must incorporate the programmatic requirements of 10 CFR 20.1703.

Thank you for the opportunity of submitting these comments and recommendations. We look forward to their favorable consideration, and to timely issue of the revised respiratory protection rules.

Sincerely,



Carol D. Berger  
President



Brian A. Kelly  
Chief Operations Officer

cc: R. A. Duff (RSO)  
Douglas McAbee - Maryland Department of the Environment  
Charles Hardin - Conference on Radiation Control Program Directors



NIST

UNITED STATES DEPARTMENT OF COMMERCE  
National Institute of Standards and Technology  
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RULES & DIRECTIVES BRANCH  
US NRC

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RULES & DIRECTIVES  
ADMINISTRATIVE SERVICES

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USNRC

19 Aug 1998

Rules and Directives Branch  
Division of Administrative Services  
Office of Administration  
USNRC  
Washington, D.C. 20555-0001

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

2

Reference: 63FR38511-21 (Proposed 10CFR20.1701-5) and Draft Regulatory Guide DG-8022

Dear Sir:

Please accept the following comments on the proposed rule and regulatory guide pertaining to Respiratory Protection and Controls to Restrict Internal Exposure.

The NRC is to be commended on the many proposed simplifications to the rule, particularly those moving current portions of the rule to the proposed regulatory guide. However, the proposed rule and the interpretations reflected in the statements of consideration and the regulatory guide raise serious questions of excess and duplicate regulation. For the vast majority of licensees, internal exposure and airborne radioactive material source terms are small-to-trivial portions of worker exposure. The application of Subpart H and its attendant procedures and oversight is totally out of proportion to the related radiological benefits. This is the primary context for the following comments, *i.e.*, licensees where internal exposures are less than 10% of the regulatory limits, and in most cases much less than these limits.

First let us emphasize that there is no question that OSHA rules must be followed. The issues discussed below do not concern worker safety or effectiveness of the respiratory protection for the hazardous environment.

The primary issue is one of excess and duplicate regulation. Despite the NRC assertion that an OSHA respiratory protection program meets the requirements of the NRC rules, the mere fact that 20.1703 states something beyond the phrase "comply with OSHA" creates a different program. And the fact of the matter is that organizations have different organizational elements to implement 10CFR and 29CFR. Hence the mere existence and forced applicability of this rule creates different programs to achieve the same objective. This is a simple fact of life.

The rule is excessive because it is applied to situations where the radiological benefits are negligible or at best a secondary issue, even though the user is complying with the

appropriate OSHA requirements. Prior published interpretations from NRC, e.g., regarding the implementation of the revised 10CFR20, made it clear that Subpart H applies regardless of the concentration level, no matter how small. In the proposed regulatory guide the sentence in section 3.1, i.e., "Unless the licensee can clearly show otherwise, any use of respirators is considered to be for the purpose of limiting intake of radioactive material," makes this point very explicitly.

These NRC interpretations and the statement in the proposed regulatory guide in fact seem contrary to the simple English in both the current and proposed 20.1703. That is, the phrase "if a licensee assigns or permits the use of respiratory equipment" is qualified by "to limit the intake of radioactive material." The straightforward reading of this is that if the licensee's basic purpose is not to limit the intake, then regardless of secondary benefits relating to this, this section would not apply. The NRC interpretation of the current rule with its added phrase "pursuant to section 1702" seems even more at variance with a simply reading of the sentence. We suggest that the current phrase in 20.1702 be retained and that the commonsense interpretation suggested above be used. This aspect of the rule, i.e., the intent to reinforce this interpretation by deleting the above phrase in 1703, is not adequately addressed in the Statement of Consideration and, because of its substantial impact on many licensees, deserves added notice from the NRC.

An open question not addressed by the NRC in the Statement of Consideration is the NRC choice not to simply require OSHA compliance of any respiratory usage. The current 20.1703 in fact is excess baggage in 10CFR since NRC and OSHA signed their agreement on joint enforcement of the respiratory (and other) OSHA rules. If 20.1703 contains elements that are essential for radiological applications for specific licensee usage situations (and this is not explicitly discussed in the statements of consideration) beyond what is in 29CFR, then 20.1703 should identify and restrict its applicability to those situations. To the extent that licensee respirator usage is no different from other non-radiological applications, NRC should simply require OSHA compliance.

And to extend the above argument, to the extent that respirator usage is to control exposures at levels less than 10% of the regulatory limits, NRC should simply require OSHA compliance. The simple fact is that this level of worker internal exposure (or some other arbitrarily lower level of the NRC's choosing) does not justify the administrative and worker resources necessary to administer a 20.1703 program, particularly for the mostly infrequent but appropriate usages of such devices.

In fact, the complexity and burden added by 20.1703 to meeting the basic OSHA requirement is detrimental to implementing ALARA for internal exposures. In the common situation where external exposures are absent or minimal and airborne concentrations are sufficiently low that engineering controls are not justified, 20.1703 in fact discourages any added ALARA measures via respiratory protection. It is not sufficient to simply comply with the OSHA performance requirements. One must also have license conditions detailing how this will be done, have implementing procedures, have quality assurance programs, make additional measurements and assessments,

have auditing programs, etc. While all this is justified for work in life threatening environments and for high dose rate situations, for most licensees it is an avoidable burden for work tasks in airborne atmospheres that are equivalent to at most a few mrem per hour. If NRC has made the judgement that use of respirators for ALARA purposes at such exposure levels is generically not justified, even when in compliance with OSHA requirements, then this should be so stated. Otherwise NRC should allow simple OSHA compliance with no further approval needed from NRC for such situations.

Specific comment follow on various portions of the proposed rule and on the draft regulatory guide titled *Acceptable Programs for Respiratory Protection*.

1. 20.1703(b) requires specific application for non-certified respirators with evidence of the needed protection factor. Since the proposed rule is being applied to situations where the licensee needs no protection factor this section should exempt such licensees from needing NRC approval. Only OSHA issues regarding such usage should be a concern.

2. 20.1703(c)(1) and (2) require certain surveys, bioassays, and measurements simply because a respirator is used and not because other relevant portions of 10CFR20 require these measurements. NRC should clarify that these are not required unless other sections of 10CFR20 so require them. For example, if the airborne radioactivity levels are 1% of DAC there is no requirement for bioassays, personal air sampling, exposure records, etc. And mere use of a respirator should not precipitate such a requirement.

3. 20.1703(c)(3) requires fit testing, but if no credit is being taken for a protection factor because the working atmosphere is less than 1 DAC, this should not be an issue with NRC. Other non-radiological reasons for such usage of a respirator should only be an OSHA issue.

4. 20.1703(d) should be stronger. Since no radiological work would be in an airborne concentration sufficiently high to represent an immediate risk to life, the user should be advised that a respirator can be immediately removed in any situation where the user judges that his health is at risk. Presumably, adequate health screening would minimize the possibility of such a situation arising, but NRC should acknowledge that the radiological risks of such an exposure are unlikely to justify continuing respirator use in a high-stress situation.

5. Regarding 20.1703(i), these statements would appear to be self-evident given the requirements of 10CFR20.1204. There is no discussion in the Statement of Consideration identifying the ambiguity that necessitates this section. If there is some situation envisioned by NRC that is not adequately addressed in 20.1204, then it should be identified. Otherwise it is suggested that this be moved to a footnote in the proposed regulatory guide.

6. The Statements of Consideration states, "All licensees who possess radioactive material in a form that requires a respiratory protection program are identified during the license application, amendment, or renewal process." This is used to justify the useful elimination of the notification requirement. But unless this is simply referring to self-identification by the license applicant, this seems to refer to some sort of an NRC classification criterion that is not elsewhere discussed in this proposal. If the result of this criterion is to expand coverage of Subpart H to more licensees, this should be explicitly discussed and those licensees should be alerted to comment on this proposed rule.

The following comments are on the draft regulatory guide titled *Acceptable Programs for Respiratory Protection*.

1. In section B it is stated that "If a respiratory protection device is assigned or permitted to be used, the device is considered by the NRC as being used to limit intakes of airborne radioactive materials unless the device is clearly and exclusively used for protection against nonradiological hazards. Whether or not credit is taken for the use of the device to reduce intake and dose, Section 20.1703 would apply ... ."

To repeat what was previously stated, we submit that this is needless, duplicate regulatory coverage. Subpart H is clearly and explicitly targeted to controlling exposures at levels greater than 1 DAC, and sections 1703-4 are intended for situations where respirators are needed to lower internal exposures. Most research reactor facilities have airborne radioactive material at some low level, almost universally at a trivial level (e.g.,  $<10^{-6}$  DAC), but this proposal mandates section 1703 coverage for any industrial usage of a respirator, regardless of the fact that such usage is controlled by OSHA rules and that the radiological exposure reductions are minimal. This requirement is made even more redundant by the fact that NRC has an agreement to enforce OSHA rules, and hence presumably does not need section 1703 to control improper use of respirators, and by the fact that exposures at such concentrations are a diminishingly small fraction of the facility TEDE. We suggest that this guide clarify that Subpart H is only explicitly invoked for concentrations that are likely to produce exposures greater than 10% of the limits, and that at levels below this, all that is required is an OSHA compliant program.

Similarly, the wording in section 3.1 ("Unless the licensee can clearly show otherwise, any use of respirators is considered to be for the purpose of limiting intake of radioactive material.") mandates this duplicative regulatory coverage.

We would like to emphasize that duplicate regulatory coverage like this, no matter how similar the rules, is not free. Both human and dollar resources are expended that could profitably be used elsewhere.

2. The discussion of ALARA in section C.2 is excellent and should be retained.

3. The sentence in section 3.1, *i.e.*, "Unless the licensee can clearly show otherwise, any use of respirators is considered to be for the purpose of limiting intake of

radioactive material," is refreshingly honest. The licensee is guilty unless he can prove beyond doubt that he is innocent. However, it would seem more in keeping with an effective regulatory program to assert that the NRC should have to demonstrate that the usage in question was primarily for radiological protection purposes or necessary to meet ALARA objectives. A licensee should not be required to perform surveys that are not otherwise required just to prove his 'innocence.' Nor should a licensee have to avoid doing surveys for fear of invoking 20.1703 because of the possibility of demonstrating the presence of trivial levels of airborne radioactive material. As indicated by section 3.2 there are no halfway measures. Either you have a full-blown, documented 1703 program suitable for any level of respirator usage or you have none.

4. Section 3.3 is mathematically questionable. If the airborne concentration is less than 0.1 DAC, then the APF could be zero and the provisions of 20.1502 would permit the 'no record' allowance. But this zero would not meet the section 3.3 ratio requirement.

Also it would seem that the absence of a factor of 10 in section 3.3 in order to meet the 20.1502 10% requirement implies the reasonable presumption that respirator usage is less than 10% of a work year. But should not this presumption be mentioned? More likely there is simply something in this section that we do not understand, in which case added discussion would be useful.

Sincerely,



Lester A. Slaback, Jr. C.H.P.  
NIST  
Gaithersburg MD 20899

**From:** Les Slaback <lester.slaback@nist.gov>  
**To:** Multiple recipients of list <radsafe@romulus.ehs.u...>  
**Date:** 8/4/98 3:10pm  
**Subject:** DG-8022, Resp. Protection

1. Responses to pskierkowski's note were, I think, missing the point. The point is that non-radiological risks are explicitly acknowledged to be part of the risk balancing process. And once the camel has its nose under the tent one's expectations of what might follow are a bit clearer.

2. Section C has some very clear, explicit, and (in my opinion) excellent statements about ALARA, which in effect address the standard-of-care issue. \*\*\*\*Question: Have these appeared elsewhere as an official NRC position (besides public statements)?

3. In section B it is stated "If a respiratory protection device is assigned or permitted to be used, the device is considered by the NRC as being used to limit intakes of airborne radioactive materials unless the device is clearly \*\*\* and exclusively \*\*\* used for protection against nonradiological hazards." [emphasis added is mine] References to NRC Q&As are noted.

Since one cannot design a respirator that does not offer some protection from airborne radioactivity, and this statement seems unconcerned as to how low the level of the airborne activity might be, in effect this says that one cannot use a respirator at a licensed facility without having a NRC-compliant and approved program. Other words make clear that NRC does not allow such nonradiological use based on 'intent', but only on the end result. As I read this one has two choices, have a NRC approved program or do not have any respirators in the facility for any reason (unless all you have are sealed sources). \*\*\*\*Question: Is there any experience otherwise?

4. OPINION: This whole topic of detailed guidance on respiratory protection seems like a legacy of the 'old days' when avoiding internal exposure was paramount. Despite all the words on minimizing TEDE, in effect 20.1701-3 is micromanagement of mrem exposures. Internal exposures are a very small portion of total exposures. Aside from meeting basic OSHA safety objectives/requirements (which could be done more simply) this would seem to be a prime example of misdirected resources of both the regulator and the licensees. [Said before, but I cannot resist repeating myself when the opportunity presents itself.]

Disclaimer: the above are the personal musings of the author, and do not represent any past, present, or future position of NIST, the U.S. government, or anyone else who might think that they are in a position of authority.  
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The RADSAFE Frequently Asked Questions list, archives and subscription information can be accessed at <http://www.ehs.uiuc.edu/~rad/radsafe.html>

**From:** Les Slaback <lester.slaback@nist.gov>  
**To:** Multiple recipients of list <radsafe@romulus.ehs.u...>  
**Date:** 8/11/98 11:01am  
**Subject:** Respiratory Protection

(This is a resend of this posting. I did not see it appear on RADSAFE after sending it last Friday. I apologise if it is in fact a duplicate.) In the 17 July proposed revision of Subpart H is "All licensees who possess radioactive material in a form that requires a respiratory protection program are identified during the license application, amendment, or renewal process." This is used to justify the useful elimination of a notification requirement. This is a somewhat ominous, but probably innocuous, statement. But the overall thrust of this proposal, and the related draft reg guide, is to explicitly cover virtually any use of a respirator in a licensed facility.

Even if the usage purpose is strictly non-radiological the reg guide is explicit that Subpart H is required unless you can prove no intake involvement. Assuming a zero protection factor will not do it. These proposals offer some simplifications to the rules, but primarily remove ambiguity on the part of licensees relating to past interpretations of the NRC.

If you **\*\*\*possess\*\*\*** a respirator I suggest that these proposals should be reviewed.

Questions: OSHA recently revised its respiratory rules (29CFR1910.134).

1. What is the benefit of subpart H over 29CFR?
2. Is this duplicate regulation? If you implement 10CFR can you ignore 29CFR, or vice-a-versa?
3. Do the smaller licensees get their safety departments to implement Subpart H along with their OSHA program? Despite similarities they are different.
4. Do masks in medical situations qualify as respiratory protection so that presumably all medical licensees would have a Subpart H program?

Opinion: For materials licensees (i.e., all but power reactors) Subpart H is a great inducement to eliminate any sort of respiratory protection in your facility, even for 'ALARA' uses.

No, I am not a shill for my friends down the road. Just stirring the pot.

Disclaimer: the above are the personal musings of the author, and do not represent any past, present, or future position of NIST, the U.S. government, or anyone else who might think that they are in a position of authority.

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**BWX Technologies, Inc.**

Babcock & Wilcox, a McDermott company

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Naval Nuclear Fuel Division

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September 10, 1998  
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OFFICE OF  
RULEMAKING  
ADJUDICATION

DOCKET NUMBER  
PROPOSED RULE PR 20  
(63FR 38511)

Secretary  
ATTN: Rulemakings and Adjudications Staff  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Gentlemen:

BWX Technologies, Inc., Naval Nuclear Fuel Division, submits the following comment regarding the proposed revision of 10 CFR 20, that was published in the Federal Register of July 17, 1998, Vol. 63, No. 137, page 38511.

BWX Technologies, Inc. (BWXT) requests NRC to add provisions for the allowance of combination full facepiece pressure demand supplied air respirators (SAR) with auxiliary self-contained air supply to Appendix A, 10 CFR 20, for use during emergency entry into an unassessed environment.

BWXT believes the addition of this type of apparatus is justified by the following:

1. The National Institute of Occupational Safety & Health (NIOSH) has provisions for approving the reference SAR for emergency entry into hazardous environments. 42 CFR 84.70 states:
  - (b) The following respirators may be classified as designed and approved for use during emergency entry into a hazardous atmosphere:
    - (1) A combination respirator which includes a self-contained breathing apparatus; and
    - (2) A Type "C" or Type "CE" supplied air respirator, where-
      - (i) The self-contained breathing apparatus is classified for 3, 5, or 10 minute service time and the air line supply is used during entry; or
      - (ii) The self-contained breathing apparatus is classified for 15 minutes or longer service time and not more than 20 percent of the rated capacity of the air supply is used during entry.

September 10, 1998

2. NIOSH's "Respirator Decision Logic" dated May 1987, tables 1,2, and 3 provide assigned protection factors (APF). Tables 1-3 each state the following for an APF of 10,000:

"Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode."

"Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode."

3. OSHA has recognized the SAR is capable of providing the same level of protection as an SCBA in its recent revision to the general industry respiratory protection regulations. 29 CFR 1910.134(d)(2) "Selection of Respirators, Respirators for IDLH atmospheres" states:

- (i) The employer shall provide the following respirators for employee use in IDLH atmospheres:
- (A) A full facepiece pressure demand SCBA certified by NIOSH for minimum service life of thirty minutes, or
  - (B) A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.

NIOSH and OSHA consider the combination full facepiece, pressure demand, supplied-air respirator, with auxiliary self-contained air supply, to provide a user with adequate protection for entry into environments where the contaminant or concentration is unknown. This type of respirator is widely used throughout the nuclear industry and its continued use should be authorized by NRC in Appendix A, 10 CFR 20.

Sincerely,



Arne F. Olsen  
Licensing Officer

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USNRC

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September 14, 1998

OFFICE OF  
GENERAL  
ADMINISTRATION

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
**(63FR38511)**

Attn: Rulemakings and Adjudications Staff

Dear Sir or Madam:

This is in response to the NRC request for comments to the proposed rule on Respiratory Protection and Controls to Restrict Internal Exposures, 10 CFR Part 20. The following comments are related to the fit testing and the assigned protection factor:

**1. The equivalency between elastomeric and filtering facepieces**

The footnote f of Appendix A to Part 20 states that "no distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the filter medium is at least 99% efficient and all other requirements of this part are met."

It appears that NRC considers that a filtering facepiece (disposable respirator) can provide the same protection as an elastomeric facepiece provided that the filtering facepiece has sealing area enhancing material and adjustable head straps. There is no assurance that a filtering facepiece meeting these design specifications would provide the same degree of protection as a respirator equipped with an elastomeric facepiece. The only method to ensure their equivalency is to compare the results of quantitative fit testing (QNFT) performed on each type of respirator. NRC should only give credit for the use of a filtering facepiece when it provides the same fit factor as the elastomeric facepiece (more in the next paragraph). NRC should also clarify that the 99% efficient filter medium means a NIOSH approved P-99 or P-100 series particulate filter.

**2. Minimum passing fit factor**

NRC requires that in order for a half-mask respirator to receive an APF of 10, the wearer must achieve a minimum fit factor of 100. The value of 100 is a product of the protection factor of 10 and a safety factor of 10. The PF of 10 is based on the quantitative fit testing (QNFT) study conducted by Edwin Hyatt of the Los Alamos Scientific Laboratory (LASL) in the early seventies<sup>1</sup>. Hyatt selected a variety of half-masks for his study. Protection factors (PF) were measured on the 25 member anthropometric test panel with facial characteristics that represents the American work

population. The test results indicate that a properly trained and fitted wearer can obtain an average efficiency of 90%, which corresponds to a PF of 10. All tested respirators had only one size and none of these masks is available today. The term "protection factor" has been changed to "fit factor" in the current respiratory protection standards.

Warren Myers of the University of West Virginia has conducted a QNFT study for the Mine Safety Appliances Company (MSA) on commonly used half-mask elastomeric facepiece respirators<sup>2</sup>. Facepieces manufactured by Aerro, MSA, North, Survivair, 3M, and Willson were selected for testing. MSA has submitted the study report to the OSHA respiratory protection docket. A total of 13 facepieces was tested. Each mask has three sizes. Fit factors were measured on a 25-member test panel. Test subjects both male and female were selected to fit the facial characteristics of the Los Alamos half-mask anthropometric test panel. The fit tests were performed on the TSI Portacount. The test results are shown on Table 1. The results indicated that fit factors varied between 100 and 81,300. The geometric mean of each mask varied between 1,400 and 6,600. The fifth percentile fit factor varied from 100 to 1,150. This study would be representative for the half-masks available today.

The currently available half-masks are made of very pliable silicone rubber that would achieve a much higher fit factor than the facepieces used in the Hyatt study. It is very common to achieve fit factors more than 1,000. The Myers study indicates that respirator A-2 has the lowest fifth percentile value of 100 and respirator C-3 has the highest fifth percentile value of 1,150.

Many professionals in the respirator community have criticized the low passing factor of 100 which permits a poor fitting facepiece to be used. However, the Myers study is the only study that compares the fit tested results of various currently available elastomeric facepieces. The current NIOSH respirator testing and certification regulation, 42 CFR 84, has no fit testing requirement for respirator certification. The current passing fit factor of 10 for the half-mask respirator is based on the test results of respirators that are no longer available. The passing fit factor derived from the currently available half-mask respirators should be used for assigning the minimum passing fit factor. To ensure that approved respirators would provide adequate fit, NRC should require a minimum passing fit factor base on the currently available information. There are two approaches in assigning the minimum passing fit factor. The first one is to require a minimum fit factor of 1,000 which is based on the lowest fifth percentile fit factor of 100 and a safety factor of 10. The second approach is to require that QNFT be performed on a given respirator. If the respirator achieves a fifth percentile fit factor of 100 on the Los Alamos 25 subject anthropometric test panel, it can be assigned a protection factor of 10. NRC should require a minimum passing fit factor of 1,000 for a half-mask and a minimum fit factor of 5,000 for a full facepiece.

### 3. Facepiece seal check

To ensure that a respirator would provide adequate protection during use, a user seal check must be performed after donning. A satisfactory method to ensure adequate facepiece to face seal is to perform a *negative pressure* and a *positive pressure* seal check. These two seal check methods can be performed easily on elastomeric facepieces. Since most filtering facepieces have no inhalation or exhalation valve, or have an inaccessible exhalation valve, it is difficult or impossible to perform these two seal check methods on the filtering facepieces. Many filtering facepiece manufacturers recommend a 3M developed "positive pressure fit check" (PPFC) that requires the respirator wearer

to cup both hands over the filter area of the filtering facepiece and inhale. The purpose of a negative pressure fit check test is to block the inhalation area, which is easily performed by blocking the air vents of the filter cartridges on an elastomeric facepiece. The disposable respirator manufacturers' recommended method cannot block all the filter area of the respirator. It is not clear what this test accomplishes. Unfortunately, the ANSI Z88.2-1992 respiratory protection standard accepts any manufacturer's recommended fit check method.

The Occupational Safety and Health Administration (OSHA) has reviewed the validation data of the PPFC method submitted by 3M<sup>3</sup>, and which claims that filtering facepieces can be effectively fit checked to allow for a protection factor of 10. A total of 23 subjects was tested in several trials to see how many of those who failed a QNFT would also fail a positive pressure fit check (PPFC) procedure performed by 3M. Using a QNFT screen level of 1008, as many as 37 per 100 improperly-fitted wearers of 3M's 8710 respirator could be erroneously passed by 3M's PPFC procedures. If a QNFT screening level of 10 is selected, as many as 41 per 100 improperly-fitted wearers of 3M's filtering facepiece could be erroneously passed by 3M's PPFC procedures.

NIOSH has deleted the fit testing and user seal check requirements for respirator certification. To ensure adequate wearer protection, NRC should require the use of an effective user seal check method that results in a minimum number of inadequate fits.

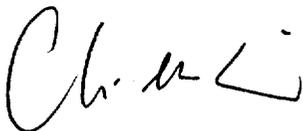
#### 4. Qualitative fit testing methods

There are three qualitative fit testing (QLFT) methods available: isoamyl acetate, irritant smoke and sodium saccharin. Based on information in the OSHA Docket H-049A, the mass medium aerodynamic diameter (MMAD) of sodium saccharin is between 3 and 5 micrometers. The facesal leakage studies conducted by Hinds of the University of California at Los Angeles and Willeke of the University of Cincinnati indicate that particles larger than one micrometer are less likely to challenge the facesal of a respirator. NRC should not adopt any QLFT method in which the challenge agent does not penetrate the facesal.

NRC should also specify the detailed protocol regarding the performance of the QNFT. Parameters such as the maximum particle diameter (geometric mean and standard deviation), exercise regimen, exercise time, etc., should also be specified by NRC.

Since the radioactive particulates are highly toxic, a higher standard should be applied for worker protection. I would like to thank you for the opportunity to comment and also to offer my assistance in developing the amended rule.

Sincerely,



Ching-tsen Bien, PE, CIH

**TABLE 1 FIT FACTORS OF ELASTOMERIC FACEPIECES**

Manufacturers: Aearo, MSA, North, Survivair, 3M, and Willson.

Respirator	Fit Factor	Geometric Mean	Geo. Std. Deviation	Fifth % Value	95% Conf. Limit on GM	Lower 95-95 Tolerance Limit
A-1	100 - 61000	3000	7.03	120	1350 - 6740	30
A-2	100 - 20600	1400	5.04	100	740 - 2800	40
B-1	100 - 44400	4700	3.95	490	2660 - 8270	200
B-2	1000 - 35550	4800	2.58	1000	3230 - 7070	540
C-1	100 - 11500	3200	2.94	540	2040 - 4960	240
C-2	200 - 42900	6000	3.36	810	3610 - 9830	370
C-3	500 - 29800	6600	2.89	1150	4240 - 10170	580
D-1	100 - 19300	2800	3.07	440	1760 - 4430	210
D-2	200 - 51100	4600	3.58	560	2700 - 7730	250
E-1	100 - 43400	3300	3.56	410	1970 - 5630	180
E-2	300 - 41500	4600	3.72	530	2690 - 7960	230
F-1	200 - 21500	2000	3.27	290	1250 - 3320	130
F-2	100 - 81300	5800	3.76	660	3360 - 10010	280

## REFERENCES

1. Hyatt, EC: Respirator Protection Factors. Los Alamos Scientific Laboratory, UC-41 (1976).
2. Myers, WR: Fit Test Quality Assurance Report for MSA on Half Facepiece Respirators: Phase II Report. Prepared for MSA Co., March 1993
3. Letter from Patrick Tyson, Acting Assistant Secretary for OSHA to Peter G. Nash, Counsel for 3M. April 15, 1986, OSHA Docket H-033.

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September 21, 1998

OFFICE OF THE SECRETARY  
RULEMAKING AND  
ADJUDICATIONS STAFF

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Attention: Rulemakings and Adjudications Staff

DOCKET NUMBER  
PROPOSED RULE PR 20  
(63FR38511)

**Reference:** NRC Proposed Amendment of 10 CFR part 20

Dear Sir or Madam:

Minnesota Mining and Manufacturing Company (3M) through its Occupational Health and Environmental Safety (OH&ES) Division is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold approved respirators since 1972. We have developed numerous training programs, videos, computer programs and technical literature to help our customers develop and run effective respirator programs. Our sales people have trained and fit tested hundreds of thousands of respirator wearers throughout the world. Our technical staff has performed basic research on the performance of respirators and their use, presented and published these data in numerous forums and participated in the development of the ANSI Z88 standards on respiratory protection. We have substantial experience in respiratory protection and all phases of its use.

We are pleased to provide the Nuclear Regulatory Commission with our comments on the proposed revision of the standard for respiratory protection that was published in the Federal Register, 63 FR 38511, dated July 17<sup>th</sup>, 1998. Specific comments are attached that answer the questions asked by the commission.

In summary, the NRC proposed rule closely follows the advice in the ANSI Z88.2 (1992) standard. This standard represents the best advice on how to implement a respirator program. In general we support the proposed rule, except in specific areas where NRC has chosen to depart from the ANSI standard. Most of our comments will deal with Appendix A - Assigned Protection Factor Table.

Nuclear Regulatory Commission

Page 2

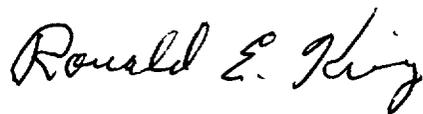
September 21, 1998

We believe that NRC needs to consider how the proposed rule will relate to the newly revised OSHA standard on respiratory protection, 29 CFR 1910.134 issued January 8, 1998, and the ANSI Z88.2 standard. In some cases, employers will be regulated by both NRC and OSHA. If there are variations in the program required by NRC, it will make it difficult to comply with both standards often requiring duplication of effort.

Enclosed are two peer reviewed journal articles by T. J. Nelson and one by W. R. Myers that are referenced in our comments to substantiate our positions. Also enclosed is a letter from 3M to A. Rocklein dated June 3, 1997 and a letter from 3M to Dr. D. Cool dated September 8, 1997. These letters detail the 3M position on the standard and are being submitted at this time so that they are a part of the permanent docket record.

We appreciate the opportunity to add our comments and knowledge to the rulemaking record and look forward to a fair, protective and useful standard.

Sincerely,



Ronald E. King  
Regulatory Affairs Manager  
3M Occupational Health and Environmental Safety Division

Attachments

## **3M Comments on specific areas of the NRC Proposal**

### **Appendix A - Assigned Protection Factor Table**

NRC has generally adopted the assigned protection factors from the ANSI standard, except for "single use - disposable" and half and full facepiece demand type respirators. For "single use - disposable" type, no APF is listed, however if an employer demonstrates through fit testing that a fit factor of 100 is achieved, then the APF of ten can be assumed (Footnote e). NRC should delete the use of the term "single use - disposable". There is no longer a single use approval category in NIOSH 42 CFR part 84. NRC is defining half mask elastomeric respirators as those with a plastic or elastomeric sealing surface and having 2 or more adjustable suspension straps.

NRC is using the ANSI APFs since they represent "state-of-the-art" guidance and reflect consensus of the technical community. However, in the case of the "single use - disposable", NRC is basing the decision to use alternative APFs on "beliefs" or reasoning other than an examination of available technical data and literature. We believe that this is inconsistent with the intent and goals of the NRC standard and that NRC should follow the ANSI APF guide in total. NRC did not reference any technical information to disagree with the ANSI standard.

Rather than relying on beliefs, NRC should rely on performance data. In determining Assigned Protection Factors, the ANSI committee used the best technical data available<sup>1</sup> so it would be reasonable for NRC to adopt these without making certain exceptions based on opinion.

Workplace data suggest that the APF of ten is appropriate for all half facepiece respirators. There are no data that suggest that a filtering facepiece respirator, without an elastomeric seal and adjustable straps, performs any less well than the elastomeric type. Nelson has shown, in an analysis of WPF studies<sup>2</sup>, that no statistical difference was found between filtering facepiece and elastomeric respirators.

This is not an unexpected result if the performance of the two styles of half facepiece respirator is examined. Performance is determined by leakage into the respirator. Leakage can occur through pathways; filter, faceseal or defect. Filter leakage, or penetration, is controlled by the certification process. The

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<sup>1</sup> Nelson, T.J., The Assigned Protection Factor According to ANSI, *Am. Ind. Hyg. Assoc. J.* 57(8)735-740 (1996)

<sup>2</sup> Nelson T. J.: The Assigned Protection Factor of Ten for Half Mask Respirators, *Am. Ind. Hyg. Assoc. J.* 56(7) 717-724 (1995)

certification tests allow the same penetration, or require the same efficiency, for filtering facepieces as for the same class of filter used on an elastomeric facepiece. The same fit tests are used for either type of respirator to limit facepiece leakage to 1% or less. If the respirator is properly maintained and inspected no difference in performance is expected and the referenced studies<sup>2</sup> show similar performance.

The Appendix is confusing in that an employer can choose to use an acceptable fit test and use the APF of ten for the filtering facepiece type of respirator. Is this acceptable fit testing not a requirement for all tight fitting facepiece respirators used for protection? If it is, then no distinction should be made in the APF of the half facepiece devices. As written, Appendix A seems to say that an elastomeric can be used with no fit testing nor medical evaluation, and still use an APF of 10.

The better solution would be for the Appendix A Table to assign an APF of 10 to all half facepiece respirators. All requirements of a good respirator program should be required, including valid qualitative or quantitative fit testing. NRC could then choose to allow the use of respirators (any kind) in "voluntary use" situations or areas where respiratory protection is not required with some relaxed requirements. Program elements such as training, medical evaluation, maintenance, inspection and storage are necessary in these situations to prevent the use of the respirator from causing "harm" to the employee. Other provisions, such as fit testing, would not be required.

This would be more in line with the recent OSHA standard, and, in reality, is what the NRC proposal is saying by way of the footnotes.

### **Additional Comments on the Assigned Protection Factor Table**

The table is not written in plain English, as regulations are now supposed to be. Terminology used in the ANSI standard should be followed, e.g., half mask, full facepiece, etc. The table should be clarified within its body so that it does not require so many explanatory footnotes.

Delete 'Particulate' and 'Gases and vapors' column headings. Replace with one column called 'Assigned Protection Factor (APF)'. Current format is more confusing than helpful. This method implies that a gas and vapor respirator with a particulate filter does not have one APF. 20.1703 (c)(1) requires proper equipment selection. This implies that the person selecting respirators knows that a filter is for particulate hazards and not for gases and vapors.

### **Footnote a**

In footnote a, it is incorrect to reference 29 CFR 1910 only. Other OSHA regulations such as 1926 may apply. We suggest simply stating that Department of Labor regulations apply.

### **Footnote b**

In footnote b, delete the 'Modes' column. Incorporate the words demand, pressure demand, and continuous flow into the plain English respirator descriptions in the body of the table, e.g., Full facepiece, pressure demand or continuous flow. Remove terms such as NP and PP, since the proposal doesn't define what the terms mean. For example, listing 'Powered Air Purifying Respirator' is clearer than 'PP'. NIOSH does not consider these positive pressure devices.

### **Footnote c**

Footnote c should be deleted. The specification of filter efficiency should be addressed in the text of the standard or the APF table, not as an obscure footnote.

Footnote c also appears to contain an error. It states that for respirators with APFs less than 100, filters that are at least 99.97% efficient are required. We believe that it is supposed to say APFs greater than 100.

In addition, for respirators with APFs less than 100, NRC proposes to require that filters be at least 99% efficient. No explanation is given for proposed requirements of 99 percent efficient filters for half masks and 99.97 percent efficient filters for full facepieces. These requirements do not appear to take into account the differences between NIOSH certification testing and real world filter performance. NRC did not identify any data indicating that a 95% filter is not sufficient.

NIOSH certifies filters in three levels of efficiency (95, 99 and 99.97%). A filter must remain above the required efficiency for the duration of the test. The tests are performed at extreme conditions that are not representative of the workplace. For example, airflow through the filter is set at 85 lpm, equivalent to a person performing at a very high work rate. The challenge aerosol is at or near the most penetrating particle size. Because these extreme conditions are not found in the workplace, filter efficiency will be essentially 100 percent for any certified filter.

Selecting a filter with a higher filter efficiency does not always have the desired result of better protection. A 99% efficient filter may not be better than a 95% efficient filter. Higher filter efficiency leads to higher pressure drop across the filter. This results in increased breathing resistance that affects comfort so that the respirator may not be worn for the time required or worn properly. In addition, the increased discomfort may affect the ability to sustain work effort and could result in the job taking longer. Increasing the time to do the work directly contradicts TEDE ALARA that NRC states as their position. Thus, not using 95% filters contradicts the NRC position. Also, laboratory experiments have shown that as pressure drop increases, leakage through the face seal increases. Therefore, requiring a higher filter efficiency may lessen the amount of protection that can be achieved due to increases in face seal leakage.

#### **Footnote d**

In footnote d, the first sentence should be modified for clarity as follows: 'The assigned protection factors are not applicable to radioactive contaminants that present an absorption or submersion hazard.' Delete last sentence. This provision should be covered in the text of the standard, not as a footnote to the APF table. The text should identify criteria to determine when use of a cartridge may be considered, i. e., demonstrated efficiency against the gas or vapor, ability to establish change schedule, etc.

#### **Footnote e**

Footnote e should be deleted. The first sentence is true of any tight fitting respirator. Footnote a states that APFs only apply to properly fitted devices.

The footnote states that it is difficult to perform a positive or negative pressure pre-use fit check on filtering facepiece type respirators. Again, this is a "belief", or opinion, that is unfounded in scientific reality and is improper in a regulatory standard. NRC did not reference any technical information to support its position. NRC would be better served by relying on technical information.

For this type of respirator, the fit check process is different. Rather than determining if pressure can be maintained inside the facepiece, a check is made whether the flow of air can be detected around the face seal. These checks have been shown to be an effective method of checking respirator fit and perform as well as the traditional fit checks on elastomeric type facepieces.<sup>3</sup>

*"Fit check methods applied to the DFF (Disposable Filtering Facepiece) respirators were found to be equivalent to the fit check methods applied to the*

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<sup>3</sup> Myers, W.R., M. Jaraiedi, and L. Hendricks: Effectiveness of Fit Check Methods on Half Mask Respirators. *Appl. Occup. Environ. Hyg.* 10(11):934-942 (1995).

*EF (Elastomeric Facepiece) respirator by all criteria used in the study to assess fit checks. The sensitivity of the fit check to detect bad donnings of previously fit tested respirators averaged 96% for all four respirators. Conversely, the percent of subjects accurately identifying properly donned respirators with the fit check averaged 66% for all four respirators. Considering that fit check methods are very simple to perform and require no ancillary equipment, the sensitivity and specificity for these methods are remarkably good."*

As discussed earlier, the fifth sentence should apply to any half mask respirator and is therefore redundant.

#### **Footnote f**

Footnote f should also be deleted based on the previous discussion of the performance of half mask respirators. No data exist that show elastomeric facepiece respirators, or respirators with a seal-enhancing material, perform better than those without. In addition, the ANSI committee could find no data to justify limiting the APF of the quarter mask. The required fit testing will detect the same level of face seal leakage for either quarter mask or half mask respirators, and eliminate ill fitting respirators of either type. Therefore, there is no apparent reason to distinguish between the two. This reasoning is used in the ANSI standard. If NRC has data to prove that this type of respirator should not be used, it would be more appropriate to change the certification system and not allow the quarter mask type to be approved rather than trying to discourage their use through artificial means.

#### **Footnote i**

The last sentence of footnote i should be deleted. This is covered by the respirator program (fit testing, maintenance or training).

### **Comments on specific sections of 10 CFR 20 Proposal**

#### **§20.1003 Definitions**

**Fit Check (User seal check):** NRC should eliminate the reference to irritant smoke check and isoamyl acetate check. This will create confusion as these are qualitative fit test materials. Users will then assume that the positive and negative pressure tests are qualitative fit tests, which they are not. We suggest following ANSI or OSHA for definitions and procedures.

NRC has added several definitions to the standard to clarify the regulation. We believe that several other ANSI standard definitions would add additional clarity to the NRC standard. Our suggestions for additional definitions are listed below:

**Filtering Facepiece Respirator:** A type of disposable respirator in which the filter is an integral part of the facepiece or with the entire facepiece composed of filter medium.

**Hood:** A respiratory inlet covering that completely covers the head and neck and may cover portions of the shoulders.

**Loose-fitting facepiece:** A respiratory inlet covering that is designed to form a partial seal with the face, does not cover the neck and shoulders, and may or may not offer head protection against impact and penetration. (Note – This is a new term in Regulations being introduced by the NRC and needs to be defined.)

**Qualitative fit test:** A pass/fail fit test that relies on the subject's sensory response to detect the challenge agent.

**Quantitative fit test:** An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

**Respiratory inlet covering:** That portion of a respirator that connects the wearer's respiratory tract to an air-purifying device or respirable gas source, or both. It may be a facepiece, helmet, hood, suit, or mouthpiece/nose clamp.

**Suit:** A respiratory inlet covering designed to cover the entire body. This term does not include protective clothing that only provides skin protection.

**Tight-fitting facepiece:** A respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece (includes quarter masks, disposable masks, filtering facepiece respirators and masks with elastomeric facepieces) covers the nose and mouth; a full facepiece covers the nose, mouth, and eyes.

### **§20.1703 (c)(6) Fit Testing**

NRC is proposing to require fit testing for all tight fitting respirators. Requirements include fitting negative pressure respirators to a fit factor of 10 times the APF and positive pressure devices to a fit factor greater than 100. Periodic refitting is required on a 3 year interval.

We believe that it would be useful for NRC to provide a reference in this section to fit test procedures. We recommend the procedures in OSHA 29 CFR

1910.134 issued 1/8/98. This provides consistent and uniform requirements for locations that are regulated by both NRC and OSHA.

The three year interval between tests in the proposed rule differs from the requirements in the OSHA and ANSI standards, each requiring an annual fit test. NRC commented that the agency believes that an employer can be alert to changes in physiology that would effect the outcome of a fit test. We know of no information that supports that belief for negative pressure respirators.

In the preamble to the final rule, OSHA summarized the information from the record. OSHA noted that data in the record supported their position to fit test negative pressure respirators on an annual basis.

"Annual retesting of respirator fit detects those respirator users whose respirators no longer fit them properly. The Lord Corporation, which already performs annual fit tests, reported that of its 154 employees who wear respirators, one to three (2 percent or less) are identified each year as needing changes in model or size of mask (Ex. 54-156). Hoffman-LaRoche only performs fit tests at two-year intervals, and it reported a much higher incidence of fit test failures. Sixteen of the 233 people tested in a recent two year cycle of fit testing (6.86%) needed a change in their assigned respirators (Ex. 54-106). The Lord experience (Ex. 54-156) indicates that annual retesting of facepiece fit detects poorly fitting facepieces, while the Hoffman-LaRoche evidence demonstrates that waiting two years for retesting can result in the discovery that quite a high percentage of workers have been relying on poorly fitting respirators. Extending the retest interval to more than one year would allow those individuals with poor fits that could have been detected by annual fit testing to wear their respirator for a second year before the poor fit is detected. "

We therefore recommend an annual fit testing requirement for all tight fitting respirators. This would also be consistent with the current OSHA standard.

#### **§20.1703 (g)**

Paragraph (g) requires the use of Grade D air for air supplied respirators as defined in the ANSI-CGA G-7.1 (1989) standard. This standard has recently been revised, the current date is 1997.

# Effectiveness of Fit Check Methods on Half Mask Respirators

Warren R. Myers,<sup>A</sup> Majid Jaraiedi,<sup>A</sup> and Lynnette Hendricks<sup>B</sup>

<sup>A</sup>College of Engineering, West Virginia University, Morgantown, West Virginia 26506; <sup>B</sup>Nuclear Energy Institute, Washington, DC

Studies were conducted to evaluate whether a positive/negative (+/-) fit check was an effective aid in helping users of respiratory protective equipment (RPE) achieve a good fit when donning the RPE. Two types of half-facepiece RPE were used in the studies: the disposable, filtering facepiece and the elastomeric facepiece. Three models of disposable, filtering facepiece and one model of dual-cartridge, elastomeric facepiece were evaluated. A population of 64 inexperienced users of RPE was randomly divided into two equal groups. One group was trained to don the RPE using the +/- fit check as an aid, while the second group was trained to don the RPE without conducting a +/- fit check. The number of successful RPE donnings achieved in the group using the fit check was compared with the number of successful RPE donnings achieved in the group not using a fit check. The data obtained from this experiment suggested that, in general, fewer unsuccessful donnings and more consistent donnings were obtained by RPE users when fit checks were used as an aid in donning both general types of RPE used in the study. This implies that a +/- fit check has value in assisting the wearer of a disposable filtering facepiece or a half mask to properly don the RPE. On a second population of 64 inexperienced users of RPE, the pass/fail outcome of fit checks was used to measure the discriminatory power of fit checks. The subjects used the +/- fit check to discriminate whether the fit of RPE preadjusted by the experimenters was good or bad. Fit checks were found to be fairly useful, easy-to-learn tools for respirator wearers to discriminate between good and poor donnings. MYERS, W.R.; JARAIEDI, M.; HENDRICKS, L.: EFFECTIVENESS OF FIT CHECK METHODS ON HALF MASK RESPIRATORS. APPL. OCCUP. ENVIRON. HYG. 10(11):934-942; 1995.

Current regulations, standards, and recommendations addressing use and selection of respiratory protective equipment (RPE) require that individual users be fit tested as part of the selection process and also that they be able to conduct fit checks when donning the RPE.<sup>(1-5)</sup>

The 1980 American National Standard for Respirator Protection recommends that each RPE wearer undergo and pass a quantitative or qualitative fit test as part of the selection process and be required to check the seal of the respirator by appropriate means prior to entering a harmful atmosphere.<sup>(1)</sup> The standard states that to check the seal the wearer should use procedures recommended by the respirator's manufacturer or by any of several field tests which are subsequently described. Among the field tests listed was a negative and/or positive

pressure sealing test. Historical referencing of negative and positive sealing test procedures in American Industrial Hygiene Association/American Conference of Governmental Industrial Hygienists and American National Standards Institute (ANSI) recommendations and standards is traced in Table 1.

After a worker has been fit tested and assigned a respirator, the U.S. Occupational Safety and Health Administration's (OSHA) RPE standard 29 CFR 1910.134(e)(5)(i) states, "... To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece fitting instructions."<sup>(4)</sup>

The 1992 American National Standard for Respirator Protection defines a fit check as a test conducted by the wearer to determine if the respirator is properly seated to the face and is performed by appropriate means each time the respirator is donned or adjusted, "appropriate means" being the procedures recommended by the manufacturer or by checks described in the standard.<sup>(3)</sup>

Based on current practice and terminology, a fit test is conducted to assess the fit of the RPE during the initial selection process or during follow-up fit tests typically conducted at 6-month or yearly intervals. In contrast to a fit test, a fit check is a simpler procedure that does not require additional equipment. The fit check is for the user of an already properly fit RPE to use with each donning to ascertain or check that the RPE is properly set on the face. The appropriate understanding of a fit check is that it is an adjunct to the formal process of fit testing, a tool to aid with each donning of the RPE.

While the ANSI standards mention several fit check procedures, the authors are aware of only the positive and/or negative pressure fit check procedures being commonly used or recommended by manufacturers of RPE. In general, the end point of these tests is to be able to maintain a +/- pressure within the facepiece for a few seconds or to be able to detect face seal leakage associated with an increased +/- pressure.

To check for maintenance of negative pressure, the user typically blocks off the air inlet(s), inhales sharply so that the mask collapses slightly, briefly holds the inhalation, and determines if a negative pressure is maintained inside the RPE for a few seconds and/or there is no detection of in-board air coming in the face seal. The positive pressure sealing test is performed similarly. The wearer blocks off the air outlet, exhales slightly to cause the RPE to inflate, briefly holds the exhalation, and then determines if a positive pressure is maintained inside the RPE for a few seconds and/or there is no

TABLE 1. Evolution of Negative and Positive Pressure Test Traced Through Selected Documents

Reference	Negative Pressure Test	Positive Pressure Test
AIHA/ACGIH 1963 <sup>(5)</sup>	Close off the inlet opening of the canister by covering it with the palm of hand or by replacing the tape seal, inhale so that the facepiece collapses slightly, and hold the breath for 10 seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the gas mask, as worn, is satisfactory.	Close off the exhalation valve and exhale gently so that a slight positive pressure is built up in the facepiece. If no outward leakage of air is detected at the periphery of the facepiece, the face fit is satisfactory.
ANSI Z88.2-1969 <sup>(6)</sup>	Close off the inlet opening of the canister or cartridge(s) by covering it with the palm of the hand(s) or by replacing the seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for 10 seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is probably satisfactory.	Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of leakage of air at the seal. For most respirators, this method of leak testing requires that the wearer first remove the exhalation valve cover and then carefully replace it after the test.
ANSI Z88.2-1980 <sup>(1)</sup>	Follow procedures recommended by the manufacturer or the inlet opening of the respirator's canister(s), or cartridge(s), or filter(s) is closed off by covering with the palms of the hand(s), by replacing the inlet seal on a canister(s), or by squeezing a breathing tube or blocking its inlet so it will not allow the passage of air. Then the wearer inhales and holds his or her breath for at least 10 seconds. If a facepiece collapses slightly and no inward leakage of air into the facepiece is detected, it can be reasonably assumed that the fit of the respirator to the wearer is satisfactory. For a respirator equipped with a mouthpiece and nose clamp, if leakage of air into the nose or mouth cannot be detected, then it can be reasonably assumed that the fit of the respirator to the wearer is satisfactory.	Follow procedures recommended by the manufacturer or the exhalation valve, or breathing tube, or both, is closed off and then the wearer exhales gently. The fit of a respirator equipped with a facepiece is considered to be satisfactory if a slight positive pressure is built up inside the facepiece without the detection of any outward leakage of air between the sealing surface of the facepiece and the respirator wearer's face. The fit of a respirator equipped with a mouthpiece and nose clamp is considered satisfactory if the respirator wearer senses a buildup of positive pressure and is unable to detect any outward leakage of air through the nose and in the area between the mouth and mouthpiece.
ANSI Z88.2-1992 <sup>(2)</sup>	Follow procedures recommended by the manufacturer or the inlet opening of the respirator's canister(s), or cartridge(s), or filter(s) is closed off by covering with the palms of the hand(s), by replacing the inlet seal on a canister(s), or by squeezing a breathing tube or blocking its inlet so it will not allow the passage of air. Then the wearer inhales gently and holds his/her breath. If a facepiece collapses slightly and no inward leakage of air into the facepiece is detected, it can be reasonably assumed that the fit of the respirator to the wearer is satisfactory.	Follow procedures recommended by the manufacturer or the exhalation valve, or breathing tube, or both, is closed off and then the wearer exhales gently. The fit of a respirator equipped with a facepiece is considered to be satisfactory if a slight positive pressure is built up inside the facepiece without the detection of any outward leakage of air between the sealing surface of the facepiece and the respirator wearer's face.

detection of outbound air exiting the face seal. These fit checks were described in early standards and recommendations as documented in Table 1.

Manufacturers of disposable, filtering facepiece RPE typically recommend covering the mask with both hands, exhaling, and checking for air flow between the face and the sealing surface of the respirator.

While these fit check methods are widely recommended and used, there is no published research that has evaluated the efficacy of fit checks in aiding wearers to don RPE. Hardis *et*

*al.*<sup>(7)</sup> did report on a study correlating results of a negative pressure qualitative fit test against fit factors obtained by standard quantitative fit test. They reported that out of 195 passing negative pressure qualitative fit tests, only one was found to provide a quantitative fit factor of less than ten.

The objective of this article is to address a number of questions and issues regarding fit checks: (1) Does performing a fit check help users of properly fit RPE detect bad donnings? (2) Does use of a fit check increase the probability of achieving a certain level of fit? (3) Does use of a fit check provide more

consistent donnings of the RPE? (4) Is the fit check recommended for filtering facepiece respirators as effective as those recommended for elastomeric respirators?

This article reports the results of two experiments. The first evaluated the usefulness of the fit check to assist subjects in correctly donning RPE by comparing the number of successful donnings achieved in two groups: one donning with the aid of a fit check, and the other without the aid of a fit check. The second experiment measured the discriminatory power of a fit check by having subjects assess the fit of RPE which had been preadjusted to cause poor fit characteristics.

## Materials and Methods

### Test Subjects

Subjects were recruited via questionnaire from a very large population (>10,000) of predominantly white-collar workers. All subjects had to meet the following minimum requirements to participate in the research study: 1. no direct affiliation or business responsibility with the research, design, or manufacture of RPE; 2. no previous training in the use of RPE; 3. no previous experience with wearing RPE in their jobs; and 4. no facial hair that would compromise the seal of the RPE.

Potential test subjects, meeting the aforementioned criteria, were given manufacturer's instructions for donning the RPE. They were then fit tested using the sodium saccharin qualitative fit test method following the protocol published in the OSHA Lead Standard 29 CFR 1910.1025.<sup>(8)</sup> This method has been validated against quantitative fit test methods to be capable of rejecting masks with fit factors of less than approximately 100.<sup>(9)</sup>

If the subject failed the initial fit test, the respirator was donned again and the fit test was repeated. If the subject failed the fit test on the second donning, that respirator was not used by that subject in the study. Subjects failing to receive adequate fit on more than one of the four respirators were not selected for the study.

Subjects were randomly divided into three groups. The 32 subjects assigned to group 1 were trained to don and adjust the respirators but were not instructed on using fit checks. The 32 subjects assigned to group 2 were trained to don and adjust the respirators with the aid of fit checks. Because of the fit test inclusion criteria discussed in the preceding paragraphs, in some cases there were less than 32 subjects wearing each of the four respirators in these two groups.

The 64 subjects assigned to group 3 were trained to don and adjust the respirators with the aid of fit checks. This group was used in experiment II to measure the discriminatory power of a fit check by having subjects assess the fit of the RPE which had been preadjusted to purposely cause poor fit characteristics.

Subjects selected for use in the studies received a small compensation for their participation.

### Respirators

Four negative-pressure, half-facepiece respirators were used in the study. Each is certified in the United States by the National Institute for Occupational Safety and Health (NIOSH). The assigned protection factor for half-facepiece respirators is ten.<sup>(2)</sup> Three of the RPE were different types of disposable filtering

facepiece (DFF) respirators. The fourth type was a dual-cartridge, elastomeric facepiece (EF) respirator.

One of the three DFF respirators was a NIOSH-certified dust/mist (D/M) class device that incorporated a moldable nose clip. The second was a NIOSH-certified dust/fume/mist (D/F/M) class device that had an exhalation valve and a moldable nose clip. The third was a NIOSH-certified, high efficiency (HE) class device that had an exhalation valve, a moldable nose clip, and an elastomeric face seal ring. The DFF respirators were available in only one facepiece size except for the HE, which was available in two sizes.

The EF respirator was configured with NIOSH-certified D/M class filter elements. This respirator was available in two facepiece sizes.

### Respirator Preadjustment for Experiment II

The moldable nosepiece on the three DFF respirators provided an opportunity to preadjust the nosepiece to purposely induce leaks around subject's nose. Oestestad *et al.*<sup>(10)</sup> found that the nose is the most common leak site for subjects wearing half-facepiece respirators. In that study, which involved 73 subjects, the nose was involved as a site of leakage approximately 78 percent of the time.

The nosepieces of the DFF respirators were preformed on one of two different head forms. One head form had a very wide, smooth nose bridge which left the nosepiece virtually unchanged from its out-of-the-package configuration. The other had a much narrower nose, which resulted in the nosepiece being squeezed together during the preforming. These two preformed nosepiece configurations, coupled with the range of facial sizes and nose shapes represented by the study population, presented the possibility for a wide range of fit outcomes.

Preadjustments on the EF respirator consisted of setting the head and neck straps 2 cm looser than where the subject had initially adjusted the straps to pass the saccharin qualitative fit test. Strap length had been noted during the training session. The head cradle construction of this respirator made it possible to preadjust strap tension for this phase of the testing while still enabling the subjects to easily don the respirator. In addition, each subject wore both sizes of the EF respirator, resulting in an even greater range of fits.

### Laboratory Protection Factor Testing

The quality of each donning was assessed from measurements of particle concentrations inside and outside the respirator during a chamber test. It is important to note that since non-high efficiency particulate air class filters were used (in contrast to requirements to conduct fit testing), filter penetration could be a significant contributor to the in-facepiece concentration. Therefore, the independent variable of the chamber test is denoted as a laboratory protection factor (LPF).<sup>(11)</sup> As defined for the purposes of this study, the LPF is the ratio of chamber particle concentration to in-facepiece particle concentration, where the in-facepiece concentration is a function of filter efficiency as well as face seal penetration.

Chamber testing was performed with a system that utilized a TSI model 3450 vibrating orifice aerosol generator to produce a 2.0- $\mu\text{m}$  diameter particle of corn oil. Particles were

counted with a TSI model 33 APS unit. The equipment and test setup have been previously described in greater detail.<sup>(12)</sup>

In-facepiece particle counts were determined at 1-second intervals and averaged over each exercise period, which lasted for 0.5 minutes. The exercises used were the standard six exercises suggested for quantitative fit testing of half-facepiece respirators.<sup>(1)</sup>

Chamber concentration was determined by averaging the particle counts from 1-minute sampling periods immediately before and after the subject performed the six exercises.

Penetration for a particular exercise ( $P_j$ ) was calculated from the average of the 30 1-second in-facepiece particle counts (FPC<sub>j</sub>) made during that particular exercise and the average chamber particle counts (CPC).

$$P_j = \frac{FPC_j}{CPC} \quad (1)$$

The average test penetration was calculated as follows:

$$P_{test} = \frac{\sum_{j=1}^n P_j}{n} \quad (2)$$

where:

$j$  = 1st to the  $n$ th exercise.

The overall test LPF was calculated as the inverse of the overall test penetration.

$$LPF_{test} = \frac{1}{P_{test}} \quad (3)$$

Measurements of in-facepiece particle counts were corrected for errors introduced by retention of particles in the lung. Models for deposition of inhaled aerosols for nose and mouth breathing were used to derive the fraction of particles deposited in the lung.<sup>(13)</sup> It was assumed that subjects spent equal time nose and mouth breathing. The particle diameter of the test aerosol was  $\sim 2.0 \mu\text{m}$ , with a particle density of 0.91. Based on breathing patterns characteristic of sedentary work rate conditions, an average flow rate of 500 ml/s was selected along with an average residence time of 2 seconds.<sup>(14,15)</sup>

Under these conditions, the models yield deposition fractions of  $\sim 0.48$  and  $\sim 0.81$  for mouth and nose breathing, respectively. Averaging these values, assuming equal time is spent nose and mouth breathing, leads to an average deposition fraction of  $\sim 0.65$ .

When calculating the correction factor to apply to the overall breathing cycle, it was assumed that inhalation and exhalation times were equal. The deposition fraction was only applied to the exhalation portion of the breathing cycle. The resulting correction factor was 0.675.<sup>(16)</sup> The correction factor was used as a constant that was applied to each test result. Correcting in-facepiece particle count data for lung deposition increases estimates of penetration.

The in-facepiece particle count data reflected total in-board leakage, that is, leakage through the filter and exhalation valve of the facepiece, as well as around the sealing surface of the

TABLE 2. Aerosol Penetration Through Filters and Valves

Respirator	Mean Percent Penetration	N	Standard Deviation	Filter Eff. Factor*
D/M DFF	1.25	6	0.153	80
D/F/M DFF	$4.50 \times 10^{-3}$	8	0.0019	22,000
HE DFF	$3.90 \times 10^{-4}$	6	0.00021	256,000
D/M EF	$5.48 \times 10^{-3}$	5	0.00134	18,200

\*A number inversely related to the penetration of the filter.<sup>(17)</sup>

facepiece. The magnitude of the filter and exhalation valve leakage on these respirators was estimated before testing began.

To evaluate filter efficiency, specimens of each respirator were sealed with an air-tight seal to a test form. Air was drawn through the respirator with a breathing machine operated with a 622 work rate cam which produced a tidal volume of 1.6 L. The stroke frequency was adjusted to produce a minute flow rate of approximately 30 L. The challenge aerosol was the corn oil aerosol used in performing the LPF testing. Table 2 shows the results of the filter penetration studies that were performed.

The filter penetrations of the D/F/M and HE filtering facepieces and the D/M EF were very small. On these devices filter penetration would not be a major source of in-board leakage. On the D/M filtering facepiece the filter penetration was 1.25 percent. For this device, filter penetration could be a significant contributor to total in-board leakage and thereby confound evaluation of the fit check.

#### Experimental Protocols

**EXPERIMENT I.** In experiment I, which was to evaluate fit checks as an aid to successful donning, two groups of 32 subjects with no previous experience wearing respirators were trained to don the four respirators following the manufacturer's instructions.

One group was trained to use fit checks as part of the donning process. The fit check outcome (i.e., pass or fail) was noted. Again, the manufacturer's instructions for conducting the fit checks were followed. With the EF respirator the fit check instructions were to use either a positive pressure or a negative pressure sealing test; therefore, one-half of the 32 subjects were randomly selected and trained on one fit check or the other.

The second group only received donning instructions (e.g., how to position the mask on the face, how to adjust the straps, and how to mold the nosepiece to the nose, etc.). They received no training or instruction in conducting or using fit checks.

Subjects were trained over a 2-day period. Two of the four respirators were randomly selected for each day. Testing was conducted over the 3 days immediately following their training.

Six replicate donnings and associated LPF measurements were made on each test subject for the respirators in which they had been successfully fit tested. The respirator test order was randomized. There is a subjective factor in how a person dons a respirator and performs a fit check. This subjectivity would tend to make the six donnings per subject not independent. For statistical analyses, sample sizes were corrected using the Satterthwaite method.<sup>(17)</sup> This method uses the es-

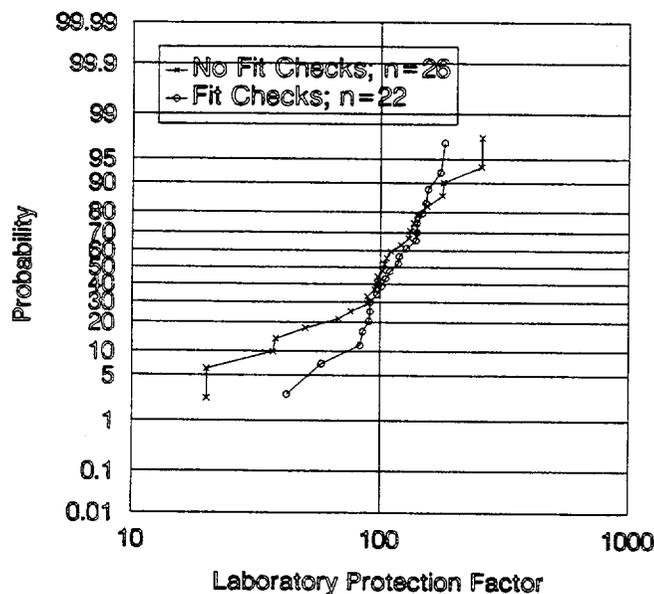


FIGURE 1. Distributions of LPFs obtained on two groups of subjects donning a D/M DFF with and without using fit checks.

estimates of intersubject and intrasubject variability to determine a modified sample size equivalent to the number of independent readings. For our data this correction reduced the sample sizes from 23 to 65 percent.

After receiving training, no attempt was made to correct donning errors made by the test subjects, such as crossing straps, forgetting to tighten straps, failure to mold nosepiece, etc., during the testing phase. In the group using fit checks, when the subject's assessment of the fit was solicited, no attempt was made to correct or assist in performance of the fit check. For this group, fit check instructions were available for reference if a subject cared to review them.

**EXPERIMENT II.** For the second experiment 64 subjects were trained to don the four respirators with the aid of the manufacturer's suggested fit check procedures. Subjects from experiment I could not participate in experiment II. The training and qualification criteria for subjects in experiment II were identical to those for the group trained to use fit checks in experiment I.

On the day following their training, subjects donned and fit checked two preadjusted versions of each of the four respirators. The respirators were preadjusted to produce a sufficient number of poor fits to test the ability of fit checks to identify poor or improper fits.

During this phase of testing, subjects were instructed to don the respirators as they normally would, except they were not to reform the nosepiece of the DFF respirators or readjust the straps of the EF respirator. The fit check outcome (i.e., pass or fail) was noted and the subject underwent the LPF testing. The outcomes of the two tests were then compared.

### Results and Discussion

LPFs from the group donning respirators without fit checks were compared to the LPFs obtained from the group donning

with fit checks. The fit check and no fit check groups were compared in several ways. First, log probability plots comparing the LPFs measured on each group were made for each respirator (Figures 1 through 4).

Figure 1 is the log probability (L-P) plot of the LPFs for the groups donning the D/M filtering facepiece with and without the aid of fit checks. Each plotting point is the geometric mean (GM) LPF for each subject. The L-P distributions of the LPF values measured on subjects using and not using fit checks are very similar between the 30th and 80th percentiles. The GM LPF for the no fit check group was 93, while the group using fit checks had a GM LPF of 110. No significant difference in GM LPF was found between the two test groups.

There is evidence in Figure 1 to suggest that using fit checks did improve the LPF values at the low end of the distribution (below the 30th percentile). The use of the fit check had the effect of shifting the low end tail of the LPF distribution to the right. These observations suggest that conducting the fit check had some value in helping to improve or eliminate poorer-quality donnings. The variability in LPF measurements was not found to be significantly lower in the test group donning with the aid of fit checks (Table 3).

Figure 2 shows the L-P plot of the LPFs for the D/F/M filtering facepiece. The distribution LPF values obtained on the test group donning with fit checks fell to the right of the group not using fit checks, that is, the group using fit checks achieved higher LPFs. The GM LPF for the no fit check group was 140, while the group using fit checks had a GM LPF of 291.

In this case the distributions were significantly different. The use of a fit check as an aid to donning this type of respirator significantly improved its overall performance in the chamber test. The variability of the two distributions was not significantly different (Table 3).

A possible explanation for the fit check causing an overall increase in the LPF distribution without changing the shape of the distribution is that performance of the fit check caused subjects to take added care during donning. The added care resulted from doing the fit check and led to better donnings, causing a shift of the entire LPF distribution and not just of the lower tail.

Figure 3 shows the L-P plot of the LPFs for the HE filtering facepiece. The GM LPF for the no fit check group was 758, while the group using fit checks had a GM LPF of 1633. In this case the distributions were not found to be significantly different.

The distribution of LPFs achieved with the group using fit checks was shifted toward higher LPFs in the lower tail region.

TABLE 3. Pooled Standard Deviations of LPFs for Groups of Test Subjects Donning Respirators With and Without Performing a Fit Check Procedure

Respirator	No Fit Check	Fit Check
D/M DFF	0.229	0.211
D/F/M DFF	0.322	0.295
HE DFF*	0.657	0.519
D/M EF	0.413	0.465

\*A significant difference in variances exists between the fit check and no fit check groups.

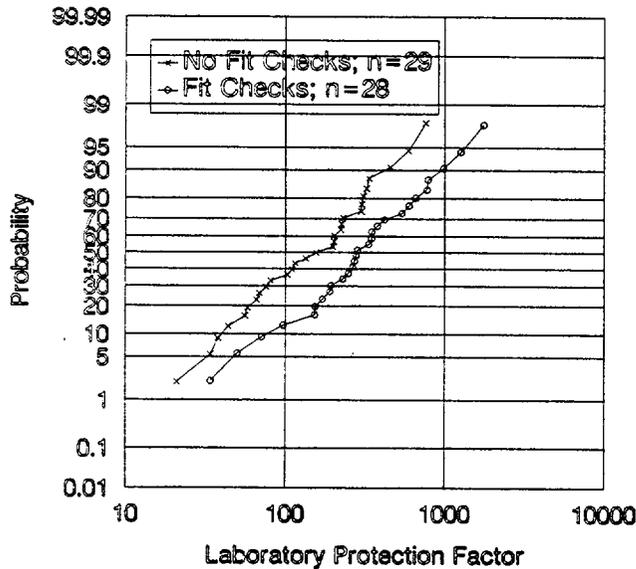


FIGURE 2. Distributions of LPFs obtained on two groups of subjects donning a D/F/M DFF with and without using fit checks.

This shift resulted in a significantly lower variability than with the no fit test group (Table 3). With the HE respirator, conducting a fit check had the effect of improving the quality of respirator donnings, thereby eliminating the lower LPFs.

The shift in the lower tail of the LPF distributions for the D/M and HE DFF respirators implies that performance of the fit check did not tend to improve the fitting characteristics of those respirators beyond removing poorer fits. For the D/F/M DFF respirator, performance of fit checks resulted in a significant average improvement in LPFs, not just in the lower tail of the distribution.

Figure 4 shows the L-P plot of the LPFs for the D/M

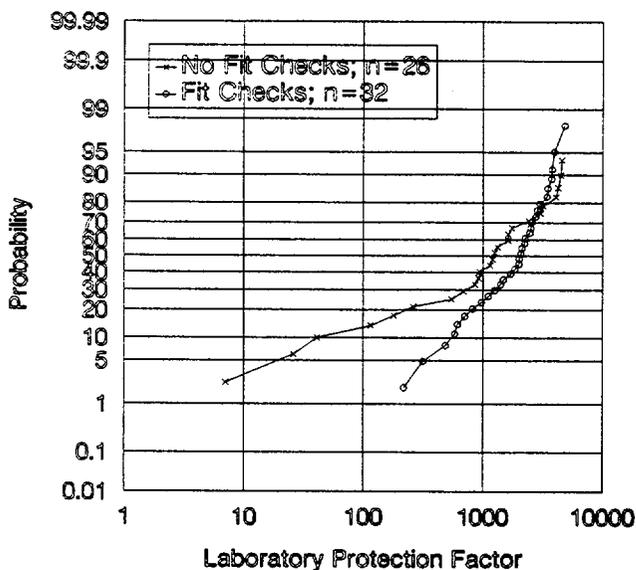


FIGURE 3. Distributions of LPFs obtained on two groups of subjects donning a high efficiency DFF with and without using fit checks.

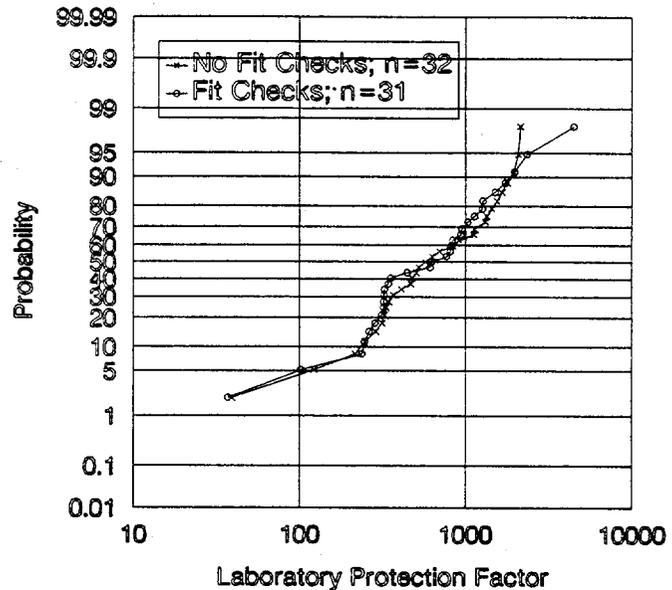


FIGURE 4. Distributions of LPFs obtained on two groups of subjects donning a D/M EF with and without using fit checks.

elastomeric facepiece. The GM LPF for the no fit check group was 608, while the group using fit checks had a very similar GM LPF of 580. The distribution of LPF values for the two groups is very similar, indicating that no improvement in the quality of donnings was achieved by doing fit checks.

A possible explanation for this observation is the small number of lower LPF values: only 5 percent of each population, or two subjects, had LPFs around 100 or less. The small number of donnings actually resulting in LPF values below 100 reduces the opportunity to observe the value of a fit check (i.e., to remove the lower LPFs). This could also explain why the characteristic shift in the tail region toward higher fit factors for the group using fit checks is not seen with this respirator, but was observed with the D/M and HE DFF respirators.

An alternative explanation for this observation is that performance of fit checks was not effective at detecting poorer donnings. However, this explanation is questioned by the results from experiment II, which found that performing fit checks on the EF respirator resulted in the best estimate of sensitivity for detecting poor fits.

The effect of performing the fit check on the proportion of subjects achieving LPFs greater than ten was also examined. The value of ten represents the assigned protection factor for half-facepiece respirators.<sup>(1,2)</sup> The LPF data collected in these studies were not always lognormally distributed (see Figures 1 through 4). As a result, binomial statistical methods were used to analyze the data collected from this phase.

The observed and corrected (Satterthwaite's correction) values of the number of donnings where resulting LPFs were less than ten are listed in Table 4. Only the corrected values were used in subsequent analysis. A binomial approximation to the hypergeometric distribution was used to compare the proportions of donnings resulting in LPFs of less than ten for the test groups donning with versus without fit checks.<sup>(18)</sup>

TABLE 4. Proportion of Donnings Resulting in LPFs of Less Than Ten

Respirator	No Fit Check Group Observed Values			Fit Check Group Observed Values		
	Uncorrected	Corrected <sup>A</sup>	% < 10	Uncorrected	Corrected <sup>A</sup>	% < 10
D/M DFF	5/152	2.34/71	3.3 <sup>A</sup>	0/132	0/87	0.0 <sup>A</sup>
D/F/M DFF	3/171	1.49/85	1.8 <sup>A</sup>	0/168	0/58	0.0 <sup>A</sup>
HE DFF	11/150	5.79/79	7.3 <sup>B</sup>	2/192	1.54/148	1.0 <sup>C</sup>
D/M EF	0/186	0/113	0.0 <sup>A</sup>	3/186	1.68/104	1.6 <sup>A</sup>
Average		9.62/348	2.76 <sup>B</sup>		3.22/397	0.81 <sup>C</sup>

<sup>A</sup>Sample size reduced via Satterthwaite statistical method.<sup>(17)</sup>

<sup>B,C</sup>Percentages of donnings resulting in LPFs of less than ten between the fit check and no fit check groups with different superscripts were significantly different.

For the HE filtering facepiece, the proportion of donnings resulting in LPFs of less than ten was significantly lower for the test group donning with fit checks as compared to the test group donning without fit checks. No difference was found with the other three respirators. However, the data in Table 4 do suggest that the performance of fit checks tends to lower the proportion of donnings, resulting in LPFs of less than ten for the D/M and D/F/M filtering facepieces.

The method of performing the fit check with the three filtering facepiece respirators differs slightly from the fit check method for the elastomeric respirator (i.e., the subject is checking for air flow around the face seal in the former case and for buildup and maintenance of positive or negative pressure in the latter case). A binomial approximation to the hypergeometric distribution was used again, this time to compare the proportions of donnings resulting in LPFs of less than ten for the elastomeric facepiece and the filtering facepieces.

For subjects donning with fit checks, there were no significant differences between the proportion of donnings resulting in LPFs of less than ten for the elastomeric facepiece or any of the filtering facepieces (see Table 4).

The effect of the fit check on the variability of LPFs achieved with multiple donnings was also examined for each respirator. The pooled standard deviations for subjects using fit checks compared with the pooled standard deviations for subjects not using fit checks are given in Table 3. The variability in LPF measurements was found to be significantly lower for subjects using fit checks with the HE filtering facepiece. No significant differences were seen in the variability of LPF measurements for the other respirators. However, a slight reduction in pooled standard deviations for subjects using fit checks was observed with the D/M and D/F/M filtering facepieces.

Experiment II was conducted to measure the discriminatory power of fit checks to differentiate between acceptable donnings (i.e., those donnings resulting in LPFs of ten or better) and unacceptable donnings (i.e., those donnings resulting in LPFs of less than ten). The discriminatory power of a test is determined by its specificity and sensitivity. Specificity is the ability of the test to accurately identify a correctly donned respirator. Sensitivity is the ability of the test to accurately identify an incorrectly donned respirator.

Of these two parameters, the sensitivity of the test is most important. In this case, sensitivity relates to the chance of a worker unknowingly wearing a respirator that is not properly donned into a hazardous environment. The specificity is not as critical since the consequence of this error is most likely that

the worker will readjust a respirator that is already donned correctly. Perhaps in the process the quality of the donning will be improved.

Sensitivity of the fit check was calculated by taking the number of donnings resulting in LPFs of less than ten where the subject said the respirator failed the fit check and dividing by the total number of donnings that actually resulted in LPFs of less than ten. For a test to have perfect sensitivity, this value would be 100 percent. Table 5 gives the sensitivity and the 95 percent confidence intervals determined for each respirator. The values were corrected for sample size via the Satterthwaite formula.

The sensitivity of the elastomeric facepiece fit check procedure was not significantly different than the sensitivity of the fit check procedure used for the filtering facepieces.

Specificity was calculated by dividing the number of donnings resulting in LPFs of ten or higher, where the subjects said they passed the fit check, by the total number of donnings resulting in LPFs of ten or higher. For a test with perfect specificity, this value would be 100 percent. Table 6 shows the specificity determination made on each respirator corrected for sample size via the Satterthwaite formula, and the 95 percent confidence interval for each value. A contingency table analysis of the specificity values found that fit checks done on the D/F/M DFF respirator resulted in significantly better specificity than with the other respirators. There is no obvious explanation for this finding.

TABLE 5. Sensitivity Estimates Determined for Fit Checks Conducted on Four Types of Half Facepieces

Respirator	Best Estimate <sup>A</sup>	95% Confidence Intervals
D/M DFF	24.3/27 (90%)	73.4–97.5%
D/F/M DFF	3.2/4 (80%)	45.0–96.2%
HE DFF	23/23 (100%)	85.0–100%
D/M EF <sup>B</sup>	31/31 (100%)	89.0–100%

Sensitivity is calculated by taking those donnings resulting in LPFs of less than 10 that were identified by the test subject as a fit check failure, divided by all the donnings resulting in LPFs of less than 10.

<sup>A</sup>The observed values reported here have been corrected for sample size via the Satterthwaite formula.<sup>(17)</sup>

<sup>B</sup>Sensitivity value determined for the EF was not significantly different than the sensitivities observed on the DFFs.

TABLE 6. Specificity Estimates Determined for Fit Checks Conducted on Four Types of Half Facepieces

Respirator	Best Estimate <sup>A</sup>	95% Confidence Intervals
D/M DFF	35.4/64 (55%)	43-68%
D/F/M DFF	75.9/88 (86%) <sup>B</sup>	77-93%
HE DFF	39.4/69 (57%)	45-70%
D/M EF	36.8/64 (57%)	45-70%

Specificity is calculated by taking the number of donnings with fit factors of ten or greater that were fit check passes and dividing by the total number of donnings with fit factors of ten or greater.

<sup>A</sup>The observed values reported here have been corrected for sample size via the Satterthwaite formula.<sup>(17)</sup>

<sup>B</sup>A contingency table analysis found that the specificity for this respirator is significantly better than the specificity of the other respirators.

### Conclusions

The LPF results obtained from these studies found that employing a manufacturer's recommended fit check when donning a respirator helped detect and prevent poorer-quality donnings of the respirator. As the quality of donnings increases, the usefulness of fit checks as a tool to evaluate the donning—with the goal of further improvement—becomes less. The better the facepiece seals to the face, the more difficult it is for the wearer to differentiate whether subtle changes in pressure or air flow have occurred.

Results observed on the D/M DFF respirator suggest that when fit checks are used for donning respirators which have considerable filter penetration, the resulting improvement in the quality of a donning may be considerably less important in determining the net performance. A fit check helps evaluate the integrity of the face seal. As filter leakage becomes a more significant component of total in-board leakage, the relevance of conducting a fit check decreases.

Donning respirators with fit checks did decrease the likelihood from 2.8 to 0.81 percent of those donnings resulting in LPF values of less than ten. However, the decrease was only statistically significant with the HE DFF respirator.

Performing a fit check was found to produce a general reduction in the variability of the LPFs measured on the three DFF respirators. The reduction was significant for one of the three.

The general trend toward fewer unsuccessful donnings and more consistent donnings when fit checks were used implies that fit checks have value in assisting the wearer to properly don a respirator.

Fit check methods applied to the DFF respirators were found to be equivalent to the fit check methods applied to the EF respirator by all criteria used in the study to assess fit checks.

The sensitivity of the fit check to detect bad donnings of previously fit tested respirators averaged 96 percent for all four respirators. Conversely, the percentage of subjects accurately identifying properly donned respirators with the fit check

averaged 66 percent for all four respirators. Considering that fit check methods are very simple to perform and require no ancillary equipment, the sensitivity and specificity for these methods are remarkably good.

Inexperienced workers can be trained in performing successful fit checks on elastomeric and disposable filtering facepiece RPE. It is expected that with additional experience respirator users might develop better and more consistent fit check skills, thereby further improving the quality of respirator donning. Therefore, we conclude that for wearers of respirators that have been properly fit by a recognized fit test, conducting fit checks according to the manufacturer's instructions can be a useful tool for more consistently maintaining the quality of respirator donning.

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# THE ASSIGNED PROTECTION FACTOR OF 10 FOR HALF-MASK RESPIRATORS

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*A number of researchers have published or presented papers on workplace protection factor (WPF) studies involving half-mask respirators. Individually, each study contains a relatively small amount of data, generally less than 25 data points for any single respirator. Because of the small amount of data, any attempt to quantify the result statistically does not provide useful information on the low end of the distribution of WPFs. Several studies on half-mask respirators were combined to yield a data set with 390 observations. Of these WPF data, 1.5% were less than 10, the best estimate of the 5th percentile was 13, with a 95% confidence interval of 10 to 18. Differences between the mean WPF based on the type of filter were found, but no difference was found between the mean performance of elastomeric and disposable respirators equipped with dust/mist and dust/fume/mist filters.*

**A** number of studies have estimated the performance of half-mask air purifying respirators through the use of workplace protection factor (WPF) studies.<sup>(1,5-17)</sup> One use of the information from these studies has been the assignment of protection factors.

The reported performance of half-mask respirators for these studies has been in terms of the best estimate of the 5th percentile. Little use has been made of confidence intervals to better describe the uncertainty involved in these estimates. The problem in using confidence intervals is that the studies used to define performance have generated a relatively small amount of data with a large amount of variation. For example, in the Nelson and Dixon study of respirator performance during asbestos removal, the North respirator showed a mean protection factor of 245, with a geometric standard deviation of 6.5.<sup>(1)</sup> The best estimate of the 5th percentile was 11 with 95% confidence limits of 1.1 to 37. It is obvious that this information by itself is not useful in setting an assigned protection factor, since the range includes 1 or no protection assignable.

A second issue in assigning protection factors is how to group the widely varying styles and construction of masks. Within the group of half-mask respirators, the American National Standards Institute (ANSI) Z88.2 committee combined elastomeric and disposable types into a single class, with an assigned protection factor of 10.<sup>(2)</sup> The type of filter or cartridge also does not change the assigned protection factor according to

ANSI. Are there significant differences between these differing styles and constructions of masks that warrant different levels of assigned protection? The few studies that contain data with the differing styles and types of respirators do not contain enough data points to allow these questions to be answered. The WPF studies contain few data points because these studies are difficult to perform and require a large amount of manpower and money to collect each sample.

The technique of meta-analysis has been used to evaluate the information from clinical trials and used in epidemiology to increase the statistical power by combining the information from a number of related studies. To do such an analysis though requires several questions to be addressed:<sup>(3)</sup> Are all studies to be included or only published ones? Are all studies to be included or only the "good" ones? When the study results are heterogeneous, how may they be included in a meta-analysis, or should they be used at all?

In this analysis the data from published and unpublished studies on respirators have been reviewed. Each study was analyzed to determine if the research protocol used was similar and if flaws in study design and data collection existed that would not allow the information to be combined. Rather than a strict statistical analysis of data as would be done in a meta-analysis, the data from similar studies were simply pooled into a single data set.

## STUDIES EVALUATED

For this analysis the studies on half-mask air purifying respirators listed by Johnston et al. in their review article on performance testing were evaluated.<sup>(4)</sup> These include published and unpublished studies. A summary of the studies is provided in Table I; the unpublished studies are noted.

Dixon and Nelson studied the performance of a Survivair half-mask respirator equipped with high efficiency particulate air (HEPA) filters in a lead chromate pigment production facility.<sup>(5)</sup> To qualify for the study, a person was required to pass an isoamyl acetate qualitative fit test. Eleven people participated in the study. The samples were collected for a single wearing of the respirator that lasted from 30 minutes to 2 hours. Samples were analyzed by proton induced X-ray emission (PIXE) for lead with a detection limit of approximately 10 ng per sample. The mass mean aerodynamic diameter of the particles was measured at 1.8  $\mu\text{m}$ .

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**TABLE I. Summary of the Studies**

Study	Respirator Type	Filter Type	Fit Test	Analyte	Analytical Method	Detection Limit	Liu Probe	# People	Particle Size (Mean)
Dixon Gaboury <sup>A</sup>	elastomeric	HEPA	isoamyl	lead	PIXE	2 ng sample	no	11	1.8 μm
	elastomeric	DM	quantitative	BAP	HPLC	0.003 μg/m <sup>3</sup>	yes	22	<0.52 μm
Lenhart	elastomeric	HEPA	(100 min FF)	lead	AA	0.2 μg sample (inside resp.)	yes	25	9–16 μm or 1–10 μm
			quantitative (250 min FF)						
Reed	disposable	DM	quantitative (min FF not given)	cement dust	mass	0.01 mg sample	yes	7	8–20 μm
Nelson <sup>A</sup>	disposable elastomeric	DM, DFM, HEPA	saccharin	asbestos	fiber count	0.0006 fibers/mL	yes	17	0.49 μm
Gosselink <sup>A</sup>	disposable elastomeric	DM, DFM, HEPA	saccharin	asbestos	fiber count	0.001 fibers/mL	yes	12	—
Johnston <sup>A</sup>	disposable	DM	saccharin	Ti, Al, Si	PIXE	9–35 ng per sample	yes	5	—
Colton—brass <sup>A</sup>	disposable	HEPA	saccharin	Pb, Zn	PIXE	<10 ng per sample	yes	17	dust and fume both present
Colton—Al <sup>A</sup>	disposable	DM	saccharin	Al	PIXE	<10 ng per sample	yes	5	~10 μm
Galvin	elastomeric	Charcoal cartridge	irritant smoke	styrene	GC	1 μg/sample	no	13	—
Myers—foundries <sup>A</sup>	elastomeric	DFM	saccharin, quantitative (min 100 FF)	Zn, Pb	PIXE	<10 ng per sample	yes	25	dust and fume both present
	disposable								
	—aircraft <sup>A</sup>	elastomeric	HEPA	quantitative (min FF 100)	Ti, Cr	PIXE	<10 ng per sample	yes	22
—steel mill <sup>A</sup>	elastomeric disposable	DM	saccharin	Fe	PIXE, AA	<10 ng per sample	yes	17	dust and fume both present
Colton—welding <sup>A</sup>	disposable	DFM	saccharin	Fe, Mg, Zn, Ti	PIXE	<10 ng/sample	yes	20	dust and fume both present
Wallis	disposable	DM	saccharin	Mn	AA	0.004–0.006 mg/m <sup>3</sup> as Mn	yes C <sub>i</sub> no C <sub>o</sub>	—	~60% > 10 μm

<sup>A</sup> Studies that have not been published

Gaboury and Burd studied the performance of Wilson, Survivair, and American Optical half-mask respirators equipped with organic vapor/acid gas cartridges and either dust/mist (DM) or dust/fume/mist (DFM) filters in a primary aluminum refinery.<sup>(6)</sup> They measured benzo-alpha-pyrene, contained in the benzene soluble materials present in the process. The analytical detection limit was 0.003 μg/m<sup>3</sup>. To qualify for the study, each subject needed to pass a quantitative fit test with a minimum fit factor of 100. Twenty-two people participated in the study. Because of the heat load in the production areas, workers spent one-half hour each hour in a cool environment. The sampling was stopped during this time period. Therefore, each data point is a WPF for multiple wearings in each work shift. The mean particle size was less than 0.52 μm.

Lenhart and Campbell studied the performance of MSA half-mask respirators equipped with HEPA filters in a primary lead smelter in the sinter plant and blast furnace areas.<sup>(7)</sup> To qualify for the study a person was required to pass a quantitative fit test with a minimum fit factor of 250 required. The 25 workers who participated wore the respirators for as much of the 8-hour shift

as possible, so the data represents a WPF for multiple wearings in each work shift. The lead was analyzed by atomic adsorption with a detection limit of 2 to 5 μg for the lapel samples and 0.2 μg for the in-mask samples. The mean aerodynamic particle diameter in the sinter plant was 9 to 16 μm, and 1–10 μm in the blast furnace area.

Reed et al. studied the performance of a 3M 9910 DM respirator in a concrete patching mixing and bagging area.<sup>(8)</sup> To qualify for the study a quantitative fit test was performed, to look for gross leakage. No minimum fit factor was given for inclusion in the study group. Seven people participated in the study. The mass collected inside and outside the respirators was determined by weighing after desiccation. The mean aerodynamic diameter of the particulate was measured at 8 to 20 μm depending on location within the worksite.

The Nelson and Dixon study was conducted during asbestos abatement operations with the 3M 8710 DM, 3M 9910 DM, Survivair half-facepiece respirator with DFM and HEPA filters, and the North 7700 with HEPA filters.<sup>(1)</sup> To qualify for the study, subjects passed a saccharin qualitative fit test. Seventeen people

participated in the study. Samples were collected for 30 minutes to 2 hours. Each WPF data point represented a single wearing. The asbestos fibers were analyzed by phase contrast microscopy, with a modification to increase the number of fields counted to increase sensitivity. The detection limit of the method was approximately 0.0006 fibers/mL for a 100 L sample, with a reliable limit of quantification of approximately 0.006 fibers/mL.

Gosselink et al. evaluated the performance of the 3M 8710 DM, 3M 9910 DM, 3M 9920 DFM, and 3M 7000 series half-facepiece respirator with HEPA or DM filters in a brake manufacturing facility.<sup>(9)</sup> To qualify for the study, the person needed to pass a saccharin qualitative fit test. Twelve people participated, and samples were collected for approximately 0.5 hours. The asbestos fibers were counted using phase contrast microscopy, with a modification to increase the number of fields counted to increase sensitivity. The detection limit for the sample size collected inside the respirator (2 L/min, 0.5 hour) would have been about 0.001 fibers/mL based on the modified counting method.

Johnston and Mullins studied the performance of the 3M 8715 DM respirator in a metal fabricating facility.<sup>(10)</sup> The dusts analyzed were titanium, aluminum, and silicon. Samples were collected for 35 to 235 minutes and included multiple wearings for a single WPF determination. The metals were analyzed by PIXE. To qualify for the study, the person needed to pass a saccharin qualitative fit test. Five subjects participated.

Colton and Mullins measured the performance of a maintenance-free high efficiency respirator in a brass foundry.<sup>(11)</sup> The respirators were worn for 30 minutes to 4.5 hours, each sample a single wearing of a respirator. To qualify as a participant, each person was required to pass a saccharin qualitative fit test. Seventeen people participated. The samples collected outside the respirator were respirable dust samples. Dust and fume were both present. Depending on the area of the plant, 20 to 60% of the mass of the aerosol was greater than 10  $\mu\text{m}$ . The samples were analyzed for lead and zinc by PIXE, with a level of quantification of less than 10 ng.

A study by Colton et al. was conducted in an aluminum smelter.<sup>(12)</sup> The respirator studied was a 3M 9906 with a DM filter. The samples collected outside the respirator were respirable dust. The samples were analyzed by PIXE, with a level of quantification less than 30 ng. To qualify as a participant, each person was required to pass a saccharin qualitative fit test. Workers were sampled for the duration of the task, so each data point represents a single wearing of the respirator. Twenty-four workers were sampled over five days. The particle size analysis by a cascade impactor shows approximately 50% of the dust was greater than 10  $\mu\text{m}$  in diameter.

Several studies not listed in the Johnston article also were evaluated.<sup>(4)</sup> These included a study by Colton and Mullins, who determined WPFs for a DFM disposable respirator worn during welding and grinding operations.<sup>(13)</sup> Twenty employees wore the respirators. Samples were collected for 40 to 190 minutes with four sample sets a day collected. Fit testing was done by the saccharin method. Samples were analyzed by PIXE for iron, magnesium, zinc, and titanium. Particle size analysis showed both dust and fume were present.

Another study not listed was one by Galvin et al.<sup>(14)</sup> They studied the performance of a half-mask respirator equipped with organic vapor cartridges in a styrene atmosphere. The samples were collected for three to six 1-hour periods for each of the 13 people who participated in the study. To qualify for the study, the person needed to pass an irritant smoke qualitative fit test. Samples were analyzed by gas chromatography-flame ionization for styrene. The inside samples were corrected for lung retention.

A study by Myers<sup>(15)</sup> that is being prepared for publication was also evaluated. In this study, DM, DFM, and HEPA filter respirators with both disposable and elastomeric face pieces were studied in a variety of workplaces. These included three foundries, an aircraft painting facility, and a steel mill. Fit testing was accomplished with a quantitative fit test for the elastomeric respirators and the saccharin qualitative fit test for the DM and DFM disposable respirators. The minimum fit factor required to pass the quantitative fit test was 100. Sixty-four people participated in the study. Samples were analyzed by PIXE for the inside samples and all outside samples except those from the steel mill. Because of the large amounts of material collected on the outside filters at the steel mill, the samples were analyzed by atomic absorption.

Wallis et al. studied the performance of a 3M 8710 disposable respirator in a battery manufacturing facility.<sup>(16)</sup> Seventy samples were collected on a number of people in various areas of the operation. Employees were not trained or fit tested during the time of the study, but had prior training and fit testing. The samples were collected on cellulose ester filters and analyzed by atomic absorption. The detection limit was 0.004 to 0.006  $\text{mg}/\text{m}^3$ , and the concentration of manganese outside the respirator ranged from 0.14 to 77.4  $\text{mg}/\text{m}^3$ . Area samples collected for particle sizing showed that more than 60% of the mass was greater than 10  $\mu\text{m}$  in diameter, the largest size selector used in the impactor. Less than 10% of the dust was smaller than 2  $\mu\text{m}$  in diameter.

A recently reported WPF study by Pallay was not included in the analysis.<sup>(17)</sup> For this study preliminary results have been reported at various meetings, but the data collected were not available.

Several of the very first half-facepiece respirator studies, such as those by Revoir,<sup>(18)</sup> Moore, Smith,<sup>(19)</sup> and Smith et al.<sup>(20)</sup> were not included in this analysis, since they were not WPF studies. They were effective protection factor studies, where in-mask sampling included the time while the respirator was not being worn. Also, they were conducted before the more recently developed and validated fit test methods became available.

## ANALYSIS OF THE STUDIES

For the data from several studies to be combined, the methods used to collect the WPF data needed to be evaluated to determine if they were similar enough in design and execution to allow them to be grouped. The portions of a WPF study that have an effect on the outcome include the test subjects familiarity with the respirator, motivation to participate, their training in proper fitting and use, the method of fit testing, and the methods for sample collection and analysis.<sup>(4)</sup> Training, familiarity with the

respirator, motivation, and proper use are variables that are generally described but cannot be evaluated objectively. Methods of fit testing and sample collection and analysis can be evaluated objectively.

Fit testing is an important variable. The protection factor is strongly dependent on the properties of the facepiece, including how well the facepiece seals to the wearer's face.<sup>(21)</sup> Fit testing determines which respirators are suitable. This is recognized by many standards, such as ANSI Z88.2, that require a fit test to select respirators.<sup>(2)</sup> The definition of a WPF also requires that the respirator be properly selected, fitted, and tested.<sup>(22)</sup>

To determine a WPF requires that the concentrations outside and inside the respirator be measured. Since a WPF is calculated as the ratio of these two concentrations, sample collection and analysis directly affect the WPF observed.

Analytical methods used need to be specific and accurate over a wide range of concentrations. A study of half-mask respirators may result in WPF values from less than 10 to over 10 000 based on observed quantitative fit factors. The environment inside a facepiece is high in humidity and at a temperature near 35°C. The concentration inside the facepiece will likely be 10 to 10 000 times lower than the ambient concentration, where the analytical method has been validated. The collection of samples from this environment must not be affected by these extreme conditions.

#### ***Studies Rejected Because of Inadequate Fit Tests***

The study by Galvin et al. used the irritant smoke fit test as outlined in the ANSI Z88.2 (1980) standard.<sup>(14)</sup> The level of smoke that leads to a response by the person being tested is checked, but the concentration at which a response occurs is not known. Unlike the isoamyl acetate and saccharin fit tests,<sup>(23)</sup> the level of irritating smoke generated during a test was not measured with the specific protocol. Both the saccharin<sup>(24)</sup> and the isoamyl acetate test protocols<sup>(25)</sup> have been studied, and experiments have verified the concentrations for taste or odor sensitivity and test concentration.

In the study by Reed et al. the quantitative fit test used was not appropriate for the respirator being used.<sup>(8)</sup> An oil mist quantitative fit test requires the use of HEPA filters so that face seal leakage can be separated from filter leakage. In this study the respirator had a DM filter. In addition the analytical method was a mass determination by weighing. Since the material being measured was a cement product, the inside-the-mask samples would have been in a humid environment and would include moisture that would be chemically reacted in the cement matrix. In addition the test is not specific; other material such as sweat and sputum collected on the filter also would be included in the inside mass. These factors would bias the inside-the-respirator samples, increasing filter weights and decreasing the observed WPF.

#### ***Studies Rejected Because of Inadequate Concentration Measurements***

In the WPF study by Johnston and Mullins a relationship between the mass of the analyte outside the respirator and the

WPF value was found.<sup>(10)</sup> It appears that in the workplace studied, the concentration of the contaminants was so low as to affect the WPF results seen. In their data they used a cut-off point of at least 10 times the mean blank value, but suggest that a value of 100 be used as a minimum. The review article by Johnston also recommends that the outside sample weight equal at least 10 times the assigned protection factor times the mean field blank.<sup>(4)</sup> For a half-mask this would equal a value of 100. Because the low outside concentrations had an effect on the WPF measured, this study was eliminated from the analysis.

In the Colton and Mullins study, the outside-the-respirator samples were collected as respirable dust samples.<sup>(11)</sup> Myers et al. have shown using transmission electron microscopy that large particles do penetrate inside the respirator facepiece.<sup>(26)</sup> Collecting outside-the-respirator samples as respirable dust samples will bias the observed WPF, making the WPF appear lower than actual if a large part of the material in the workplace is removed by the cyclone. Depending on the area of the plant, 20 to 60% of the mass of the aerosol was greater than 10 µm and would not be collected by the cyclone.

In the Colton et al. study at an aluminum smelter, respirable dust samples were collected as outside samples.<sup>(12)</sup> Impactor data collected during the study suggests that approximately 50% of the dust present was not collected on the outside samples. Therefore the outside samples biased the observed WPFs, making them appear lower than actual.

In the Wallis study several points need to be examined.<sup>(16)</sup> First, the C<sub>o</sub> and C<sub>i</sub> samples were collected by different methods. The C<sub>i</sub> samples were collected by probing the respirator with a sample inlet designed by Liu<sup>(27)</sup> to minimize sample loss at the inlet. In contrast, the C<sub>o</sub> samples were collected with a closed face and the Liu probe was not used. This caused the outside samples to underestimate the concentration of manganese. As shown by Liu, a similarly designed inlet would have almost 30% of the particles larger than 10 µm deposited in the inlet compared to almost no deposition with the Liu probe. The authors point out that the concentration outside the respirator was related to the WPF found. For all data points the best estimate of the 5th percentile was 7.5; when only data for C<sub>o</sub> samples greater than 100 times the detection limit are used, the 5th percentile is 10.8; when data 1000 times the detection limit are used (5 mg), the 5th percentile is 35.

#### ***Acceptable Studies***

The following studies are included in the analysis. They included an acceptable qualitative fit test with a protocol based on one listed in the Occupational Safety and Health Administration lead standard<sup>(23)</sup> or a quantitative fit test. The analytical methods employed were specific, and the ratio of the outside concentration to the detection limit was in each case 100 or more.

In the Lenhart and Campbell study, the ratio of the outside concentration to the detection limit of the analyte was at least 40 and averaged well over 100.<sup>(7)</sup> The lowest outside mass reported was 92 µg/m<sup>3</sup>, with a detection limit of 2 µg/m<sup>3</sup>; the lowest ratio was 46 (based on a sample time of 8 hours at 2 L/min with a detection limit reported at 2 µg/m<sup>3</sup>). Fit testing was

**TABLE II. Summary of Study Parameters**

Study	N	GM	GSD	5th Percentile	95th Percentile	Reason Not Included
<i>Studies included in the analysis</i>						
Dixon	42	3360	4.8	254	44 400	
Gaboury <sup>A</sup>	18	47	2.5	10	210	
Lenhart	25	166	3.8	18	1500	
Nelson <sup>A</sup>	76	258	5.2	17	3900	
Gosselink <sup>A</sup>	44	96	2.3	24	390	
Colton—welding <sup>A</sup>	32	147	2.5	33	660	
Myers <sup>A</sup>	153	346	7.2	14	8800	
<i>Studies not included in the analysis</i>						
Reed	19	18	3.17	2.7	120	nonspecific analytical, biased inside samples, QNFT not HEPA filters
Johnston <sup>A</sup>	18	44.8	2.85	8	251	low inside the facepiece weights
Colton—brass foundry <sup>A</sup>	38	28.2	2.06	8.6	92	outside samples biased
Colton—Al smelter <sup>A</sup>	42	469	3.87	50	4338	outside samples biased
Galvin	63	75	3.1	11.7	482	used unvalidated QLFT
Wallis	70	50	3.5	7.5	400	biased and low outside concentrations

<sup>A</sup> Studies that have not been published

by a recognized quantitative fit test method. The required fit factor to be included in the study was 250, which is higher than the other studies under consideration. The effect of this higher fit factor on the observed WPFs is unknown. However, fit factors have not been shown to be a predictor of WPFs.<sup>(5,27)</sup>

In the Dixon and Nelson study, the ratio of the outside concentration to the detection limit was well above 100 (the average outside concentration was 225  $\mu\text{g}/\text{m}^3$ , based on a 1-hour sample time and the detection limit; the lowest concentration that could be measured was approximately 0.1  $\mu\text{g}/\text{m}^3$ ).<sup>(5)</sup> Fit testing was done using the isoamyl acetate fit test. The in-mask samples were collected without the probe designed by Liu,<sup>(28)</sup> which was designed to minimize sample loss on the probe surfaces. The effect of the use of a non-Liu designed probe on the sample results is unknown, since most of the particles were of the size range where the probe design has less of an effect on deposition.

In the Gosselink et al. study the average asbestos fiber concentration was 2.21 fibers/cc, approximately 100 times the detection limit of 0.02 fibers/cc.<sup>(9)</sup> Fit testing was with the saccharin protocol.<sup>(23)</sup> In the Nelson and Dixon study with asbestos, the median fiber concentration was 2.6 fibers/cc outside the respirator, approximately 100 times the detection limit of 0.02 fibers/cc.<sup>(1)</sup> Fit testing was with the saccharin protocol.<sup>(23)</sup> In both studies the closed-face sampling technique was verified not to have adversely affected the deposition of fibers on the filter surface by a comparison of closed-face and open-faced sampling. Nelson and Dixon also measured the deposition of fibers on the filter, which was zoned into three concentric and equal areas (outer, middle, inner). For both closed- and open-faced samples, the fiber density was not significantly different among the zones.

In the Gaboury and Burd study, the ratio of benzo-alpha-pyrene was more than 2500 times the average concentration outside the respirator (detection limit of 0.003  $\mu\text{g}/\text{m}^3$  versus an average concentration of 7.97  $\mu\text{g}/\text{m}^3$ ).<sup>(6)</sup> Fit testing was done using a quantitative fit test method with a minimum fit factor of 100.

In the Colton and Mullins study, samples were analyzed for zinc, titanium, magnesium, and iron during welding.<sup>(13)</sup> For zinc the inside concentration ranged from 0.1 to 9.7  $\mu\text{g}/\text{m}^3$ . For outside-the-respirator samples, concentrations were from 4.2 to 1062  $\mu\text{g}/\text{m}^3$ . With a detection limit of approximately 15 ng/filter (or approximately 0.05  $\mu\text{g}/\text{m}^3$ ), the concentration outside the respirator averaged well over 100 times the detection limit. The WPF values for zinc were used in the analysis purely for convenience.

In the Myers et al. study the mean concentration inside the respirator was well above 100 times the detection limit.<sup>(15)</sup> For example, the concentration of zinc outside the respirator in the first study site was 12.2 to 629  $\mu\text{g}/\text{m}^3$ . The detection limit was approximately 0.08  $\mu\text{g}/\text{m}^3$  for a 2-hour sample. In the foundry portion of the study the outside samples were collected as respirable dust samples; however, these were corrected to yield total dust weights, and these data were used in the calculation of the WPFs. For the other study sites total dust samples were collected on outside samples. Fit testing was by either the saccharin qualitative fit test<sup>(23)</sup> or a quantitative fit test with minimum fit factor of 100 required.

## RESULTS OF THE ANALYSIS

Using the WPF results from the included studies, geometric means (GM), geometric standard deviations (GSD), and the best

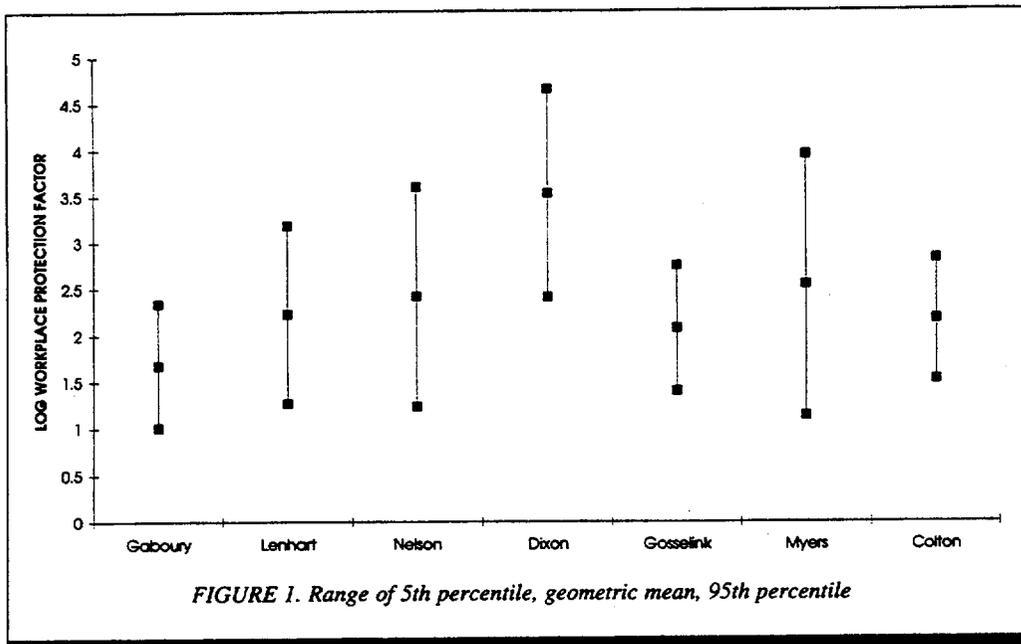


FIGURE 1. Range of 5th percentile, geometric mean, 95th percentile

estimates of the 5th and 95th percentiles were calculated using LOGAN.<sup>(28)</sup> These values are shown in Table II. A plot of the geometric mean, 5th, and 95th percentiles from each included study show that the studies resulted in comparable ranges of WPF measurements (Figure 1). Since the studies cover comparable ranges of data, they were combined into a single data set.

This resulted in 390 data points. Of these 390 data points, 6 WPF values (or 1.5% of samples) were less than 10. A log probability plot of the data is shown in Figure 2. The geometric mean is estimated at 290, with a GSD of 6.5. The best estimate of the 5th percentile is 13, with a 95% confidence interval of 10 to 18. This is consistent with the assigned protection factor of 10 listed by the ANSI Z88.2 (1992) standard.<sup>(2)</sup>

A one-way analysis of variance of these data separated into categories by filter type (Table III) showed there was a significant difference among the mean WPFs with a p-value less than 0.00001 (Table IV). Using an  $\alpha$  of 0.001, a multiple t confidence

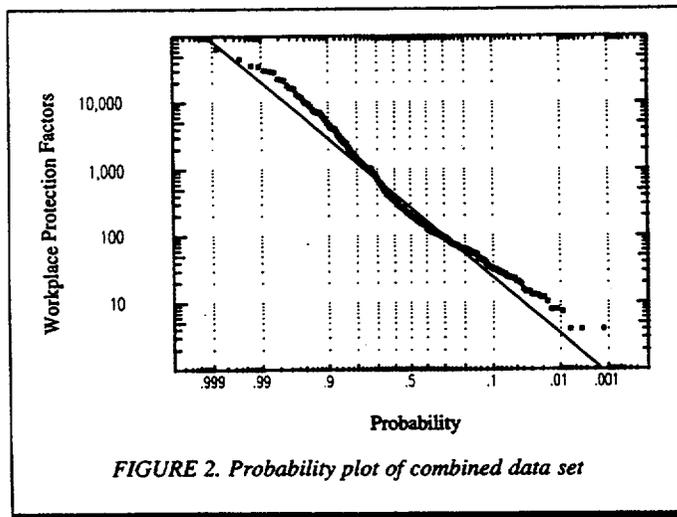


FIGURE 2. Probability plot of combined data set

interval was calculated to determine which types of filters were significantly different.<sup>(29)</sup> The mean performance of respirators equipped with HEPA filters was found to be significantly higher than the respirators equipped with either DM or DFM filters. The mean WPF for the respirators equipped with DM filters was significantly higher than that for the respirators with the DFM filters.

Next the data were grouped and analyzed according to respirator type: elastomeric or disposable. Since there were significant differences between filter types, each was examined separately. For the DM filter types, elastomeric respirators were used in the Gaboury (4), Gosselink (8), and Myers (30) studies; disposable

respirators were used in the Nelson (32), Gosselink (22), and Myers (21) studies. For the DFM filter types, elastomeric respirators were used in the Gaboury (14), Nelson (15), and Myers (46) studies; disposables in the Gosselink (8), Myers (20), and Colton welding (32) studies. Tables V and VI summarize the statistical parameters for the respirators equipped with the two types of filters. A student's t-test shows that the WPFs do not differ between mask types with a P (two tailed) of 0.54 for the DM and 0.25 for the DFM.

A comparison cannot be made for HEPA filter respirators, since there are no disposable HEPA-filtered respirators included in this analysis.

## CONCLUSION

The ANSI Z88.2 (1992) standard defines the assigned protection factor as "the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users."<sup>(2)</sup> The assigned protection factor for half-mask respirators is 10. For the studies examined in this analysis, the 5th

TABLE III. WPF Data for Filter Type

Study	Dust-Mist		Fume		HEPA	
	Number	GM	Number	GM	Number	GM
Gaboury	4	48	14	46	—	—
Lenhart	—	—	—	—	25	166
Nelson	32	428	15	183	29	177
Dixon	—	—	—	—	42	3356
Gosselink	22	93	8	233	6	56
Myers	51	260	66	144	36	3983
Colton	—	—	32	146	—	—

**TABLE IV. Analysis of Variance for Filter Type<sup>A</sup>**

	<i>N</i>	<i>Avg (as Log<sub>10</sub>)</i>			<i>SD</i>	
Dust/Mist	117	2.32			0.35	
Dust/Fume/Mist	135	2.08			0.34	
HEPA	138	2.96			0.88	
	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>p</i>	<i>F<sub>crit</sub></i>
Between filters	56	2	28	52.28	>0.0001	3.51
Within filters	208	387	0.54			

<sup>A</sup> Where *N* = number of data, *SD* = standard deviation, *Avg* = mean, *SS* = sum of squares, *df* = degrees of freedom, *MS* = mean square, *F* = *F* statistic, *p* = probability

percentile of WPFs was 13 with the lower 95% confidence interval of 10. This appears to support the assigned protection factor for this class of respirators. This conclusion is based on the combination of data from a number of studies assumed to be similar. Many factors can affect the data collected during a WPF study, and several of these factors cannot be evaluated objectively, such as the level of motivation of a subject participating in a study. As noted by Johnston, many studies have been reported at professional and scientific meetings, but not yet published in the literature.<sup>(4)</sup> This required that a critical review be performed with these before they were included with the published studies.

When type of filter was examined, the mean WPF for respirators equipped with HEPA filters was significantly higher than that for respirators equipped with either DM or DFM filters, and the respirators equipped with DM filters have a significantly higher mean WPF than the respirators equipped with DFM filters.

Leakage into a respirator will be governed by several factors including filter efficiency, face-seal leakage, and leakage through defects such as a faulty valve. Depending on the particle size of an aerosol, a respirator with a HEPA filter may be expected to perform better than a respirator with either a DM or DFM filter.

Campbell<sup>(21)</sup> predicts that a comparison of two filters, one with higher particle penetration and lower filter resistance, will have a GM WPF value that is higher than the other filter. He compared a filter with a penetration of 0.001 and a resistance of 25 mm (Hg) to a filter with a penetration of 0.003 and resistance of 10 mm (Hg), and predicted GM protection factors of 70 and 106, respectively. A DM filter may have higher filter penetration and lower filter resistance when compared to a DFM filter, which would explain in part the difference in the mean WPF found in these studies.

**TABLE V. Comparison of Elastomeric and Disposable Respirators With DF Filters**

	<i>Elastomeric</i>	<i>Disposable</i>
Number	42	75
GM WPF	191	224
GSD	3.75	4.05
5th perct.	21.7	22.4
95th perct.	1680	2240

**TABLE VI. Comparison of Elastomeric and Disposable Respirators With DFM Filters**

<i>Study</i>	<i>Elastomeric</i>	<i>Disposable</i>
Number	75	60
GM WPF	107	141
GSD	4.4	3.3
5th perct.	9.5	19.4
95th perct.	1210	1020

When the differing styles of respirators were examined, the disposable respirators had a mean WPF that was not significantly different from that for the elastomeric respirators equipped with either DM filters or DFM filters. Therefore, there appears to be no reason to assign different assigned protection factors to the two types of mask construction, elastomeric and disposable, for these two types of filters.

The performance of DM, DFM, and HEPA filters when comparing the 5th percentiles was not that different and was not inconsistent with the assigned protection factor of 10. If the assigned protection factor was based on an average level of protection, then the differences seen would be significant. Other factors will effect the protection a respirator provides, such as wear time (which is not considered in WPF studies). Wear time may be affected by comfort, employee motivation, and other factors. These other factors are further reasons why a higher assigned protection may not be reasonable, even though differences in mean performance have been seen.

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# The Assigned Protection Factor According to ANSI

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The American National Standards Institute (ANSI) standard for respiratory protection (ANSI Z88.2 1992) lists assigned protection factors (APFs) for various respirators. The committee that developed the APFs based its decisions on a review of available studies of respirator performance. If workplace studies were available, these formed the basis for the number assigned. If no such studies were available, then laboratory studies, design analogies, and other information were used to decide what value to assign. For half-mask air purifying respirators, four workplace protection factor studies were consulted to arrive at an APF. For loose-fitting facepiece powered air purifying respirators (PAPRs), five workplace studies and two laboratory studies were reviewed. For full-face air purifying, helmet/hooded PAPRs, and most supplied air respirators no workplace studies were available. The APF was based on laboratory studies or decided by analogy to other equipment. For the remaining respirators only single workplace protection factor studies were available, and these were used by the committee to assign an APF. The database available to the ANSI committee was limited. Most of the studies available for review were not published. The committee in a sense was required to perform peer review on the information to use the data. Studies completed after the ANSI committee finished its deliberations, when added to the data used, continue to support the APFs assigned by ANSI.

**Keywords:** ANSI Z88.2, assigned protection factor, respirators

The assigned protection factor (APF) is defined as the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to a stated percentage of properly fitted and trained users.<sup>(1)</sup> The APF is used to select respirators based on the expected concentration of a contaminant in the workplace. A respirator with an APF greater than the hazard ratio is chosen as the minimum required respirator.<sup>(2)</sup> The hazard ratio is defined by ANSI as the concentration in the workplace divided by the exposure limit.<sup>(2)</sup>

In developing the list of APFs, the American National Standards Institute (ANSI) Z88.2 committee based its decisions on a review of available studies of respirator performance.<sup>(3)</sup> Most of the studies that have been done are not in the published literature. The committee had to review the information available for a study and make a determination of acceptability of the work. If workplace protection factor (WPF) studies were available

(published or unpublished), these formed the basis for the number assigned. If no such studies were available, then laboratory studies, design analogies, and other information were used to decide what value to assign. Table I lists the APFs developed by the committee. For each type of respirator a summary of the workplace and laboratory studies used by the ANSI committee and studies completed after their review are given below.

The summary statistics for each study are shown in Tables II through IV. For each study the statistics have been recalculated where inside samples were below the detection limit of the analytical method. This was done to make the calculations uniform and to minimize the bias for estimates of the geometric mean and geometric standard deviation. Waters has shown that a value of 60 to 70% of the detection limit when substituted for samples with concentrations below the detection limit minimizes the bias in estimating these statistical parameters.<sup>(4)</sup> A value that was 70% of the detection limit was used.

## RESPIRATOR TYPES EVALUATED

### Air Purifying Respirators

An air purifying respirator is a respirator in which ambient air is passed through an air purifying element that removes the contaminant(s).<sup>(2)</sup> Air is passed through the air purifying element by means of the breathing action (negative pressure) or by a blower (powered air purifying respirators, or PAPRs). Negative pressure air purifying respirators are equipped with either quarter-mask, half-mask, or full facepieces. ANSI places quarter masks and elastomeric and disposable half masks in the same category of half masks. ANSI classifies PAPRs as half-mask, full-face, helmet/hoods, or loose-fitting facepieces.

### Half-Mask Air Purifying Respirators

Nelson<sup>(5)</sup> reviewed a number of WPF studies that included those used by the ANSI committee and studies that were conducted at a later date. Table II lists the statistical data from these studies. Based on the estimates of the 5th percentile for these studies, the ANSI committee assigned an APF of 10 for half-mask air purifying respirators.<sup>(6)</sup>

The study by Reed<sup>(25)</sup> was not considered to be a valid indicator of performance by the ANSI committee. The analytical method used to measure the dust inside the facepiece was mass, which is nonspecific. The dust was a cement product, so water from hydration was included in the measurement of the mass. Also, the respirator studied, the 3M 9920, cannot be fit-tested properly with an oil mist quantitative fit-test. The fit-test requires that high efficiency particulate air (HEPA) filters be used. With dust/mist filters, facepiece leakage and filter leakage are measured. Therefore, the fit-test is not measuring respirator fit.

The author concluded that the assigned protection factor of 10 was appropriate based on a statistical analysis that showed the 5th percentile of the WPF data to be greater than 10. The studies used

**TABLE I. Assigned Protection Factors from ANSI Z88.2 (1992)<sup>A</sup>**

Type of Respirator	Respiratory Inlet Covering			
	Half Mask <sup>B</sup>	Full Facepiece	Helmet/Hood	Loose-Fitting Facepiece
Air purifying	10	100		
Powered air purifying	50	1000 <sup>C</sup>	1000 <sup>C</sup>	25
Atmosphere supplying				
SCBA (demand) <sup>D</sup>	10	100		
Air line (demand)	10	100		
Air line				
Pressure demand	50	1000	—	—
Continuous flow	50	1000	1000	25
Self-contained breathing				
Apparatus pressure				
Demand open/closed Circuit	—	E	—	—

<sup>A</sup>This material is reproduced from the American National Standard ANSI Z88.2 copyright 1992 with permission by the American National Standards Institute (ANSI). Copies of this standard may be purchased from ANSI, 11 W. 42nd St., New York, NY 10036.

<sup>B</sup>Includes quarter mask, disposable half mask, and half masks with elastomeric facepieces.

<sup>C</sup>Protection factors listed are for high-efficiency filters and sorbents (cartridges and canisters). With dust filters, an APF of 100 is to be used due to the limitations of the filter.

<sup>D</sup>Demand SCBA should not be used for emergency situations such as firefighting.

<sup>E</sup>Although positive pressure respirators are currently regarded as providing the highest level of respiratory protection, some recent simulated workplace studies concluded that all users may not achieve protection factors of 10,000. Based on this limited data a definitive APF could not be listed for positive pressure SCBAs. For emergency planning purposes where hazardous concentrations can be estimated, an APF of no higher than 10,000 should be used.

Note: Assigned protection factors are not applicable for escape respirators. For combination respirators, e.g., air-line respirators equipped with an air purifying filter, the mode of operation in use will dictate the APF to be applied.

included the studies used by ANSI and other studies conducted after the ANSI committee concluded their deliberations.

### Full-Facepiece Air Purifying Respirators

The ANSI committee did not find any data from studies on full-facepiece air purifying respirators that were conducted after the APF of 100 was assigned by the 1980 ANSI standard.<sup>(6)</sup> Based on not finding any new data, no change in the APF was warranted.

Since then Colton reported on a WPF study in a secondary lead smelter.<sup>(7)</sup> The subjects who participated were quantitatively fit-tested, with a minimum fit factor of 500 required to participate. Samples were analyzed by proton induced X-ray emission (PIXE) with a detection limit of 10 ng lead per filter. Particle size analysis showed that both fume and dust were present. Approximately 65% of the particles were greater than 10  $\mu\text{m}$ , and 15% were less than 0.9  $\mu\text{m}$ . Thirty-two WPF values were obtained. The geometric mean WPF was 4790, with a geometric standard deviation of 7. The best estimate of the 5th percentile was 194, which is consistent with the ANSI APF of 100.

### Half-Mask PAPRs

Myers and Peach studied the performance of half- and full-facepiece PAPRs equipped with HEPA filters in a silica bagging operation.<sup>(8)</sup> Samples were collected on 5  $\mu\text{m}$  pore size polyvinyl chloride filters, analyzed gravimetrically and by X-ray diffraction. The detection limit for the mass determination was 0.03 mg silica/sample; for the X-ray diffraction method, 0.005 mg silica/sample. Samples were collected for multiple wearings, with the PAPRs removed during meal times and other breaks. Individual samples were collected for morning and afternoon shifts. Four workers were involved. The mass mean aerodynamic diameter was measured at 5.5 and 5.8  $\mu\text{m}$  on two of the three days the study was conducted. The researchers reported that leakage of silica occurred where the breathing tube connected to the blower, which could have let unfiltered air pass the filter and enter the blower housing. Thus this study may not predict actual performance of a half-mask PAPR.

Lenhart and Campbell studied the performance of a half-mask PAPR equipped with HEPA filters in a primary lead smelter.<sup>(9)</sup> Twenty-five subjects participated. To participate, each had to pass a quantitative fit-test with an MSA half-mask respirator with a fit factor of 250. The samples were analyzed by atomic absorption, with a detection limit of 2–5  $\mu\text{g}$  lead per sample. Inside-the-facepiece samples ( $C_i$ ) of less than 10  $\mu\text{g}$  lead were analyzed by graphite furnace atomic absorption with a detection limit of 0.2  $\mu\text{g}$  lead per sample. The study was conducted in two separate areas of the facility. The sinter plant area particle size had mass mean aerodynamic diameters of 9–16  $\mu\text{m}$ , while the furnace area had mass mean aerodynamic diameters of 1–8  $\mu\text{m}$ . Three  $C_i$  samples were below the limit of detection. Using a value of 70% of the detection limit, the geometric mean WPF is 431; the best estimate of the 5th percentile is 58.

daRoza et al. reported on a simulated workplace protection factor (SWPF) study on a half-mask PAPR.<sup>(10)</sup> The penetration into the facepiece was measured during exercise on a treadmill. Airflow was controlled to the facepiece

**TABLE II. Workplace Protection Factors—Negative Pressure Air Purifying Respirators**

Studies Available to Committee	N	Geometric Mean	Geometric Standard Deviation	Best Estimate 5th Perct.
<i>Half mask</i>				
Dixon <sup>(24)</sup>	42	3360	4.8	254
Reed <sup>(25),A</sup>	19	18	3.17	2.7
Lenhart <sup>(26)</sup>	25	166	3.8	18
Nelson <sup>(27)</sup>	76	258	5.2	17
<i>Subsequent data</i>				
Gosselink <sup>(28)</sup>	44	96	2.3	24
Gaboury <sup>(20)</sup>	18	47	2.5	10
Colton (welding) <sup>(29)</sup>	32	147	2.5	33
Myers <sup>(30)</sup>	153	346	7.2	14
Johnston <sup>(31),B</sup>	18	44.8	2.85	8
Colton (brass foundry) <sup>(32),B</sup>	42	469	3.87	50
Colton (Al smelter) <sup>(33),B</sup>	38	28.2	2.06	8.6
Galvin <sup>(34),B</sup>	63	75	3.1	11.7
Wallis <sup>(35),B</sup>	70	50	3.5	7.5
<i>Full facepiece</i>				
No WPF studies available; since no new data, no change from 1980 standard				
<i>Subsequent data</i>				
Colton(7)	32	4790	7	194

<sup>A</sup>ANSI and Nelson concluded that sampling bias may have been a factor in the WPF measured  
<sup>B</sup>Nelson concluded that sampling bias may have been a factor in the WPF measured

by replacing the battery pack with a DC power supply and varying the voltage to obtain the airflow desired. Simulated WPFs were measured by a light-scattering photometer. For the half-facepiece PAPR the penetration remained constant at the varying work levels, with an SWPF of approximately 5000.

Skaggs et al. reported on simulated workplace studies with an MSA half-mask PAPR.<sup>(11)</sup> Simulated WPFs were measured by light-scattering photometry in a chamber with temperature and humidity controls. Various exercises were performed, such as shoveling, hammering, moving blocks, and pounding a board with a sledgehammer. The mean SWPFs for the various temperatures and humidities were from 14,300 to 20,000.

Since the Myers and Peach data may not have been a realistic estimate of performance, the Lenhart data was the only WPF data available to the ANSI committee.<sup>(6)</sup> The APF selected by the ANSI committee was 50. With a geometric mean WPF of 431 and a 5th percentile of 58, the APF selected is consistent with the Lenhart data. The two simulated workplace studies are consistent with the APF. No new studies have been reported on the half-mask PAPR since the ANSI committee completed their work.

**Full-Facepiece PAPRs**

The committee did not have any WPF data on full-face PAPRs (other than the Myers and Peach<sup>(8)</sup> study discussed above).<sup>(6)</sup> A value of 1000 was chosen for the APF based on being consistent with the APF chosen for the helmet/hood style as discussed below. Some felt that the full-face PAPR would perform better than a helmet or hooded PAPR. Choosing the same value is a conservative approach.

The committee also reviewed a report by Ayer on a laboratory study of full-facepiece PAPRs equipped with HEPA filters in a chamber with a silica dust aerosol.<sup>(12)</sup> Samples inside the facepiece were collected at 12 L/min, outside samples at approximately 1.5 L/min. Four subjects participated in the test and were sampled while moving bags of material inside the chamber. Samples were analyzed by weighing the filters. The simulated protection factor obtained showed a correlation with the chamber concentration. When the data were divided into two groups, low and high chamber concentration, the mean simulated protection factors were 3389 (low) and 5580 (high). These data were considered consistent with the APF chosen.

Since the APF was assigned, Colton et al. reported on a study with a full-facepiece PAPR in a secondary lead smelter.<sup>(13)</sup> Twenty workers were quantitatively fit-tested with TSI Portacount<sup>®</sup> fit-test units. The minimum fit factor required was 500. Samples were collected for a period of 1 to 4 hours. All samples were analyzed for lead by PIXE, with a detection limit of 10 ng lead/sample. Samples less than 1000 times the detection limit were excluded from the analysis. The 5th percentile WPF of 1400 is consistent with the APF of 1000.

**Helmet/Hooded PAPRs**

There were no WPF studies available for PAPRs with helmets or hoods. The APF of 1000 was assigned by the ANSI committee based on analogy to an air-line respirator operating at the same flow rates.<sup>(6)</sup>

Since then Keys et al. reported on the performance of three helmet/hood type PAPRs in a pharmaceutical manufacturing facility.<sup>(14)</sup> The respirators were a Racal Breathe Easy 10, Bullard Quantum, and the 3M Whitecap II. Inside the inlet, covering samples were collected for 30 minutes to 3 hours and analyzed for estradiol benzoate by a radio immunoassay technique with a limit of quantification of 50 picograms estradiol benzoate per sample. Outside the respirator, samples were analyzed by high performance liquid chromatography. Probe loss was determined to be less than 1%. The best estimate of the 5th percentile WPF, 1470, is consistent with the APF assigned by the ANSI committee.

**Loose-Fitting Facepiece PAPRs**

The committee had several WPF studies on loose-fitting facepiece PAPRs to guide them in assigning an APF. The summary statistics for the studies are shown in Table II.

Meyers et al. studied the performance of the 3M Airhat<sup>®</sup> and the Racal model AH3 loose-fitting facepiece type PAPRs equipped with dust/mist filters in a battery manufacturing facility.<sup>(15)</sup> Twelve workers participated in the study, with samples collected for the full 8-hour shift, with the sampling pumps turned off during the times the PAPR was not being worn. The inside-the-facepiece probe was located approximately 1-2 inches from the mouth. The inside-the-facepiece samples were analyzed by graphite furnace atomic absorption with a detection limit of 0.3 µg lead per sample. The outside samples were analyzed by atomic absorption with a detection limit of 3 µg lead per sample. The particles in the workplace had a mass mean aerodynamic diameter of 17 µm. The geometric mean WPF was 127, and the best estimate of the 5th percentile WPF was 32.

Gosselink et al. studied the performance of the 3M Airhat with HEPA filters in a brake manufacturing facility.<sup>(16)</sup> The asbestos fibers were analyzed by phase contrast microscopy, with a modification to increase the number of fields counted to increase sensitivity. The detection limit was 1 fiber/filter. The geometric mean WPF was 199, and the best estimate of the 5th percentile WPF was 41.

Myers et al. studied the performance of Racal AH3 and 3M Airhat loose-fitting facepiece PAPRs equipped with high-efficiency filters in a secondary lead smelter.<sup>(17)</sup> Twelve subjects participated, and each was given a quantitative fit-test before being included in the study. A fit factor of 1000 was required, and since no one had a fit factor less than 1000, the fit-test was not a factor in the study outcome. Samples were collected during the entire shift while the respirator was worn. The inside-the-facepiece samples were analyzed by graphite furnace atomic absorption with a detection limit of 0.3 µg lead per sample, the outside samples by atomic absorption with a detection limit of 3 µg lead per sample. The particle size of the aerosol varied by area of the plant. At the furnace and caster, approximately 35% of the aerosol was greater than 17 µm, and 30% smaller than 0.68 µm. At the blast furnace, 60% was greater than 17 µm and 8% smaller than 0.68 µm. The geometric mean WPF was 184, and the best estimate of the 5th percentile WPF was 27.

Que Hee and Lawrence studied the performance of Racal Airstream AH3 and AH3-1 loose-fitting facepiece respirators equipped with high-efficiency filters for two job classes in a brass foundry.<sup>(18)</sup> For furnace room attendants, samples were collected for 4 to 8 hours including breaks and lunch. For the ladle attendants, samples were collected only during pouring, which lasted 3 to 4 hours. Seven subjects participated in the study. Samples were analyzed by flame atomic absorption spectroscopy. In this study, the C<sub>1</sub> samples included time in which the shield of the PAPR was raised, making most of the data an effective protection factor study. Also, the authors noted that low flows were measured due to low battery charge. The committee did not use the information from this study in setting an APF.

Dixon et al. performed a program protection factor (PPF) study on the 3M Airhat loose-fitting facepiece PAPR equipped with dust/mist filters.<sup>(19)</sup> As opposed to WPF studies where the equipment is verified to be properly working and used, the PPF data is collected as the respirator is used in the workplace. No checks are made on the function of the equipment and its use. Seven subjects participated in the study. Samples were collected for the duration of a specific task that lasted 30 minutes to 2 hours. Analysis of samples was by PIXE with a limit of detection of 10 to 100 ng, depending on the analyte, per filter. The geometric mean PPF was 230, but the data did not play a role in the decision to assign an APF.

Two simulated workplace studies were also reviewed, one by daRoza and the other by Skaggs, that were previously described. daRoza tested two loose-fitting facepiece PAPRs, a 3M Airhat and Racal Breathe Easy 1. Skaggs tested 3M Airhat and Racal AH3 loose-fitting facepiece respirators. daRoza found mean SWPFs of 100 and 10 when the work rate was at the maximum. Skaggs found mean SWPFs of 1900 to 5600 for the 3M Airhat and 1200 to 3500 for the Racal AH3.

After reviewing the WPF studies described above, the ANSI committee concluded that an APF of 25 was appropriate for loose-fitting facepiece PAPRs.<sup>(6)</sup>

Since the committee completed their work, two more studies have been reported. First, Gaboury and Burd measured the workplace performance of a Racal Breathe-Easy PAPR equipped with HEPA filters.<sup>(20)</sup> They measured benzo-alpha-pyrene, which is contained in the benzene soluble materials present in the particulate in the aluminum smelting process. Benzo-alpha-pyrene was detected at 0.003 µg/m<sup>3</sup>. Seventy-five percent of the benzo-alpha-pyrene was contained in an aerosol with an aerodynamic diameter of 0.93 µm. Samples were collected outside the respirator at a

point above the visor. Because of the heat load in the production areas, workers spend one-half hour each hour in a cool environment; for this time period the sampling was stopped. Therefore, each data point equals the WPF for multiple wearings in each work shift. Both bearded and clean-shaven subjects were included in the study. The geometric mean WPF was 1410; the best estimate of the 5th percentile was 306.

Stokes et al. studied the 3M Airhat loose-fitting facepiece PAPR equipped with dust/mist or HEPA filters, and a version of the equipment with a Tyvek® shroud.<sup>(21)</sup> The study was conducted in a roofing granule production plant and measured silica dust. Five subjects participated. Samples were collected for 30 minutes to 1 hour. Only samples with inside concentration greater than 25 or 100 times the mean blank concentration were included in the analysis. The geometric mean WPF was 1530; the best estimate of the 5th percentile was 85.

These studies support the APF assigned by the ANSI committee.

### Atmosphere-Supplying Respirators

Atmosphere-supplying respirators supply a respirable atmosphere independent of the workplace atmosphere.<sup>(2)</sup> One type is commonly called an air-line respirator and operates in one of three modes: demand, continuous flow, or pressure demand. Demand and pressure demand can be equipped with either half-face or full-facepiece inlet coverings. The continuous flow type can also be equipped with a helmet/hood or a loose-fitting facepiece. A second type of atmosphere-supplying respirator is equipped with a self-contained air supply. These are either self-contained breathing apparatus or are used in combination with a pressure demand supplied air-line respirator. A summary of the information used by the ANSI committee is presented in Table III.

#### Demand Supplied Air, Half- or Full-Facepiece Respirators

The ANSI committee did not find any new information on these types of units. The APF of 10 was based on analogy to the half-mask air purifying respirators.<sup>(6)</sup>

#### Continuous Flow Atmosphere Supplying Respirators

There were no workplace studies on half-mask or loose-fitting facepiece supplied air respirators. The APF of 50 for the half-mask and 25 for the loose-fitting facepiece was based on analogy to the PAPRs, where the same airflows are required by NIOSH for certification.<sup>(6)</sup> For the full-facepiece supplied air respirator, there was no workplace data. The APF was set at 1000 to be consistent with the helmet/hood style, with no evidence to set it either higher or lower.

For helmet/hood type supplied air respirators, the committee was briefed on a WPF study by Johnston.<sup>(6)</sup> The study, which was later reported at a technical conference,<sup>(22)</sup> was conducted during sand blasting of a barge. Samples were analyzed for silica by PIXE. A relationship was found between the loading on the outside filters and the mean WPF. When samples with mean loadings greater than 1000 times the mean blank loading were used to estimate the 5th percentile, the estimate was 1038. Skaggs studied a helmet/hood type in the simulated workplace study. The mean simulated WPFs for the various conditions ranged from 7500 to 20,000. Based on this information, an APF of 1000 was assigned.<sup>(6)</sup>

#### Pressure Demand Respirators

Pressure demand respirators can have the air supply delivered by an air line, a self-contained cylinder, or in combination. There was no workplace data on either a half-mask or full-face pressure demand

**TABLE III. Workplace Protection Factors—Powered Air Purifying Respirators**

Studies	N	Geometric Mean	Geometric Standard Deviation	Best Estimate 5th Perct.
<i>Half mask</i>				
Lenhart <sup>(26)</sup>	25	431	3.4	58
Myers & Peach <sup>(8)</sup>	7	49	2.5	11
daRoza (simulated work data) <sup>(10)</sup>	—	5000	—	—
Skaggs (simulated work data) <sup>(11)</sup>	—	14300-20000	—	—
<i>Full facepiece</i>				
Ayer (simulated work data) <sup>(12)</sup>	—	—	—	—
Myers & Peach <sup>(8)</sup>	3	66	3.6	8
Subsequent data				
Colton <sup>(13)</sup>	55	10300	3.4	1400
<i>Helmet/hood</i>				
Decision based on analogy to atmosphere supplied helmet/hood data				
Subsequent data				
Keys <sup>(14)</sup>	60	10400	3.3	1470
<i>Loose-fitting facepiece</i>				
Myers (battery) <sup>(15)</sup>	47	127	2.3	32
Gosselink <sup>(16)</sup>	7	199	2.6	41
Myers (smelter) <sup>(17)</sup>	43	184	3.3	27
Que Hee <sup>(18)</sup>	—	—	—	—
daRoza (simulated work data) <sup>(10)</sup>	—	—	—	—
Skaggs (simulated work data) <sup>(11)</sup>	—	—	—	—
Dixon (program protection factor) <sup>(19)</sup>	—	230	—	—
Subsequent data				
Gaboury <sup>(20)</sup>	20	1410	2.5	306
Stokes <sup>(21)</sup>	39	1530	5.8	85

supplied air respirator. Skaggs et al. did include a full-face air-line model in their study. The mean simulated WPFs for the various conditions ranged from 8500 to 20,000. daRoza reported to the committee on a simulated workplace study with a self-contained air supply.<sup>(6)</sup> The respirators were MSA self-contained breathing apparatus (SCBA) models with regulators that comply with the airflow requirements of the National Fire Protection Association standard.<sup>(2,3)</sup> Simulated WPFs were measured while the subjects walked on a treadmill with the speed and elevation set to achieve a work rate of 80% of the maximum heart rate. The lower 95% confidence level of the geometric mean was 6000; the best estimate of the 5th percentile was 300. One subject had simulated WPFs less than 1000.

The APFs of 50 for the half-mask and 1000 for the full-face-piece pressure demand respirators were set based on analogy to PAPRs and continuous flow supplied air systems.<sup>(6)</sup> The committee believed that setting a higher APF because of the pressure demand feature was not warranted, but rather that the total airflow was critical.

For self-contained breathing apparatus, no APF was assigned. During the balloting process, consensus could not be reached on an APF. The committee noted that data have shown the performance of this type of respirator may not be as good as previously

measured in quantitative fit-test chambers. SCBAs are generally chosen not by the need for a definitive level of protection, but rather for specific situations (e.g., firefighting, emergencies). They are considered the highest level of protection available for these types of situations. The APF is considered less meaningful.

## CONCLUSION

The assigned protection factor (APF) is defined as the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users.<sup>(1)</sup> The stated percentage of properly fitted users has not been set by any group.

In reporting the results of WPF studies, the best estimate of the 5th percentile has been reported as representing an estimate of the APF by a number of authors.<sup>(7-9,13-17,20-24,31-33,35)</sup> The ANSI committee used the estimate of the 5th percentile as one of the factors in judging the results of WPF studies.<sup>(6)</sup> There appears to be some consensus that the APF should be set so that at least 95% of the time a subject wearing a respirator will not be exposed above the exposure limit.

For some types of respirators very little data beyond single workplace studies are available for analysis and estimating performance. In most cases the APF assigned by the ANSI committee was based on operational analogies to similar types of equipment.

If the goal is to have assurance that the exposure limit will not be exceeded, more research on the performance of respirators in the field is needed. Also, agreement is needed to define the statistical parameters of performance that will be assumed. Is an APF, defined as the 5th percentile of workplace data, protective of worker health? Or should another definition for the APF be defined?

**TABLE IV. Workplace Protection Factors—Atmosphere Supplying Respirators**

Type of Respirator	APF Assignment
<i>Demand</i>	
Half mask	No WPF data, APF assigned based on analogy to negative pressure respirators
Full facepiece	No WPF data, APF assigned based on analogy to negative pressure respirators
<i>Continuous flow</i>	
Half mask	No WPF data, APF assigned based on analogy to powered air purifying respirators
Full face	No WPF data, APF assigned based on analogy to powered air purifying respirator
Helmet/hood	N=15, Geometric Mean=4076, GSD=2.3, Best Estimate 5th Perct.=1038; Johnston <sup>(22)A</sup>
Loose-fitting facepiece	No WPF data, APF assigned based on analogy to powered air purifying respirator
<i>Pressure demand</i>	
Half mask	No WPF data, APF assigned based on analogy to powered air purifying respirator
Full facepiece	No WPF data, decision based on daRoza <sup>(10)</sup> (simulated work data) and by analogy to continuous flow respirator

<sup>A</sup>WPFs with outside filter weights > 1000X the background level on the blanks

While answers are clearly needed for these questions, the practicing industrial hygienist still has to make decisions on the respirators that will be used in the workplace. The APFs that were assigned by the ANSI committee appear to be appropriate based on the limited amount of information available.

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June 3, 1997

Mr. Alan Roecklein  
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Dear Mr. Roecklein:

It has recently come to the attention of the Minnesota Mining & Manufacturing Company (3M) that the Nuclear Regulatory Commission is updating its regulations governing the use of respiratory protection at nuclear facilities. 3M is the leading U.S. manufacturer of industrial respirators, many of which are used at NRC-regulated facilities every day.

On behalf of 3M's Occupational Health & Environmental Safety Division, I submit the following comments for you to consider as these changes are being drafted. The comments are based on recent conversations with NRC staff and on early drafts of the revisions to 10 CFR Part 20 and Regulatory Guide 8.15, which delineate requirements for respiratory protection against radiation.

The regulation and guide closely follow the guidelines in the American National Standards Institute's voluntary consensus standard ANSI Z88.2 (1992), "American National Standard for Respiratory Protection." ANSI Z88.2 (1992) represents a consensus reached by experts in the field representing organized labor, industry, the federal government and respirator manufacturers. In several places, however, the NRC regulation and guide deviate from the program recommended in the ANSI standard.

In particular, there are significant discrepancies between some of the assigned protection factors (APFs) identified in the draft NRC documents and those in the ANSI standard. While there is considerable science supporting the protection factors assigned by ANSI, we are not aware of any scientific or technical support used by NRC to support the alternate values assigned in its documents. In the comments and attachments that follow, we provide a great deal of data supporting the ANSI values.

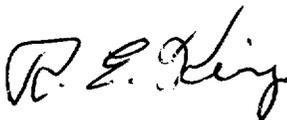
Mr. Alan Roecklein  
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In addition, the NRC regulation and guide need to consider recent changes to the National Institute for Occupational Safety and Health's (NIOSH) criteria for certification of respirators. As you are probably aware, NIOSH published 42 CFR 84 in July of 1995. This regulation completely revised the minimum performance characteristics for negative pressure air-purifying respirators. Many of these products, which constitute the largest class of respirators, have very recently been tested and certified by NIOSH. Guidance in selecting and using these new 42 CFR 84 filters need to be incorporated into the NRC documents.

Enclosed is a copy of the Industrial Safety Equipment Association's (ISEA) 1996 "Use and Selection Guide For Non-Powered Air Purifying Particulate Respirators." This document, which 3M helped develop as a member of the ISEA Respiratory Protection Group, identifies a decision logic for selecting among the new 42 CFR 84 respirators. It may be helpful to you while drafting the proposed revisions to 10 CFR 20 that will eventually be made available for public comment.

In the event that you desire clarification of any of these issues or the supporting documentation, please do not hesitate to contact me. I appreciate your consideration of 3M's comments and look forward to any feedback or further questions you may have.

Sincerely,



Ronald E. King  
Regulatory Affairs Manager  
3M Occupational Health & Environmental Safety Division

REK:llb/11

Attachments

- c: M.E. Flora - OH&ESD - 275-6W-01
- A.R. Johnston - OH&ESD - 260-3B-09
- R. McArver - The Jefferson Group
- M.L. Runge - OH&ESD - 260-3A-02

## **Comments on a draft of 10 CFR Part 20 and Regulatory Guide 8.15**

**§ 20.1703 (a)(1):** This provision requires the use of equipment certified by NIOSH and the Mine Safety and Health Administration (MSHA). With the changes in the certification process embodied in 42 CFR part 84, MSHA is no longer involved in the direct certification of respirators. MSHA is only involved in the certification of respirators used in mine emergencies and mine rescue. The reference to MSHA certification, therefore, should be removed.

**§ 20.1703(3)(vi):** As written, the paragraph is somewhat confusing. It requires "Fit testing, with fit factor  $\geq 10$  times the APF for negative pressure devices and  $\geq 100$  for positive pressure and pressure demand devices. . . ." This implies that a fit factor of 100,000 (100 multiplied by the APF of 1,000) would be required for a pressure demand full facepiece supplied air respirator. In Regulatory Guide 8.15 it is clear that NRC only requires a fit factor of 100 for positive pressure devices. This should be clear in 10 CFR 20.1703(3)(vi) as well.

**§ 20.1703(7):** This paragraph requires that respirable air meet the minimum quality specified in the Code of Federal Regulations that describe NIOSH/MSHA approval requirements. In 42 Part 84, NIOSH lists the Compressed Gas Association Commodity Specification for Air, G-7.1 1966. This is an outdated standard. NRC should specify the current standard, which was updated in 1989.

### **Appendix A To §§ 20-1001- 20.2402: Assigned Protection Factors For Respirators**

We have several comments on the draft appendix, which lists assigned protection factors for different types of respirators. Specifically, 3M is concerned that:

- 1) NRC needs to update the draft APF table to reflect the changes in NIOSH's respirator certification criteria found in 42 CFR 84;
- 2) by assigning a protection factor of 1 to several types of respirators in the draft APF table, NRC appears to be implementing a policy against the use of these types of respirators in nuclear facilities. Not only is such a policy unfairly damaging to manufacturers' products and misleading to end users, it also is not supported by technical studies. The policy of precluding the use of certain respirators by assigning them a protection factor of 1 is not justifiable and should be changed;
- 3) for one type of half mask respirator, the "single use disposable" respirator, the draft NRC documents not only assign a protection factor of 1, they also assert that fit checking these products is not possible. The draft also states that NRC does not believe medical evaluations are necessary for workers who use these products. 3M believes that these

provisions are factually wrong and should be eliminated. As is documented in the ANSI standard, an APF of 10 is the appropriate designation for "single use disposable" respirators, and the NRC assertions regarding fit testing and medical evaluation for users of these products are mistaken.

#### NIOSH Certification of Filters Under 42 CFR Part 84

When it published 42 CFR 84 on November 15, 1994, NIOSH changed the certification criteria for particulate filters. According to NIOSH's final rule, filters certified under 30 CFR 11 will no longer be available for sale or distribution after July 10, 1998. There is no one-to-one correspondence, however, between the 30 CFR 11 and the 42 CFR 84 filters. As a result, NRC needs to provide guidance on which 42 CFR 84-certified filters will be acceptable for use in relevant exposures.

Nine new classes of filters are certified under 42 CFR 84. The new filter classification system establishes three filter efficiency levels and three categories of resistance to oil. The three efficiency levels (95%, 99%, and 99.97%, i.e. 100%) reflect the ability of the filter to protect against airborne particulates. Every respirator submitted to NIOSH must provide at least that level of protection for which they are seeking certification while at least 200 mg of test agent is loaded onto the filter. Filter efficiency is measured continuously and filter penetration must never exceed the established threshold.

Two types of challenge aerosol are used, either a relatively non-degrading particle, sodium chloride, or a degrading oil, dioctylphthalate (DOP). Filter degradation is defined as a decrease in filter efficiency that may occur as more test aerosol is loaded onto the filter. In some way, the aerosol changes or interferes with the way particles are trapped by the filter.

The three levels of resistance to the test agents are categorized as "N", "R" and "P." "N" series filters, which are tested against the sodium chloride aerosol, may only be used as protection against solids, water based liquids or other non-oil liquids.

"R" and "P" series filters, which are tested against DOP, are recognized as highly resistant to oil and considered appropriate for protection against all workplace aerosols. "R" series filters are tested up to 200 mg of loading. No information is available about their continued effectiveness beyond this point. As a result, use of "R" filters is limited to a single shift or an estimated 200 mg loading. These filters must be replaced sooner, however, in the event of damage to the filter or an excessive increase in breathing resistance.

"P" series filters are tested until the filter efficiency is stable or increasing. The minimum loading is 200 mg, but testing continues beyond this level. In a recently released users notice, NIOSH indicated that "P" series filters should be replaced according to schedules recommended by individual manufacturers.

In developing the test criteria, NIOSH adjusted several of the variables to approximate worst case conditions. The worst-case conditions selected were a mass mean aerodynamic diameter particle of about 0.3  $\mu\text{m}$ , an air flow rate of 85 lpm, a neutralized test aerosol and, for "N" series filters, preconditioning at 85% relative humidity and 38°C for 24 hours immediately prior to testing. Exposures in the vast majority of workplaces will have larger particles and lower breathing rates. Thus, in any workplace it is expected that the actual filter efficiency will be greater than the tested filter efficiency.

There are two factors involved in the selection of respirators certified under 42 CFR 84. The first is a determination of whether an oil is present in the workplace. If no oil is present, employers can select "N" series respirators. If an oil is present, employers must select either an "R" series or "P" series respirator.

Next, employers must decide on the appropriate filter efficiency. When making this determination, employers should consider overall filter effectiveness. Even though a 100% filter may have a higher tested efficiency than a 95% filter, in most workplaces you would not be able to detect any difference in actual performance between the two filters. This is true for two reasons.

First, while the 42 CFR 84 test conditions are based on hypothetical worst case exposures, most exposures are not worst case. The larger particle sizes and lower breathing rates typically found in the workplace result in increased filter efficiency. A 95% filter will be essentially 100% efficient in the workplace. Second, higher filter efficiencies can increase breathing resistance, which in turn can result in an increase in face seal leakage. As a result, there is likely to be no observable difference in performance among the three levels of filter efficiency when they are used.

To achieve the desired level of protection, therefore, employers need not select a filter with an efficiency greater than 95% for a half mask respirator (APF = 10). Any NIOSH-certified half mask respirator will achieve this level of protection, regardless of the filter selected. Likewise, a 95% filter is acceptable for use with a full facepiece respirator (APF = 50), which will provide the desired level of protection with any NIOSH-certified filter.

The NRC draft should be revised to reflect the changes in respirator certification implemented by NIOSH in 42 CFR 84 and to provide guidance to end users on the appropriate respirators for use in relevant exposures.

### Assigned Protection Factor Of One

In the draft APF table, NRC assigns a protection factor of 1 to several types of respirators used against airborne particulate hazards. Of the air purifying respirators, "single use disposables" are assigned the APF of 1. Similarly, both half mask and full facepiece

atmosphere supplying respirators operated in the demand mode are assigned this minimal protection factor.

### *Disposable Half Mask Respirators*

There is no basis for separating half mask respirators into two classes. Nevertheless, NRC's draft APF table assigns a protection factor of 10 to "half masks" and an APF of 1 to "single use disposables." NIOSH tests and certifies half masks and their filters, and NIOSH approves half masks as a single class. The tests a half mask respirator must pass to be NIOSH-certified do not vary within the class. Thus, NIOSH implicitly recognizes the fact that all half masks form a single class of respirator.

Before making a distinction between these two respirator types, therefore, NRC should first demonstrate that a real, quantifiable difference exists. There are few areas of performance on which the agency could base such a distinction. In fact, there are no data showing that the performance of "single use disposables" and other half mask respirators differs during use. Leakage into any half mask respirator can occur as a result of filter penetration, face seal leakage or defective valves or other parts. There is no data supporting the position that "single use disposables" are more susceptible to such breakdowns in performance.

As discussed above, filter efficiency should not be an issue since all filters for half masks must pass the same test criteria. Defects also should not be a basis on which to differentiate among half mask respirators. All respirators must be maintained according to the manufacturer's instructions, which should limit the occurrence of defects. In fact, some "single use disposable" respirators do not have any potentially defective parts, such as valves, connectors or detachable parts.

To avoid the problems of face seal leakage, fit tests are used to select the appropriate respirator for a specific person to use. OSHA permits the use of both qualitative and quantitative fit tests to determine the best fit for an individual face. Neither OSHA nor ANSI distinguishes between these fit tests regarding their ability to identify an adequate fit. The initial assessment of fit as determined by fit testing, therefore, is not an issue in evaluating subsequent performance.

Similarly, there is no validity to claims that a "single use disposable" respirator may not fit as well during use or that the fit achieved during the fit test may not be as easily reproduced as it would be for other half masks. If this were the case, it would be possible to look at the performance of these respirators in the workplace and find differences. However, a 1995 study that examined the performance of different half mask respirators did not find a statistically significant difference in performance.<sup>1</sup>

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<sup>1</sup> Nelson T.J.: The Assigned Protection Factor of Ten for Half Mask Respirators, American Industrial Hygiene Association Journal 56(7) 717-724 (1995).

For all of the reasons given above, therefore, there is no logical or scientific basis for separating "single use disposables" from other half mask respirators. NRC should eliminate this distinction in the final draft and assign all half mask respirators a protection factor of 10.

### *Atmosphere Supplying Respirators*

As with "single use disposable" respirators, there is no logical or scientific basis for assigning a negligible protection factor to half mask and full facepiece atmosphere supplying respirators operated in the demand mode.

Both half mask and full facepiece atmosphere supplying respirators function in the same manner as their air purifying counterparts. When negative pressure is created inside the facepiece by inhalation, air flows into the mask. The inhaled air is either purified by the cartridge, canister or filter, or is supplied from an independent source of air. In either situation, the air that reaches the wearer's lungs is pure. Because of this extreme similarity in function, there is no logical reason to assign different protection factors to similar air purifying and atmosphere supplying respirators.

### *Scientific Data Supports Higher APFs*

The low protection factors in the draft table do not accurately reflect the products' ability to filter airborne particles. A number of studies demonstrate that the APF of 10 is appropriate for "single use disposables."<sup>2</sup> OSHA and ANSI both accept that these products protect the wearer at exposure levels up to 10 times the PEL. If NRC arbitrarily assigns these products a different protection factor, employers familiar with the OSHA and ANSI values will likely be confused by the resulting inconsistencies. NRC may be attempting to implement a policy on acceptable and unacceptable respirators, but it would better serve the regulated community to state clearly that NRC does not approve of a particular type of respirator, rather than to assign a needlessly low protection factor.

### *Fit Checks And Medical Clearance*

In footnote "e" to the table, the draft states that it is not possible to perform an effective pre-use fit check on a "disposable" respirator. This statement is incorrect. To the contrary, there is research showing that following the manufacturer's instructions for fit checking produces acceptable results. As summarized by Myers<sup>3</sup>:

Fit check methods applied to the DFF respirators were found to be equivalent to the fit check methods applied to the EF respirator by all criteria used in the study to assess fit checks. The sensitivity of

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<sup>2</sup> Ibid.

<sup>3</sup> Myers, W.R., M. Jaraiedi, and L. Hendricks: Effectiveness of Fit Check Methods on Half Mask Respirators. *Appl. Occup. Environ. Hyg.* 10(11):934-942 (1995).

the fit check to detect bad donnings of previously fit tested respirators averaged 96% for all four respirators. Conversely, the percent of subjects accurately identifying properly donned respirators with the fit check averaged 66% for all four respirators. Considering that fit check methods are very simple to perform and require no ancillary equipment, the sensitivity and specificity for these methods are remarkably good.<sup>4</sup>

The draft also implies that medical screening is not required for the use of "disposable" respirators. We disagree. Each respirator wearer needs to be evaluated under the supervision of a physician to determine their fitness to wear a respirator.

In the draft Regulatory Guide 8.15 on page 11 similar statements are made regarding the fit testing, fit checking and medical evaluations needed to use this type of respirator. As explained above, we believe the guide is in error and should be revised.

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<sup>4</sup> DFF refers to disposable filtering facepiece respirators, EF refers to elastomeric facepiece respirators.



September 8, 1997

Dr. Donald A. Cool  
Director, Industrial and Medical  
Nuclear Safety Division  
Nuclear Regulatory Commission  
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Rockville, MD 20852-2738

Dear Dr. Cool:

On behalf of the Minnesota Mining & Manufacturing Company's (3M) Occupational Health & Environmental Safety Division, I would like to address an issue of particular concern to 3M regarding a pending notice of proposed rulemaking from the Nuclear Regulatory Commission (NRC).

We have learned that NRC is nearing completion of proposed revisions to its standard on respiratory protection for workers at nuclear facilities. As with the rule's counterpart for general industry that is under revision at the Occupational Safety and Health Administration (OSHA), the assigning of protection factors to half mask air-purifying respirators is likely to be among its more controversial provisions.

Based on recent conversations with staff at NRC, however, it appears the proposed rule as currently drafted would deviate significantly from the current consensus on protection factors. The state of the art on protection factors is found in ANSI Z88.2-1992, the American National Standard for Respiratory Protection, which represents a consensus reached by experts in the field representing organized labor, industry, the federal government and respirator manufacturers.

For the reasons outlined below, we ask that you revise the protection factors assigned in the draft before issuing the proposed rule.

#### Earlier Comments

3M submitted detailed recommendations to NRC's Office of Research in June, prior to completion of the draft proposed rule. In those comments, we outlined several

Dr. Donald A. Cool  
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concerns we had with an early draft of the rule and offered several peer-reviewed studies as support for our recommendations. In particular, we noted that:

- NRC needs to revise its terminology to reflect the changes in respirator certification criteria found in 42 CFR 84;
- there is no scientific justification for assigning a protection factor of one to NIOSH-approved, filtering facepiece half mask respirators (referred to as single use disposable respirators in the proposed rule), which would be unfairly damaging to manufacturers' products and misleading to end users; and
- the proposed rule is incorrect in asserting that "single use disposable" half mask respirators cannot be properly fit checked.

A copy of these earlier comments is enclosed.

### **Half Mask Respirators**

Traditionally, half mask negative pressure air-purifying respirators have been separated into two broad categories: disposable and reusable. All half mask respirators have a facepiece that goes over the user's nose and under their chin. Filtering facepiece half mask respirators are constructed of a material that filters harmful airborne particulates from air inhaled through the facepiece. These respirators are referred to as disposable respirators.

Reusable respirators generally consist of a facepiece that is built of plastic or rubber, with an elastomeric edge designed to enhance the seal against the face and replaceable filter cartridges that are screwed into the facepiece. Some disposable respirators are made of similarly-constructed facepieces but have permanently attached filters and are designed to be discarded at the end of their service life.

While it used to be easy to distinguish between these two types of half mask respirators, design improvements and technological advancements have blurred the line between them. In both filter technology and facepiece design, 3M has led the industry in advancing respirator technology. Several of 3M's disposable filtering facepiece respirators, for instance, now incorporate an elastomeric face-to-facepiece seal. The existence of an elastomeric seal, however, is not essential to the proper functioning of a disposable half mask respirator.

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Modern respirator technology enables 3M to produce highly efficient disposable and reusable products. 3M's disposable products, in particular, are able to protect wearers while providing a considerable cost-savings to employers. These products also are significantly lighter, more comfortable and easier to breathe through than reusable respirators. This design aspect reduces the likelihood that wearers will remove the respirator in hazardous environments because of excessive heat or discomfort, which otherwise would significantly increase worker exposure. Heavy, uncomfortable reusable respirators, on the other hand, increase the likelihood of an interruption in respiratory protection. 3M believes this is an extremely important factor that should be taken into consideration when establishing regulations governing the use of respirators.

### **Assigned Protection Factors**

Protection factors are assigned to classes of respirators based on their overall ability to protect the wearer. An assigned protection factor (APF) is primarily a function of filter efficiency, the integrity of the face-to-facepiece seal and comfort and breathability. In the past, OSHA has referenced the APFs in ANSI Z88.2 in compliance directives and other documents. This voluntary consensus standard, which was updated in 1992, assigns a protection factor of ten to all half mask respirators based on actual workplace data. This data was cited in the Nelson paper referenced in our earlier comments. A review of Nelson's conclusions will clarify the science supporting the decisions of the ANSI committee.

OSHA's pending final respiratory protection rule is not expected to revise the currently accepted APFs, but will likely reserve the right to insert an APF table that will be developed in a subsequent rulemaking. In the interim, OSHA is expected to reference the protection factors in ANSI Z88.2-1992.

### **Proposed Rule**

Our understanding is that NRC's proposed rule will differentiate within the class of half mask respirators. Specifically, the proposed NRC approach as drafted assigns a protection factor of ten to those filtering facepiece half mask respirators equipped with adjustable straps and an elastomeric face-to-facepiece seal. All other filtering facepiece respirators would be assigned a protection factor of one.

To assign such a low protection factor to a NIOSH-approved respirator would render it useless: a protection factor of one is the same as no protection factor at all. The

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protection factor of one assigned in the draft effectively bans the use of certain products. Although the direct impact of this decision would not be excessive at nuclear facilities, we are particularly concerned about the policy implications behind the decision and the potential repercussions of this decision as a federal precedent.

Such a distinction among disposable half mask respirators represents a flawed policy decision. Furthermore, unlike the protection factors established in ANSI Z88.2-1992, this decision is not justified by any scientific research. In fact, NRC staff concede that the proposed rule offers no scientific support for its arbitrary distinction.

Several published, peer-reviewed studies, on the other hand, demonstrate that disposable and reusable respirators afford wearers similar levels of protection against airborne particulate hazards. These studies were referenced in and submitted with 3M's earlier comments. Each of these studies is based on research performed on disposable respirators that lack an elastomeric face-to-facepiece seal.

While we were assured by NRC staff that this information was considered, it is not reflected in the draft proposed rule. The rule reaches a conclusion that is contradicted by the documented research 3M submitted, and no scientifically valid information is offered to support the seemingly arbitrary distinction made in the proposed rule. This is a significant issue that could draw a great deal of negative attention to NRC's rulemaking.

### **Impact of Proposed Rule**

If NRC was to issue a rule distinguishing between disposable and reusable half mask respirators, manufacturers of disposable respirators would be unfairly and significantly damaged. This also would be confusing to end users. The release of even a proposed rule that separates disposable and reusable half mask products could have a significant impact on the market, not just at nuclear facilities but at many other industrial facilities as well. Many 3M customers make purchasing decisions on the basis of proposed rules.

In addition to having an unjustified negative effect on end users, the rule as proposed would create a confusing and arbitrary distinction in the way two different federal agencies treat the same products. While NRC need not defer to OSHA when establishing respirator selection and use regulations, it seems logical to look to the precedent established by the agency charged with jurisdiction over the nation's workplaces. In the absence of an overriding need to differ from OSHA on such basic matters as assigning protection factors—and no such need has been demonstrated in

Dr. Donald A. Cool  
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the proposal—NRC should not create unnecessary confusion by introducing an APF scheme that is inconsistent with OSHA's.

In addition to the logic supporting adoption or incorporation of the assigned protection factors in the ANSI voluntary consensus standard, White House Office of Management and Budget (OMB) Circular A-119 requires federal agencies to follow existing voluntary consensus standards when adopting those standards would achieve the purpose of the agency rulemaking and eliminate unnecessary and redundant uses of agency resources. Clearly, adoption of the consensus-based APFs in ANSI Z88.2-1992 would satisfy the OMB directive.

### Conclusion

For these reasons, 3M urges NRC to maintain the existing classification of half mask respirators as a single category. This is a generally accepted practice adhered to by both OSHA and ANSI. For NRC to do otherwise would trigger an adverse impact on 3M and other respirator manufacturers based on an arbitrary new policy with no scientific support and an unjustified dismissal of peer-reviewed evidence that supports grouping these product designs together. Because of similarities in faceseal design that effectively create a continuum of products, it also would create enormous problems for those trying to distinguish between disposable and reusable products.

3M hopes that you will reconsider the policy decisions that went into drafting the propose rule as it currently exists, and we would be willing to offer any technical or other assistance you desire.

We appreciate your consideration of these comments.

Sincerely,



Ronald E. King  
Regulatory Affairs Manager  
3M Occupational Health & Environmental Safety Division

REK:llb/15  
Enclosure

DOCKETED  
USNRC



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OFFICE OF  
RULEMAKING  
ADJUDICATION AND  
HEARINGS

September 21, 1998

Secretary  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
**(63FR38511)**

**Attention:** Rulemakings and Adjudications Staff

**Subject:** Osram Sylvania Products, Inc., Docket No. 040-00185, License No. STB-281, Comments on "Respiratory Protection and Controls to Restrict Internal Exposures", 10 CFR Part 20.

**Reference:** Federal Register, 63 FR 38511, July 17, 1998, Proposed Rule.

In the proposed modification to 10 CFR 20.1703(c)(2), "Use of Individual Respiratory Protection Equipment", Osram Sylvania notes that the USNRC has made the following change (shown in *italics*):

"If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, the licensee shall implement and maintain a respiratory protection program that includes surveys and bioassays, *as necessary*, to evaluate actual intakes."

The USNRC's reasons for changing the wording of this provision from "as appropriate" to "as necessary" were not explained. Whether the term "as appropriate" or "as necessary" is used, OSRAM SYLVANIA Products, Inc. applauds the agency for acknowledging in the regulations that bioassays are not required in all cases.

A case in point is during the use of Y-class thorium compounds. The Annual Limit on Intake (ALI) for <sup>232</sup>Th is one of the very lowest of those listed in Appendix B of 10 CFR 20. In addition, thorium dioxide, a widely used thorium compound, exhibits extremely low solubility in body fluids. These facts, coupled with the relative low detection capability for thorium by conventional internal radiation monitoring methods (i.e., whole body or organ counting, urine bioassay and fecal bioassay), clearly make the use of bioassays for evaluating intakes by respirator users unnecessary when intakes are expected to be below the ALI.

The USNRC recognized these circumstances and provided the following guidance to thorium licensees (see Information Notice 96-18, "Compliance with 10 CFR Part 20 for Airborne Thorium"):

"Although bioassay techniques are still useful in assessing relatively large intakes, they are not capable of providing routine monitoring for intakes substantially below the ALI. The air monitoring program therefore usually must assume a much greater importance at facilities using unsealed thorium than for other radionuclides. Facilities using thorium need to rely on accurate air sampling to estimate intakes that cannot be detected by bioassay techniques, which, in effect, includes all intakes other than those that approach or exceed the ALI."

Because of the difficulties of implementing a conventional bioassay program at facilities using thorium dioxide, and because air monitoring cannot be used to confirm the level of protection afforded by the respirator, it is clear that the bioassays required in proposed 10 CFR 20.1703(c)(2) would be unnecessary.

A related example is cases where respirators are used, but no "credit" for the protection factor afforded is taken in the assignment of the dose of record. The USNRC makes it clear in the preamble to the proposed rule that the requirements of 20.1703 are activated whenever a respiratory protection device is used to limit the intake of a radioactive material whether or not credit is taken for the device in estimating doses.

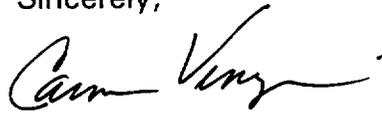
At Sylvania, and presumably other workplaces, work can take place in areas where we have determined that there is no requirement for either respiratory protection or individual monitoring of internal exposures, but where respiratory protection devices are made available to employees to use if they so chose. Under these circumstances, we would again assume that the confirmatory bioassays called out in proposed 10 CFR 20.1703(c)(2) are unnecessary.

It would be helpful to Sylvania and other licensees if, when the proposed rule is issued, a statement is made clarifying the intent of the wording change in 10 CFR 20.1703(c)(2) from "as appropriate" to "as necessary", particularly for those cases when conventional bioassay for thorium licensees would not provide data useful for confirming the effectiveness of a respiratory protection program, and when no "credit" is taken for respirator use in the dose assessment process. To add additional emphasis, the USNRC may wish to consider the following modification (shown in *italics*) to 10 CFR 20.1703(c)(2) be made:

"If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, the licensee shall implement and maintain a respiratory protection program that includes surveys and bioassays, *if necessary and if protection factors are used for dose assessment*, to evaluate actual intakes."

If you have any questions or if we can provide additional information on this matter, please contact me at (717) 268-5128.

Sincerely,

A handwritten signature in black ink, appearing to read "Carm Venezia". The signature is fluid and cursive, with a long horizontal stroke at the end.

Carmen Venezia, CIH  
Radiation Safety Officer

cc: A. M. Alper, Ph.D.  
J. Bonnell, CIH  
J. Delehant, Esq.  
C. D. Berger, C.H.P.



**WYOMING MINING ASSOCIATION**

September 22 AB 30, 1998

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OFFICE OF  
RULEMAKING  
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Attention: Rulemakings and Adjudications Staff

Subject: Wyoming Mining Association Comments on "Respiratory Protection and Controls to Restrict Internal Exposures", 10 CFR Part 20

Reference: Federal Register, 63 FR 38511, July 17, 1998, Proposed Rule

The Wyoming Mining Association (WMA) is an industry group that includes members from the uranium production industry in Wyoming and Nebraska. The Wyoming Mining Association (WMA) is a statewide mining organization whose mission is to communicate information on the significance of a healthy mining industry. WMA will promote the overall industry through active involvement in the legislative process, regulatory policy development, public education, and relevant public policy forums.

The WMA represents bentonite, coal, gold, trona and uranium companies and the mining associates (vendors, suppliers and contractors) in Wyoming. Wyoming leads the nation in the production of bentonite, coal, soda ash produced from trona, and uranium. Our membership consists of 32 mining companies, 121 supply and 5 electrical utility companies. Wyoming trona mines produce 90% of the national soda ash. Wyoming coal mines produce about 25% of the nations supply of coal.

Based upon a thorough review of the Proposed Rule to revise 10 CFR 20, Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposures", WMA believes that certain changes, if implemented in their current form, would have potential negative impacts on NRC-licensed uranium production facilities. The attached comments discuss the aspects of the Proposed Rule that are of concern to the WMA.

The WMA appreciates the opportunity to comment on the Proposed Rule.

Sincerely,  
WYOMING MINING ASSOCIATION

Marion Loomis  
Executive Director

# Wyoming Mining Association

## Comments on Proposed Rule

### 10 CFR Part 20, Subpart H

### Respiratory Protection

#### Introduction

The following comments are submitted in response to the Proposed Rule to revise 10 CFR Part 20, Subpart H "Respiratory Protection and Controls to Restrict Internal Exposures" (63 FR 38511, July 17, 1998). These comments are based upon a review by the membership of the Wyoming Mining Association (WMA). WMA members are active in the uranium mining and milling industry and in the reclamation of shutdown facilities in Wyoming and Nebraska.

#### Use of Engineering Controls

The current §20.1701 states that *"The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air"*. The proposed §20.1701 contains the same sentence with the addition of "decontamination" as an example of an engineering control and that the word "practical" is replaced by the word "practicable". The proposed change of the word "practical" represents a significantly higher level of effort and cost licensees would have to expend before using respiratory protection.

Practical is defined as "capable of being put to use" or "useful". Practicable is defined as "possible to practice or perform" or "feasible". The words are not interchangeable. The example of the difference in the meanings given in Webster's is useful in this context. The modern, low slung, high-speed automobile was *practicable* long before improved roads and fuels made it *practical*.

By proposing to change the level of effort that a licensee must expend before using respiratory protection, NRC has removed the reasonable approach to protection from airborne radioactive material. Just because an approach is feasible, it does not mean that it is also practical. This new approach to implementation of engineering controls is also apparent in the Draft Regulatory Guide DG-8022, Revision 1 to Regulatory Guide 8.15.

The proposed change could present a significant additional cost to licensees. Many uranium facilities are operating equipment and systems that were designed and installed decades ago. Under the existing rule, practical engineering controls have been implemented to control exposures from these systems at considerable expense. By requiring licensees to implement any theoretical, feasible control before resorting to respiratory protection, NRC is not allowing a cost-effective approach to ALARA. A stringent interpretation of this rule could result in requiring licensees to install expensive new equipment or replace entire components or systems if these efforts would theoretically reduce airborne radioactive material concentrations. For many uranium licensees, this is not a practical approach to radiation protection, especially given the low exposures already achieved by the industry.

NRC has recently recognized the difference that the use of these two words presents in the level of effort to maintain doses ALARA. In a Final Rule to revise 10 CFR §20.1101(b), NRC has changed the word "practicable" to "practical" in the requirement to use procedures and controls to achieve occupational doses and doses to members of the public ALARA.

Recommendation: WMA recommends that the current use of the word “practical” in §20.1701 be retained to be consistent with the Final Rule changing §20.1101(b). WMA agrees that the addition of the word “decontamination” to the examples of engineering methods available to control concentrations of radioactive materials in air is a method that licensees should consider. Therefore, WMA recommends the NRC revise §20.1701 to state:

*“The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.”*

### **Fit Testing**

The new §20.1703(c)(6) requires fit testing that achieves a fit factor greater than or equal to ten times the Assigned Protection Factor (APF) for negative pressure devices. Achieving the specified fit factor would be required in order to use the APFs. The new §20.1003 defines fit factor as “...a *quantitative* measure of the fit of a particular respirator to a particular individual” (emphasis added). Therefore, the proposed fit testing requirements would effectively preclude the use of APFs where qualitative fit testing (QLFT) methods are used.

NRC in the new §20.1003 defines fit test as “...a test, *quantitative or qualitative*, to evaluate the fit of a respirator on an individual and to determine the fit factor” (emphasis added). The definition of fit factor as a “*quantitative* measure” in §20.1003 is inconsistent with this definition of fit test. Fit factor is typically defined as the ratio of the concentration of the challenge atmosphere in ambient air to its concentration inside the respirator. By definition, this ratio is quantitative and not qualitative. Licensees cannot determine the quantitative fit factor by using qualitative techniques.

The proposed rule follows the ANSI requirements in ANSI Z88.2-1992 concerning fit factors greater than or equal to 10 times the APF. However, ANSI includes the provision that "...if a qualitative test is used, only validated protocols are acceptable". ANSI requires that these validated QLFT protocols be designed to assess fit factors ten times greater than the APF.

Z88.2-1992 further requires that fit tests be performed in accordance with ANSI Z88.10. As of this time, ANSI Z88.10 is neither approved nor published. Z88.2-1992 states that the protocol given in the OSHA Asbestos Standard (29 CFR §1910.1001) should be followed until such time as Z88.10 is available. In Draft Regulatory Guide DG-8022, NRC recommends the use of the QLFT protocols contained in OSHA's new respiratory protection standard (29 CFR §1910.134, Appendix A) to develop fit test procedures. The QLFT protocols contained in §1910.134 are generally similar to those contained in §1910.1001. However, none of these referenced OSHA standards define a "validated" QLFT protocol or provide the maximum fit factor that can be obtained through their use.

This proposed rule would have significant impacts on smaller licensees with limited respirator use that cannot afford the elaborate and expensive quantitative fit testing (QNFT) equipment. QNFT equipment involves sophisticated booths and instrumentation for measuring the concentration of the challenge aerosol in the booth and in the mask. Masks must be specifically adapted for fit testing. Personnel administering the tests must be specially qualified and trained. Most WMA licensees have a few occasional respirator users and could not justify the expense of QNFT equipment and trained testing personnel. Contract fit testing at larger facilities, if available, would raise issues of liability and compatibility of equipment and procedures.

If the rule were finalized as proposed, the practical affect may be to prevent smaller licensees from applying the APF for respirator usage. Licensees would continue to issue respirators to employees in accordance with the ALARA requirements of 10 CFR §20.1702. By permitting the use of respirators to limit internal exposure, licensees would be required to implement the

provisions of the new §20.1703. Therefore, the licensee would have to meet all of the regulatory requirements for an acceptable respiratory protection program. The only difference would be the licensee's inability to take credit for the protection afforded by the respirator. The result would be that licensees that do not have the capability to perform QNFT procedures would assign internal doses that are well in excess of those actually received by the individual employee.

Recommendation: NRC should revise the proposed rule to specifically allow the use of validated QLFT protocols. NRC has referenced ANSI and OSHA for use by licensees to determine acceptable QLFT protocols and to determine the fit factors afforded by these protocols. However, the fit factor information is not available from the referenced ANSI or OSHA standards. Therefore, if NRC proceeds with requiring the fit test factor to exceed the APF by a factor no less than ten, NRC should also provide the acceptable fit factors achievable by these validated protocols.

#### **Footnote c to Appendix A**

There is apparently an error in this footnote. The footnote states "*Air purifying respirators with APF  $\leq$  100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APF  $\leq$  100 must be equipped with particulate filters that are at least 99.97 percent efficient*". As written with both symbols indicating  $\leq$  the footnote implements conflicting requirements for respirators with an APF  $\leq$ 100.

Recommendation: WMA assumes that the second sentence should state "Air purifying respirators with APF  $\geq$ 100 must be equipped with particulate filters that are at least 99.97 percent efficient".



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

8

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
**(63FR38511)**

DOCKETED  
USNRC

'98 SEP 29 P 2 :45

National Institute for Occupational  
Safety and Health  
Robert A. Taft Laboratories  
4676 Columbia Parkway  
Cincinnati OH 45226-1998

OFFICE OF  
REGULATORY  
ADJUDICATION

September 28, 1998

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Dear Sir/Madam:

Staff of the National Institute for Occupational Safety and Health (NIOSH) have reviewed the proposed rule on *Respiratory Protection and Controls to Restrict Internal Exposures*, published in the *Federal Register* on July 17, 1998 [63 FR 38511]. Our comments and references are enclosed.

If you have any questions regarding our comments, please call me at 513/533-8302.

Sincerely yours,

Paul A. Schulte, Ph.D.  
Director  
Education and Information Division

Enclosure



# *Comments to NRC*

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**Comments of the  
National Institute for Occupational Safety and Health  
on the  
Nuclear Regulatory Commission  
Proposed Rule on  
Respiratory Protection and Controls to Restrict Internal Exposures**

**[10 CFR Part 20]**

**U.S. Department of Health and Human Services  
Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health**

**9/28/98**

The National Institute for Occupational Safety and Health (NIOSH) has the following comments on the Nuclear Regulatory Commission (NRC) proposed rule, *Respiratory Protection and Controls to Restrict Internal Exposure* (10 CFR 20), published in the *Federal Register* on July 17, 1998 [63 FR 38511]. These comments are intended to help improve the quality of the proposed rule.

**20.1003 Definitions.** The proposed definition for fit check includes irritant smoke check as an example of an acceptable fit check. NIOSH recommends against the use of irritant smoke as the challenge agent for respirator fit testing or fit checking because of the health risk associated with exposure to irritant fume (hydrogen chloride) [NIOSH 1995]. A negative pressure check, positive pressure check, or isoamyl acetate are acceptable substitutes for irritant smoke.

**20.1703 Use of individual respiratory protection equipment. (a).** This proposed paragraph requires licensees to use "*only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health.*" This proposed wording removes the language "*or had certification extended by NIOSH*" from the existing 20.1703(a)(1). NIOSH agrees with the proposed change to this paragraph; the approval labels for NIOSH-certified respirators do not reflect extensions of certification. Therefore, it is difficult for a user to distinguish whether a respirator was manufactured under an original certification or an extension. However, the rationale for this change presented in the Preamble on page 38513 is inaccurate and misleading. The Preamble states, "*The words 'or had certification extended' would be deleted because all these extensions have expired and no new extensions will be granted.*" The expiration of extensions referred to by NRC applies only to the particulate filter respirators previously certified by NIOSH and MSHA under the respirator certification regulations of 30 CFR part 11. The certification requirements for only this limited class of respirators were updated with the promulgation of 42 CFR part 84 on June 8, 1995. The requirements for certification of all other classes of NIOSH-certified respirators are unchanged. NIOSH continues to issue new certifications and extensions of certifications for all classes of respirators certified under 42 CFR 84.

The respirator certification regulations at 42 CFR part 84 replaced those previously at 30 CFR part 11. With the July 10, 1995 effective date of 42 CFR part 84, NIOSH no longer issued new certifications or extensions of certification to particulate respirators certified under 30 CFR part 11. As a transition to the new respirators, manufacturers were allowed to sell and ship particulate respirators as approved under 30 CFR part 11 until July 10, 1998. While the manufacturers' authority to produce additional particulate respirators under the 30 CFR part 11 certifications has expired, the certifications have not been withdrawn. Any particulate respirator manufactured and maintained in accordance with 30 CFR part 11 remains a NIOSH-certified device. Particulate respirators certified under 42 CFR part 84 have demonstrated improved performance over their 30 CFR part 11 predecessors and should be available to users.

NIOSH suggests that the preamble explanation for the removal of the wording referring to the NIOSH extensions of certification be expanded to provide a clearer discussion of the replacement of 30 CFR part 11 respirator certification provisions with 42 CFR part 84.

**20.1703(b)** The identical wording removed from paragraph (a) is proposed to be removed from this paragraph, and the basis for this change provided in the Preamble is the same. NIOSH suggests that the Preamble be modified to correctly explain the change in respirator certification regulations as noted above.

**20.1703(c)(3)** This proposed paragraph requires an operability check (fit check or functional test) immediately prior to use only if there is an APF associated with the respirator. Single-use disposable and air-line suits are listed in Appendix A as respirator classes without an associated APF. Thus the requirement to perform operability checks immediately prior to use of these classes of respirators would not apply. Footnotes (e) for the single-use and (g) for the suit state that fit testing requirements of § 20.1703 also do not apply.

NIOSH recommends that all tight-fitting respirators, including the single-use disposables class, should be fit tested and, as appropriate, fit checked. NIOSH also recommends that a user should verify that an air-line suit will perform properly before putting it on. The risk of carbon dioxide build-up with low airflow may be increased by the potentially large dead air space in the suit. Verification of the integrity of the suit is also recommended. If operability checks are intended for these respiratory protection devices, the preamble and regulatory language should clarify the intent. If operability checks are not required, NRC should modify the preamble to provide further information as to why disposables and air line suits would be exempted from an operational check prior to being worn.

**20.1703(c)(6)** This provision would require fit testing for tight-fitting, face-sealing respirators prior to first field use. NIOSH agrees that fit testing should be performed with these respirators prior to first field use. As written, all fit-tested respirators that are not negative pressure devices would only have to achieve a fit factor of  $\geq 100$ , while negative pressure devices would be fitted to 10 times the APF. The fit factor of 100 is the same as the APF proposed for a full facepiece negative pressure respirator, while the APF of respirators other than negative pressure devices would be 50, 1000, or even 10,000. A fit factor of 1,000 (10 times the APF) would be required for a full facepiece used on a negative pressure respirator, but only 100 would be required if the same facepiece were used on the devices assigned higher protective values.

A fit factor of 100 for the devices other than negative pressure air-purifying respirators is consistent with ANSI Z88.2-1992. However, proposed 20.1703(c)(6) does not require the fit factor to be achieved in the non-operational mode, as specified in ANSI Z88.2-

1992 and OSHA's 29.1910.134. NIOSH recommends that fit factors be achieved with the respirator in the non-operational mode to assure adequate fitting requirements for a facepiece type, regardless of the respirator operational mode in which it is used, consistent with ANSI Z88.2-1992 [ANSI Z88.2-1992, clause 9.1.2].

Because of the uncertainties involved in correlating the fit factors achieved in fit testing with protection factors reported in the workplace, NIOSH concurs with the minimum fit factor of ten times the APF value using the facepiece in order to successfully complete the fit test. This is the same safety factor required by OSHA in the Respiratory Protection Standard, 29 CFR 1910.134. As noted on page 38515 of the Preamble, footnote 'a' to Appendix A retains the requirement to select and use respirators for non-radiological hazards in accordance with 29 CFR 1910.134. These Department of Labor regulations require the same minimum fit factor for a tight-fitting facepiece, regardless of the respirator's operational mode. As proposed, a user could be required to have different size facepieces for a respirator to be used for non-radiological hazards and for radiological hazards due to fit testing to different fit factor requirements. NIOSH recommends that NRC modify the proposal to require the same fit factor for the facepiece regardless of the respirator's operational mode to eliminate potential user confusion. Thus, according to the APF values proposed, any respirator using a half mask would be fit tested in a negative pressure mode to assure a fit factor  $\geq 100$  (APF of  $10 \times 10 = 100$ ), while any respirator using a full facepiece would be fit tested in a negative pressure mode to assure a fit factor  $\geq 1000$  (APF of  $10 \times 100 = 1000$ ).

**20.1703(c)** On page 39514, the Preamble incorrectly states, "*Current 20.1703(c) would be removed because it requires licensees to use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH. This approval category no longer exists.*" Under 42 CFR 84.51, NIOSH continues to certify respirators for this category as previously required under 30 CFR 11.

**20.1703(c)(6)** The proposed requirement for fit-testing of respirators in this paragraph is "*a frequency not to exceed 3 years.*" Whenever respirators are used to protect the health of workers, periodic fit testing is recommended by NIOSH [1987] and the American Industrial Hygiene Association [AIHA 1993]. Annual fit testing is the accepted standard of professional practice endorsed by the American National Standards Institute (ANSI) [ANSI Z88.2-1992, clause 9.1.4] and the National Fire Protection Association (NFPA) [NFPA 1404, 1989 edition, paragraph 4-2.3]. Annual fit testing is required by OSHA's recently issued respiratory protection standard (29 CFR 1910.134). All of these authorities recognize periodic fit testing as the means to assure that a respirator is selected, fits, and is worn properly.

Industry data from OSHA's rulemaking record for respiratory protection [Docket No. H-049] suggest that 1% to 2% of users require a different size or model if retesting is annual, increasing to over 6.6% on a 2-year cycle. On the basis of these data and other considerations, OSHA concluded that annual fit testing represented an appropriate balance between unproductively testing too frequently versus testing so infrequently that too many workers would be at risk of harm because of poorly fitting respirators.

We are not aware of any evidence that the judgment of a physician or other licensed health care professional (or any other individual) can be an adequate substitute for periodically retesting respirator fit. Neither do we know of any evaluation criteria that could be used by a physician or other health care professional to guide a *"surveillance of workers for physiological changes. . . , including being alert to circumstances such as significant weight loss or gain, facial changes, etc., that would suggest more frequent fit testing,"* as suggested on page 38513 of the Preamble.

**Appendix A to Part 20** This appendix lists a positive pressure (PP) operational mode for some air purifying respirator types. We believe that this designation refers to powered air purifying respirators (PAPR) and recommend that the designation be changed accordingly. A respirator must meet the performance requirements of a pressure demand operational mode for NIOSH to consider it as a positive pressure device. NIOSH has not issued an approval for an air purifying respirator certifying that it meets this level of performance.

Footnote c. on page 38520 has a typographical error and should read, *" . . . Air purifying respirators with APF > 100 must be equipped with particulate filters that are at least 99.97 percent efficient."*

## REFERENCES

AIHA [1993]. Respiratory protection: a manual and guideline. 2nd ed. Fairfax, VA: American Industrial Hygiene Association.

NFPA [1989]. Standard for a fire department self-contained breathing apparatus program. Washington, DC: National Fire Protection Association, Inc.

NIOSH [1987]. Respirator decision logic. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-108.

NIOSH [1995]. NIOSH comments on the Occupational Safety and Health Administration's proposed rule on respiratory protection, May 15, 1995, OSHA Docket No. H-049. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

**Respiratory  
Protection:  
A Manual  
and Guideline**

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**SECOND EDITION**

Edited by

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## **Program Surveillance and Evaluation**

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Lisa M. Brosseau and  
Michael G. May

Periodic review and evaluation of the respiratory protection program are required by the Occupational Safety and Health Administration (OSHA) so that adjustments can be made for changes in operations, exposures, etc. Evaluations should occur at least annually and should include updated industrial hygiene monitoring results. If necessary, written operating procedures should be modified to reflect that reevaluation and retraining should occur.

An evaluation should include discussions with all appropriate parties, including management, program administrators, supervisors, and the actual respirator users. A relatively simple audit form, the Evaluation Form RP.6 (located at the end of this chapter), has been developed by the authors to be used as a guide when the evaluator reviews the various elements of a company's respiratory protection program.

This evaluation form has been developed for two purposes:

1. To serve as a checklist for the development of a respiratory protection program
2. To serve as an evaluation device to determine how well a respiratory protection program is functioning

This form is by no means exhaustive and is presented as a starting place for developing an evaluation suited

to a particular respiratory protection program. In most cases, the questions are very general, and reference to the appropriate sections of this manual should be an integral part of the use of this evaluation form.

Careful consideration should be given to the choice of reviewer. The person(s) responsible for the day-to-day operation of a respiratory protection program should not be the exclusive judge(s) of its proper functioning. An outside party, preferably one knowledgeable in respiratory protection, should be asked to evaluate the program periodically as well.

Points have been assigned to each answer. The guidelines found at the end of the evaluation form were included as a suggestion for use of the point system and should also be adapted to each particular reviewer's needs.

For additional information on developing and using audits, a text developed by Arthur D. Little is recommended.<sup>(1)</sup>

### **References**

1. Arthur D. Little, Inc.: *Environmental Auditing, Fundamentals and Techniques*, 2d ed., by J.L. Greene, G.S. Hedstrom, and M. DiBerto. Cambridge, Mass.: Arthur D. Little, Inc., 1987.

*Respiratory Protection: A Manual and Guideline**Program Surveillance and Evaluation*

**Evaluation Form  
(Form RP.6)**

**I. Program Administration**

<b>A.</b>	<b>Is there a written standard operating procedure for respirator use?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
<b>B.</b>	<b>Does the standard operating procedure contain reference to the following:</b>		
	<b>1. Hazard recognition/measurement criteria (TLVs, sampling)?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>2. Respirator selection criteria?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>3. Use of approved equipment only (National Institute for Occupational Safety and Health, Mine Safety and Health Administration, other standards)?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>4. Training requirements and regularity of repetition?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>5. Fit testing requirements (both qualitative and quantitative) and regularity of repetition?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>6. A stated policy on facial hair and other fitting problems?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>7. Procedures for issuing respirators to users?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>8. Procedures for inspection and maintenance of respirators?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>9. Medical evaluation of respirator users?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
	<b>10. Program evaluation criteria?</b>	<b>yes</b>	<b>1</b>
		<b>no</b>	<b>0</b>
<b>C.</b>	<b>Has responsibility and authority for the respiratory protection program been assigned to a single individual?</b>	<b>yes</b>	<b>10</b>
		<b>no</b>	<b>0</b>
<b>D.</b>	<b>Does the program administrator have sufficient knowledge of respiratory protection?</b>	<b>yes</b>	<b>10</b>
		<b>no</b>	<b>0</b>
<b>E.</b>	<b>Are adequate resources allocated to ensure success (budgeted money with specific expenses itemized for equipment, training, etc.)?</b>	<b>yes</b>	<b>10</b>
		<b>no</b>	<b>0</b>
	<b>Total points possible:</b>		<b>50</b>
	<b>Total points obtained:</b>		_____

-- more --

Form RP.6 Cont.

II. Selection Background Information

A.	Have all toxic substances in the plant been listed and their use described (e.g., flow charts, material safety data sheets, etc.)?	yes	5
		no	0
B.	Have all toxic substances in the plant been sampled or in some other appropriate manner have their concentrations been determined?	yes	5
		no	0
C.	Have the concentrations for all toxic substances been determined within the last year or some other appropriate time period? (Verify this by examining records, etc.)	yes	5
		no	0
D.	Is odor threshold data, if applicable, available on all toxic substances listed in (II.,A.)?	yes	5
		no	0
E.	Have OSHA permissible exposure limits (PELs) or other applicable levels been identified for all toxic substances listed in (II.,A.)?	yes	5
		no	0
F.	Have all immediately dangerous to life and health (IDLH) situations/concentrations been identified?	yes	5
		no	0
G.	Have all toxic substances listed in (II.,A.) been evaluated for eye irritation potential?	yes	5
		no	0
H.	Have all possibly exposed employees been identified by job category, including information on job task, duration and frequency, location, and physical demands?	yes	5
		no	0
I.	Have all job environments been measured for temperature, relative humidity, and pressure conditions?	yes	5
		no	0
J.	Have all jobs been identified in terms of work load (e.g., ACGIH or other criteria)?	yes	5
		no	0
K.	Have all confined space situations been identified?	yes	5
		no	0
Total points possible:			55
Total points obtained:			_____

- more -

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**NFPA 1404**

**Standard for a**

**Fire Department Self-Contained**

**Breathing Apparatus Program**

**1989 Edition**

This edition of NFPA 1404, *Standard for a Fire Department Self-Contained Breathing Apparatus Program*, was prepared by the Technical Committee on Fire Service Training and acted on by the National Fire Protection Association, Inc. at its Annual Meeting held May 15-18, 1989 in Washington, DC. It was issued by the Standards Council on July 14, 1989, with an effective date of August 7, 1989.

The 1989 edition of this document has been approved by the American National Standards Institute.

**Origin and Development of NFPA 1404**

This is a new standard, developed in response to a perceived need. The Committee on Fire Service Training saw that there were no standards on a fire department program for self-contained breathing apparatus, and that the lack of guidance on subject areas like training, maintenance, and SCBA program evaluation could cause serious problems for the fire service. It is the hope of the Technical Committee that the void has been filled in a practical and reasonable manner.

## Chapter 3 Emergency Scene Use

### 3-1 Criteria for Use.

3-1.1 The authority having jurisdiction shall require respiratory protection to be used by all personnel who may be exposed to respiratory hazards in the performance of their duties.

3-1.2\* Respiratory protection shall be used by all personnel who are exposed to respiratory hazards or who may be exposed to such hazards without warning. Personnel who are operating in areas that may be subject to the hazards with sufficient warning to don respiratory protection equipment, shall have respiratory protection equipment readily available for use.

3-1.3\* Respiratory protection equipment shall be used by all personnel operating in confined spaces, below ground level, or where the possibility of a contaminated or oxygen deficient atmosphere exists until or unless it can be established by monitoring and continuous sampling that the atmosphere is not contaminated or oxygen deficient.

3-1.4 When used, respiratory protection equipment shall be properly worn according to the manufacturer's requirements.

3-1.5\* Personnel shall be monitored for indications of fatigue or other factors that can result in unsafe conditions.

3-1.6 Members using SCBA shall operate in teams of two or more who are in communication with each other through visual, audible, physical, safety guide rope, electronic, or other means to coordinate their activities and are in close proximity to each other to provide assistance in case of an emergency.

3-1.7\* When members are involved in operations that require the use of SCBA or other respiratory protective equipment, at least one member shall be assigned to remain outside the area where respiratory protection is required. This member shall be responsible for maintaining a constant awareness of the number and identity of personnel using SCBA, their location and function, and time of entry. Members with SCBA shall be available for rescue.

## Chapter 4 SCBA Training

### 4-1 Recruit Training Program.

4-1.1\* All training related to the use, maintenance, and care of respiratory protection equipment shall be provided by instructors meeting the objectives of Level I of NFPA 1041, *Standard for Fire Service Instructor Professional Qualifications*.

4-1.2\* Records shall be maintained of all respiratory protection training including training of personnel involved in maintenance of such equipment.

4-1.3\* Minimum performance standards shall be established by the authority having jurisdiction for donning respiratory protection equipment.

### 4-2 Annual Personnel Certification.

4-2.1 Prior to initial training, personnel shall be examined and certified by a physician as being medically and physically fit in accordance with Chapter 2 of NFPA 1001, *Standard for Fire Fighter Professional Qualifications*.

4-2.1.1\* If the physician certifying personnel for respiratory protection equipment use is other than the fire department physician, the examination report shall be subject to the approval of the fire department physician.

4-2.2 All personnel who may be required to use respiratory protection equipment shall be medically certified by a physician on an annual basis in accordance with 5-3.6 of NFPA 1500, *Fire Department Occupational Safety and Health Program*.

4-2.3\* The facepiece seal capability of each member qualified to use SCBA shall be verified by qualitative fit testing on an annual basis and any time that new types of SCBA are issued. Each new member shall be tested before being permitted to use SCBA in a hazardous atmosphere. Only members with a properly fitting facepiece shall be permitted by the fire department to function in a hazardous atmosphere with self-contained breathing apparatus.

4-2.4 Beards or facial hair that interfere with the facepiece seal shall be prohibited for personnel required to use respiratory protection equipment. If eyeglasses are worn, the person shall use frames that do not pass through the seal area of the facepiece.

4-2.5\* Personnel required to wear respiratory protection equipment in conjunction with specialized protective equipment, for example, proximity suits or totally encapsulated suits, shall be evaluated for physical and emotional stresses associated with these specialized applications.

4-2.6 The authority having jurisdiction shall be responsible for establishing a program that provides personnel training in the proper and safe use and limitations of respiratory protection equipment and related equipment, on the policies and procedures related to the authority having jurisdiction's respiratory protection program, and in those areas outlined by this standard.

The program shall also provide a means of evaluating fire fighter performance in the use of respiratory protection equipment, and their knowledge of the respiratory equipment used. Respiratory protection training shall be conducted as an ongoing training program.

4-2.7 All members who are permitted to use SCBA shall at least annually successfully demonstrate their ability to meet the performance standards set by the authority having jurisdiction.

4-2.8 All fire fighters shall meet the training and performance requirements of this standard prior to actual emergency operations during which they may be expected to wear respiratory protection equipment.

**NIOSH**

**Comments to DOL**

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**COMMENTS OF THE  
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
ON THE  
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION  
PROPOSED RULE ON RESPIRATORY PROTECTION**

**29 CFR Parts 1910, 1915, and 1926  
Docket No. H-049**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health**

**5/15/95**

The National Institute for Occupational Safety and Health (NIOSH) supports the proposed modifications to the Occupational Safety and Health Administration (OSHA) standard on the use of respiratory protection (29 CFR 1910.134, 1915.152, and 1926.103) published in the *Federal Register* on November 15, 1994 [59 FR 59884]. We offer the following comments for consideration.

#### SCOPE AND APPLICATION (Section a)

When respirators are required to protect the health of workers, paragraph (a) (2) of the proposed OSHA standard adequately describes employer responsibilities. There are several voluntary respirator use situations where an employer would not have to comply with all aspects of the OSHA respirator use standard, including when employees voluntarily use their own respirators or when employees voluntarily use employers' respirators to further reduce exposures. Although a respiratory protection program that is established and maintained by the employer is advisable for all respirator use situations, this should not be a mandatory OSHA requirement for voluntary respirator use. Because the risk to workers involving the improper use of negative-pressure, air-purifying respirators is thought to be low, situations for which an employer does not voluntarily establish and maintain a respiratory protection program should be restricted to these devices. OSHA should consider adding a paragraph (a) (3) on the voluntary use of respirators, such as:

*(3) When respirators are used in the absence of a regulatory requirement or when employees are not at risk, a respiratory protection program established and maintained by the employer is advisable but is not required. Respirators used without a respiratory protection program shall be restricted to NIOSH-approved, negative-pressure, air-purifying respirators.*

#### DEFINITIONS (Section b)

- The following definition of fit check should be added to the final OSHA respiratory protection standard:

*Fit check is a brief test done by a respirator wearer after donning a respirator to evaluate the seal between the respirator's facepiece and its wearer's face.*

- Quantitative fit testing systems are available that do not involve the generation of challenge agents in chambers. Therefore, reference to the use of a challenge agent in a test chamber for determining a fit factor should be deleted from the definitions of fit factor and quantitative fit test (QNFT) in the proposed rule. The following definitions are suggested:

*Fit factor is a quantitative estimate of the extent to which a respirator prevents leakage through the seal between the respirator facepiece and the wearer's face. Fit factors range from 1 (representing no protection) to several thousand.*

*Quantitative fit test (QNFT) is an objective assessment of the extent to which a respirator prevents leakage through the seal between the respirator facepiece and the wearer's face.*

- Later in these comments (see section on Fit Testing and Appendix A), the health risk associated with exposure to irritant fume is presented. The definition of qualitative fit test in the proposed respiratory protection standard should be changed to emphasize that a test agent used during a qualitative fit test be safe for exposure by both the test subject and the test administrator. The definition should also reflect the subjective nature of the test. The following definition is suggested:

*Qualitative fit test (QLFT) is a subjective assessment of the fit of the facepiece of a respirator to its wearer's face using a nonhazardous test agent which is detected either voluntarily or involuntarily by the respirator wearer upon exposure to the test agent.*

On page 58932, OSHA requested comments on whether the definition of service life in the proposed rule should be replaced with the definition in the NIOSH RDL. For the purposes of the OSHA respiratory protection standard, using the more concise definition from the American National Standard for Respiratory Protection (ANSI Z88.2-1992) is recommended. The ANSI definition of service life is the period of time that a respirator provides adequate protection to the wearer.

#### ASSIGNED PROTECTION FACTORS (Section d)

OSHA has proposed to adopt the assigned protection factors (APFs) from the NIOSH *Respirator Decision Logic* [NIOSH 1987]. In determining the APF values, NIOSH began with laboratory measurements of respirator performance conducted by the Los Alamos National Laboratories in the early 1970s. These measurements were mostly based on quantitative fit-testing that was conducted in fit-test chambers. Because studies indicated that laboratory measurements of performance did not correlate well with workplace measurements of performance, NIOSH also considered published government reports and studies that were published in the peer-reviewed journals to modify the original laboratory-based APFs. Several peer-reviewed articles were rejected in this process because the protocol for performing the study did not include fit testing or did not ensure that the respirators were properly worn and functioning.

The NIOSH definition for an APF was the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage (95%) of properly fitted or trained users. When workplace data existed from studies that met our minimum criteria, NIOSH used the point estimate equation ( $p=0.95$ ) to determine the APF for a given class of respirators. While workplace data were considered for several classes of respirators, only the APFs for powered air-purifying respirators (PAPRs) and continuous flow supplied-air respirators were changed. The APFs for continuous flow supplied-air respirators were based on analogy with the PAPR field studies because the minimum air flow requirements are the same for these respirators in 30 CFR 11. Data on other classes of respirators basically confirmed the APFs from the laboratory studies. Because of concerns about fit, disposable respirators were given an APF of 10 only if they have been properly fitted using a quantitative fit test; otherwise, the APF would be 5.

NIOSH will soon publish (42 CFR 84) modifications to the current respirator certification standard (30 CFR 11). This first change in a planned series of updates will establish improved filter efficiency tests and a new performance-based classification scheme for particulate filters. NIOSH will also be publishing a respirator user's guide that will provide APFs and other information that will be needed for the new classes of respirators [59 Fed.

Reg.<sup>1</sup> 26850 (1994)]. NIOSH APFs in the *Respirator Decision Logic* will continue to apply to respirators certified under 30 CFR 11.

#### **FILTER USE (30 CFR 11)/AEROSOL SIZE CRITERION (Section d)**

Respirator experts have been concerned for many years about the potential for small particles to penetrate Dust and Mist (DM) and Dust, Fume, and Mist (DFM) filters certified under 30 CFR 11. Laboratory research beginning in the early 1970s and continuing into the 1990s demonstrated that some but not all members of these filter classes allow significant penetration of submicron-sized particles. Some of the more recent of these studies conducted by NIOSH or through NIOSH grants, continue to show significant penetration of submicron particles for DM and DFM filters [Hinds and Kraske 1987; Hinds and Bellin 1987; Moyer and Stevens 1989a; Moyer and Stevens 1989b; Stevens and Moyer 1989; Chen et al. 1992]. Additionally, submicron particulates present special medical concerns because they can diffuse throughout the respiratory system. Furthermore, published data are limited describing worksites where substantial exposures occur to submicron particles and published research is inadequate to characterize the prevalence and types of worksites and work processes where DM and DFM filters are being used for protection against submicron particulates.

The existing information on small particle penetration led the American National Standards Institute (ANSI) in 1992 to recommend that DM and DFM filters be used only in workplaces where the aerosols had been characterized and were known to have a mass median aerodynamic diameter (MMAD)<sup>2</sup> of 2  $\mu\text{m}$  and larger. Where the aerosol is smaller or of unknown size distribution, ANSI recommended only HEPA-filter respirators be used [ANSI 1992].

For particulate-filtering respirators certified under 30 CFR 11, NIOSH recommends that OSHA adopt a particle-size/filter-selection criterion that will be as protective as the ANSI recommendation for filter selection. The aerosol size-based filter selection recommendation would apply only to filters certified under 30 CFR 11. It would not apply to the new classes of filters that will be certified by NIOSH under 42 CFR 84 because those new filters will be certified against the most penetrating size range of submicron particles. This will ensure that all filters certified under 42 CFR 84 are fully effective against any particle size, including small and submicron particles.

#### **IMMEDIATELY DANGEROUS TO LIFE AND HEALTH (IDLH) VALUES (Section g)**

NIOSH concurs with OSHA on the definition (page 58938) of immediately dangerous to life and health (IDLH). That definition is consistent with the definition in the *NIOSH Respirator Decision Logic* [NIOSH 1987] and the *NIOSH Pocket Guide to Chemical Hazards* [NIOSH 1994a].

#### **Oxygen Deficient Atmosphere**

NIOSH will be providing posthearing comments to OSHA on oxygen deficient atmospheres.

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<sup>1</sup>Federal Register. See Fed. Reg. in references.

<sup>2</sup>50% of the particulate mass is contained in particles below the MMAD and 50% of the particulate mass is contained in particles above the MMAD.

## Chemical Contaminant IDLH Atmospheres

NIOSH has recently reviewed, and in many cases made more protective, its IDLH values for chemical contaminants [NIOSH 1994a]. NIOSH recommends that OSHA use these new IDLH values as criteria for selecting the most protective respirator.

The criteria used to develop these IDLH values include the preferential use of human toxicity data followed by acute animal toxicity data. When acute toxicity data were insufficient or unavailable, then NIOSH considered chronic toxicity data or an analogy to a chemically similar substance [NIOSH 1994b].

### RESPIRATOR FIT TESTING (Section f)

Because no single fit test procedure has been demonstrated to be a reliable predictor of worker exposure, NIOSH recommends that OSHA recognize any of the following fit test procedures as acceptable:

- Quantitative fit tests using a non-hazardous challenge aerosol (such as corn oil or sodium chloride), generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.
- Quantitative fit test using ambient aerosol as the challenge agent and appropriate instrumentation to quantify the respirator fit.
- Quantitative fit tests using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.
- Qualitative fit tests using a non-hazardous test agent that is readily detected by the test subject. Qualitative fit tests using saccharin as the test agent are not recommended because it is a potential carcinogen and there is an acceptable alternative test agent (e.g., bitrex®) [Niemeier 1991; Wilmes 1994]. Qualitative fit tests using irritant fume as the challenge agent are not recommended because of the health risk associated with exposure to the irritant fume (see discussion in Appendix A).

In the future, as additional test methods are developed, OSHA should publish them and receive public comment on whether to accept their use.

NIOSH does not agree with the proposal to establish one test method as the standard against which other fit tests are to be judged. The fit test proposed by OSHA (OSHA Appendix A) as the reference standard has not itself been validated. That is, the OSHA proposed fit-test has not been demonstrated to correlate with the fit of the respirator when worn in actual workplace situations. In fact, there are data suggesting that the reference fit test proposed by OSHA does not correlate with the fit achieved in the workplace under actual conditions of use [Dixon and Nelson 1984; Myers et al. 1984; Gaboury et al. 1993]. Only the controlled negative pressure fit test system, which has been excluded in the OSHA proposal, has been subjected to limited validation [Decker and Crutchfield 1993].

### MEDICAL EVALUATION CRITERIA (Section e)

NIOSH agrees with OSHA that the fitness of an individual to wear a respirator should be determined by a physician using the detailed information of the proposed respirator use and work conditions. NIOSH also agrees that there is a considerable difference of opinion regarding the necessary elements of this

determination which cannot be resolved based on the peer-reviewed literature. The stresses imposed by the different types of respirators and work, and the fitness of potential respirator wearers vary widely.

Given the complexity of these multiple factors, NIOSH recommends that OSHA allow the content of the medical evaluation for prospective respirator wearer's be decided by a knowledgeable physician. "Medically evaluated" could mean assessment of a questionnaire by the physician or a knowledgeable health-care professional under the supervision of the physician. The physician should also determine whether symptoms or medical conditions developing between scheduled evaluations warrant an additional, interim evaluation. This approach is closest to OSHA's first proposed alternative. As suggested in OSHA's third alternative, the use of a questionnaire to screen prospective respirator wearers would frequently be an appropriate and sufficient approach to medical evaluations. Responses to the questionnaire would identify those individuals requiring further evaluation. NIOSH recommends that the frequency of medical evaluations be not less than every five years. More frequent evaluations will be indicated in many settings, depending on the respirator use, exposure and other work conditions, and employee characteristics.

The inclusion of a non-mandatory appendix may be useful, although NIOSH questions whether a medical examination should always include pulmonary function testing. OSHA could consider adding to its non-mandatory appendix a listing of medical tests (e.g., spirometry, resting electrocardiogram [ECG] and exercise tests, chest x-rays [CXRs], hearing and vision tests, and blood tests) that are sometimes used in certain situations. The decision to use a particular test would be made by the physician, based on the respirator to be used, the anticipated work activities and environment, and the worker's age and health status. For physicians seeking additional information and advice to apply to their specific situation, there are a number of published reviews of the effects of respirator wear, and recommended medical evaluation guidelines, which NIOSH would be willing to identify for OSHA.

NIOSH recommends that all individuals required to use respirators be medically evaluated, regardless of the expected duration of respirator use. The potential adverse effects of respiratory use are primarily dependent on the type of respirator, the details of the work and environment, and the individual, rather than the time of respirator use. The responsible physician should be allowed to tailor the evaluation to meet the needs of the specific situation.

In summary, the assessment of medical fitness to wear a respirator is too complex to be addressed by any predetermined algorithm. The physicians's judgement is the most critical factor in identifying workers who should be proscribed from using respiratory protection. NIOSH supports the current approach of allowing considerable latitude to the responsible physician and helping ensure that they are sufficiently informed of the relevant risk factors.

## **USE OF RESPIRATORS (Section g)**

### **1) Reuse of Disposable Respirators**

The resistance to degradation of particulate filters certified under 30 CFR 11 is not well-defined, although it is known that humidity and oil mists may degrade the performance of some. Until particulate filters certified under 42 CFR 84 become available, NIOSH recommends that reuse of disposable particulate respirators beyond a single shift be restricted to HEPA filter respirators. HEPA filters have been shown to be resistant to degradation by humidity [Moyer and Stevens 1989]. Some models may be affected by high levels of other degrading contaminants, such as oil

mists, but only at levels expected to be highly uncommon for most worksites. NIOSH does not recommend the reuse of DM and DFM respirators, many models of which may degrade in oil mists and humid environments, in any worksite.

Resistance to degradation will be better documented for particulate filters to be certified under 42 CFR 84. NIOSH recommends that after those filters become available, only Part 84 filters should be considered for reuse beyond a single shift.

Disposable respirators should be discarded whenever they become soiled, contaminated, damaged, malodorous, difficult to breathe through, or reach their end-of-service life. To minimize cross-contamination and deformation of the sealing surface from different face shapes, a disposable respirator should be worn by only one worker. Therefore, OSHA should revise paragraph (g) (9) to allow the reuse of certain disposable respirators. The following paragraph is recommended:

*"The employer shall ensure that disposable HEPA respirators certified by NIOSH under 30 CFR Part 11 and used in environments that do not contain filter-degrading aerosols (e.g., oil mist) are discarded when they become soiled, contaminated, damaged, malodorous, difficult to breathe through, or when their service life has ended; reuse may extend beyond one work shift. Disposable HEPA respirators that are used in filter-degrading aerosols and all other disposable respirators shall be discarded under the same conditions, but their use shall not exceed one work shift. A disposable respirator shall be used by only one worker."*

OSHA should also add a separate section to paragraph (g) that describes when replaceable filters, cartridges, and canisters should be discarded. The following paragraph is recommended:

*"The employer shall ensure that replaceable HEPA cartridges certified by NIOSH under 30 CFR Part 11 used in environments that do not contain filter-degrading aerosols (e.g., oil mist) are discarded when they become contaminated, damaged, difficult to breathe through, or when their service life has ended; reuse may extend beyond one work shift. Replaceable HEPA cartridges that are used in filter-degrading aerosols and all other replaceable filters, cartridges, and canisters shall be discarded under the same conditions, but their use shall not exceed one work shift."*

## 2) Beards and Respirators

On page 58921, OSHA requested comment on the issue of workers with beards who are required to wear respirators. In addition to personal preference, some men wear beards for religious or medical reasons. NIOSH recommends that OSHA state in the final rule that when the respirator-use situation permits, employers are allowed to accommodate bearded workers by providing them with a respirator whose function is not affected by facial hair. OSHA may want to cite examples of appropriate respirators that can be worn by bearded workers such as PAPRs and supplied-air respirators with hoods or other loose-fitting facepieces and inappropriate respirators such as negative-pressure respirators with tight-fitting facepieces.

## 3) Contact Lenses and Respirators

NIOSH is not aware of any documented evidence that use of contact lenses affects the performance of a respirator. Neither is NIOSH aware of any

documented evidence that use of contact lenses creates special hazards for respirator users. Therefore, OSHA should allow the wearing of contact lenses during respirator use. The National Fire Protection Association (NFPA) allows use of soft contact lenses during the use of self-contained breathing apparatus (SCBA), "...provided that the member has previously demonstrated successful long-term contact lens use" [NFPA 1992]. The NFPA standard does not allow use of hard contact lenses during SCBA use.

**4) Selection of Powered Air-Purifying Respirators**

On page 58923 of the proposed rule, OSHA requests comment on whether employees should be able to choose PAPRs rather than negative-pressure respirators because of their reduced breathing resistance. NIOSH agrees with OSHA that the respirator program administrator is responsible for respirator selection. NIOSH also agrees that OSHA should not dictate the circumstances of PAPR use involving employee requests based solely on breathing resistance and comfort. It should be clear that the employer is permitted to provide a higher level of protection than the minimum demanded by working conditions.

## Appendix A

### DISCUSSION ON IRRITANT FUME FIT TEST

The following information supports a recommendation against use of the irritant fume qualitative fit test:

The irritant fume protocol described in the proposed rule requires the use of ventilation smoke tubes to qualitatively test the fit of a respirator's facepiece to its wearer's face. The protocol recommends the use of a MSA smoke tube (part number 5645) or equivalent. Two companies (MSA and Sensidyne, Inc.) sell ventilation smoke tubes that contain stannic chloride. When stannic chloride hydrolyzes with ambient moisture, a characteristic smoke is produced consisting of white hydrochloric acid fume or smoke, stannic oxychloride, and tin compounds.

Hydrogen chloride is a strong irritant of the eyes, mucous membranes, and skin [Hathaway et al. 1991]. Because ventilation smoke tubes produce hydrogen chloride, a test subject usually reacts involuntarily by coughing or sneezing whenever the smoke leaks into the respirator's facepiece. Thus, the likelihood that a test subject will give a false indication of proper fit is reduced [Birkner 1980; Pritchard 1976]. The NIOSH recommended exposure limit and the OSHA permissible exposure limit for hydrogen chloride are a ceiling limit of 5 parts per million (ppm). NIOSH has also established an immediately dangerous to life and health (IDLH) value of 50 ppm for hydrogen chloride [NIOSH 1994a].

As part of a NIOSH HHE, NIOSH researchers measured the concentrations of hydrogen chloride emitted from Sensidyne smoke tubes in environments with low (14 percent) and moderate (53 percent) relative humidity [NIOSH 1993; Lenhart and Burroughs 1993]. Each measurement of hydrogen chloride was made as the irritant smoke was puffed from a smoke tube attached to an aspirator bulb during a simulation. Air concentrations of hydrogen chloride ranged from 100 ppm (measured at a distance of 6 inches) to 11,900 ppm (measured at a distance of 2 inches).

The irritant fume protocol in the proposed rule requires smoke production by attaching one end of a smoke tube to a low-flow air pump calibrated to deliver air at a flow rate of 200 milliliters (ml) per minute. NIOSH researchers made laboratory measurements of the concentrations of hydrogen chloride emitted from ventilation smoke tubes attached to low-flow pumps calibrated to deliver 200 ml/minute or after a single squeeze of an aspirator bulb. Hydrogen chloride measurements were made using methods similar to those used during the NIOSH HHE using a Miran 1A portable ambient air monitor set at a pathlength of 20.25 meters and an analytical wavelength of 3.4 micrometers.

All measurements were made in a room with 25 percent relative humidity and a temperature of 78°F. Table I contains the results of the hydrogen chloride measurements.

Table I

**Hydrogen Chloride Concentrations Emitted from Sensidyne  
and MSA Smoke Tubes Using an Aspirator Bulb and Using a Pump**

Distance from Tip of Smoke Tube to Tubing Inlet (Inches)	Concentration of Hydrogen Chloride (ppm)	
	Sensidyne Smoke Tube (Part No. 501)	MSA Smoke Tube Part No. 5645
<i>One squeeze of aspirator bulb</i>		
12	50	700
12	50	500
6	1000	1800
6	450	>2000
1	>2000	--
<i>Pump delivering 200 ml/minute</i>		
12	1500 (<20 sec.)	>2000 (<10 sec.)
<p>Note: During testing, the relative humidity was 25% and the temperature was 78°F.</p> <p>ppm: parts per million ml: milliliters sec: seconds</p>		

The results shown for the Sensidyne smoke tube are consistent with the hydrogen chloride concentrations reported in the NIOSH HHE [NIOSH 1993; Lenhart and Burroughs 1993]. The MSA smoke tube produced higher concentrations than the Sensidyne tube when attached to the aspirator bulb, and the MSA tube produced greater than 2000 ppm of hydrogen chloride in less than 10 seconds when attached to the pump. These sampling results show that irritant smoke tubes produce hydrogen chloride levels that should be considered a health risk.

The irritant fume protocol thus does not meet the minimum criteria for a valid qualitative fit test described in the new fit test protocols section of Appendix A, which specifies that challenge agents should be non-toxic.

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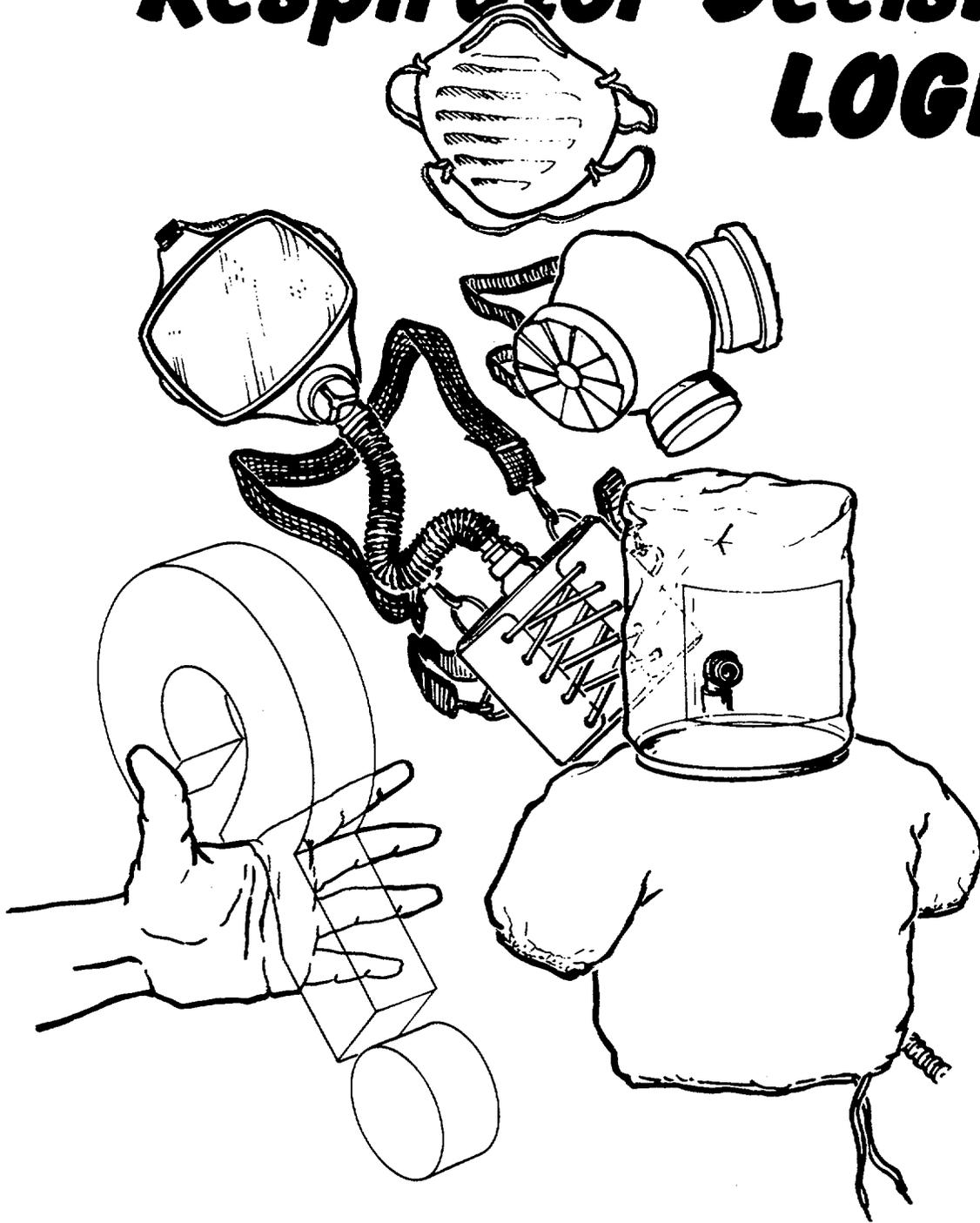
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# NIOSH

## *Respirator Decision LOGIC*



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control  
National Institute for Occupational Safety and Health

**N I O S H   R E S P I R A T O R   D E C I S I O N   L O G I C**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control  
National Institute for Occupational Safety and Health  
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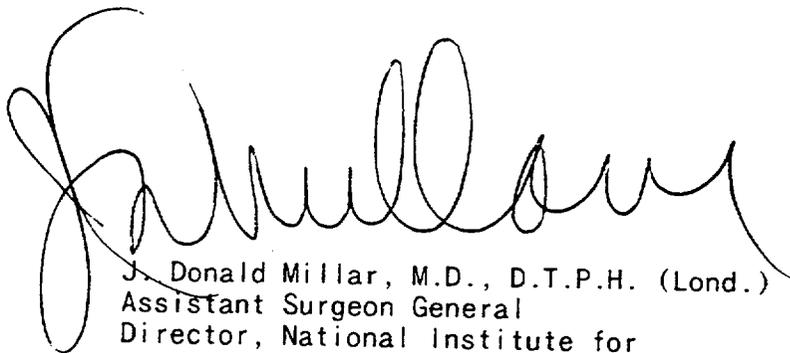
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## FOREWORD

The initial Respirator Decision Logic was developed in 1975 as part of the National Institute for Occupational Safety and Health/Occupational Safety and Health Administration (NIOSH/OSHA) Standards Completion Program and was updated in 1978. Due to technical advances in respirator design and research, NIOSH has again revised the Respirator Decision Logic.

This revision retains many aspects of the original Respirator Decision Logic, but it differs in five areas: odor warning properties with respect to air-purifying cartridge/canister respirators, recognition of the problems in assigning protection factors, changes in protection factors for certain respirator classes, respirator recommendations for carcinogens, and medical recommendations.

The recognition of wide variation among workers in their sensitivities for detection of odors has led to the recommendation that employers not rely solely on currently published data on odor thresholds to ensure that workers who wear air-purifying cartridge or canister respirators are capable of smelling the contaminant at the applicable exposure limit. Recent research on in-plant respirator testing suggests that some previously assigned protection factors based on data from laboratory fit testing may not be valid. This revised Respirator Decision Logic has incorporated assigned protection factors based on data from recent in-plant research for some powered air-purifying respirators (PAPR) and some similar respirators, such as loose-fitting and tight-fitting continuous flow air-line respirators. Since NIOSH maintains that there is no safe exposure to carcinogens, only the most protective respirators should be used to protect workers from exposure to carcinogens in the workplace. Finally, specific medical recommendations are included to assist physicians in determining an individual's fitness to wear a respirator.



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## I. INTRODUCTION

### A. Background and Scope

The National Institute for Occupational Safety and Health (NIOSH) routinely makes recommendations regarding the use of respirators for workers exposed to workplace environments that contain hazardous concentrations of airborne contaminants and/or oxygen-deficient atmospheres. Such recommendations are made only when engineering controls are not technically feasible, while controls are being installed or repaired, or when emergency and other temporary situations arise. Respirators are the least preferred method of worker protection from respiratory hazards because they can be unreliable if an adequate respiratory protection program is not established by the employer and because they require worker cooperation. The intent of this decision logic is to provide industrial hygienists and other professionals knowledgeable in respirator selection with a procedure for selecting suitable classes of respirators for particular concentrations of specific contaminants. In this decision logic, concerns are raised about limitations of the data used to set protection factors for several classes of respirators.

To ensure uniformity and adherence to proper respirator usage, NIOSH recommendations have been based on the Respirator Decision Logic developed jointly in 1975 by NIOSH and the Occupational Safety and Health Administration (OSHA) as part of the Standards Completion Program and updated in June 1978. That decision logic incorporated requirements contained in 30 CFR 11 and fit factor data developed by the Los Alamos National Laboratory (LANL). NIOSH has now modified that decision logic to reflect new developments that include increased use of respirators to control exposure to carcinogens in the workplace, introduction of new respiratory equipment, and reporting of field research data on workplace protection factors (WPF's).

This modified decision logic identifies the criteria necessary to determine the classes of respirators that will provide a known degree of respiratory protection for a given work environment, assuming that the respirators are used correctly. The degree of protection is related in part to protection factors. Many of the assigned protection factors (APF's) that appear in this decision logic are based on laboratory studies and should be regarded as approximate.

The selection of a specific respirator must be made by individuals knowledgeable about the limitations associated with each class of respirators and familiar with the actual workplace environment, including the job task(s) to be performed. The correct use of a respirator is just as important as the selection process if adequate worker protection is to be achieved. Without a complete respiratory protection program, workers will not receive the degree of protection anticipated from a respirator, even if it is a correct choice for the situation. Training, motivation, medical

evaluation, fit testing, and a respirator maintenance program are critical elements for the successful use of a respirator. As a minimum, compliance with 29 CFR 1910.134 is mandatory whenever respirators are used by workers, whether on a required or voluntary basis.

## **B. Cautionary Statements**

NIOSH concerns about the use of respirators are discussed further in various parts of the document and are summarized in the following six cautionary statements:

### **• Assigned Protection Factors**

In general, the assigned protection factors (APF's) that appear in this decision logic are not based on measurements of actual field (workplace) performance. As noted in the footnotes accompanying Tables 1, 2, and 3, in only a few instances are the APF's based on any workplace performance testing; the majority of the APF's have no workplace performance basis at all. APF's based solely on laboratory fit testing should be viewed and applied with particular caution, even when the laboratory testing involves a simulated work regimen. To date, no relation has been demonstrated between laboratory fit factors and measured workplace performance. As more performance testing of respirators is undertaken in the workplace by NIOSH and others, NIOSH may find it necessary to revise the APF's upward or downward. For the present, APF's should not be considered reliable predictors of performance levels that will be achieved during actual use, since APF's are not based on a sufficient amount of workplace testing.

### **• Fit Testing**

No qualitative or quantitative fit tests have been demonstrated to be capable of effectively identifying inadequately fitting respirators (i.e., respirator-wearer combinations that provide less protection than the APF). The presently used fit tests (e.g., ANSI-recommended, OSHA-approved) may fail to identify individual wearers with inadequate respiratory protection. Thus fit tests should be used with caution and with recognition of their possible deficiencies. As appropriate, periodic evaluations of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection.

### **• QNFT Fit Factor Screening Levels**

Regarding quantitative fit testing (QNFT), no studies are available to indicate what fit factor value (i.e., screening level) will ensure a high probability of identifying inadequately fitting respirators. That is, there are no studies demonstrating what fit factor values are adequate

accept/reject criteria for QNFT fit screening. When QNFT is used for fit screening, the fit factor screening level should be chosen with caution and with recognition of the uncertainty of its effectiveness. As appropriate, periodic evaluation of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection.

- **Adequate Warning Properties**

No physiological effects in humans (e.g., odor, taste, eye irritation, respiratory irritation) have been demonstrated as being capable of consistently providing respirator wearers with timely, consistent, persistent, and reliable warning of hazardous airborne concentrations inside a respirator. Individual wearers may be unable to detect the warning effect when necessary and may fail to take action necessary to protect themselves (e.g., leaving the area where respirators are necessary or changing the sorbent cartridge or canister). When warning properties must be relied on as part of a respiratory protection program, the employer should accurately, validly, and reliably screen each prospective wearer for the ability to detect the warning properties of the hazardous substance(s) at exposure levels that are less than the exposure limits for the substance(s). Warning properties should be regarded with caution and with recognition of their unreliability.

- **Service Life Information**

For essentially all gases and vapors, no adequate service life information is available to respirator wearers or to those responsible for respiratory protection programs. When this information is not available, respirators with air-purifying sorbent elements should be used with caution and with recognition of the wide variability of service lives under differing use conditions. Employers should possess valid and reliable estimates of service lives for all sorbent elements used in the respiratory protection program. Service life test data should be representative of all conditions of intended use that can be reasonably anticipated. Factors known to affect the service lives of sorbent elements include, but are not limited to, the make and model of sorbent element, airborne concentrations of contaminant(s), and relative humidity through each sorbent element. When appropriate service life data is available, any reliance on the data should be undertaken with caution and with recognition of the limitations and uncertainties of the information.

- **Determination of Protection Factor Levels Required for Adequate Protection**

Workers are never exposed to a single unvarying concentration of a contaminant. In a given work area, individual exposures may vary widely between workers, during a workshift, and between days. The range of potential exposures should be appropriately determined for all workers and for all circumstances that can be reasonably anticipated. The

highest anticipated exposure for each respirator wearer should be used to compute the protection factor required for each wearer. Required protection factors should be used with caution and with recognition of their uncertainties.

## II. RESPIRATOR DECISION LOGIC

This decision logic contains a series of questions regarding situations which may require the use of respirators. (See Respirator Decision Logic Sequence, page 8.) In answering these questions, the user of this decision logic is assisted in identifying specific classes of respirators, applicable restrictions, and the appropriate respirator selection table to use. When using one of the tables to identify a suitable class of respirators, the user must keep in mind the restrictions identified in the question section of this decision logic.

This decision logic identifies the criteria necessary to determine the classes of respirators that will provide the minimum acceptable degree of protection for a chemical at a given concentration. Classes of respirators offering greater protection can usually be used in place of the minimum acceptable class of respirators. Respirator classes are consistent with respirator certification groupings as specified in 30 CFR 11.

The recommendations in this decision logic are based primarily on the physical, chemical, and toxicologic properties of the contaminant and on the limitations of each class of respirators, including filtration efficiency, air supply capability, and face seal characteristics and leakage. Thus this decision logic is limited to identifying classes of acceptable respirators, rather than individual respirators.

After various classes of respirators are identified as being suitable for a given situation, an evaluation is made of other factors of the particular work environment so that the best respirator within the recommended classes can be chosen. In some situations, the selection of a respirator classified as providing a higher level of protection may be advisable.

To assist the user, this decision logic contains ten subparagraphs following the Respirator Decision Logic Sequence that describe respirator limitations, use of applicable exposure limits, warning properties, protection factors, oxygen limitations, and medical evaluation of suitability to wear respirators. Additional supporting information is contained in Appendices A through E. To properly use this decision logic, the user should carefully read the subparagraphs.

The assigned protection factors (APF's) used in this decision logic were based on quantitative fit factor data developed by Los Alamos National Laboratories (LANL) under contract to NIOSH and on field evaluation data gathered by NIOSH and others. Specific references and summaries of the data used to generate certain protection factors can be found in Subparagraph 8, page 28. Fit factors determined for the individual wearer of a respirator by quantitative fit testing or by any other method used to determine fit should not be substituted for the APF given for each class of respirators. However, the fit factor determined through quantitative fit testing must be greater than the APF; otherwise, the respirator cannot be used by the worker.

## A. Criteria for Selecting Respirators

To use this decision logic, the user must first assemble the necessary toxicologic, safety, and other relevant information for each contaminant, including the following:

- General use conditions, including determination of contaminant(s);
- Physical, chemical, and toxicologic properties of the contaminant(s);
- Odor threshold data;
- NIOSH recommended exposure limit (REL) or when no REL exists, OSHA permissible exposure limit (PEL) or other applicable exposure limit;
- Immediately dangerous to life or health (IDLH) concentration;
- Eye irritation potential; and
- Any service life information available (for cartridges and canisters).

Obtaining complete information on all criteria needed to use this decision logic may be difficult. When conflicting or inadequate data are found, experts should be consulted before decisions are made that could affect the proper use of this decision logic. In addition, the adequacy of the respirator selected is dependent on the validity of the exposure limit used. While the decision logic can be used with any exposure limit, NIOSH recommends that an REL be used when one exists for a given contaminant. For a more detailed discussion on the use of exposure limits, especially when selecting respirators for protection against carcinogens, see Subparagraph 2, page 21.

The information obtained on general use conditions for respirators should include a description of the actual job task, including the duration and frequency, location, physical demands, and industrial processes, as well as the comfort of the respirators. Some general use conditions may preclude the use of specific types of respirators in certain circumstances because the individual must be medically and psychologically suitable to wear a given respirator for a given task, particularly if the respirator is a self-contained breathing apparatus (SCBA).

Information obtained on the service life of the cartridge/canister under conditions of intended use should be evaluated regardless of the odor warning properties of the chemicals. These evaluations should be based on all gas(es) and vapor(s) present at the temperature and relative humidity extremes (high and low) in the workplace. NIOSH recommends that when the employer or a representative of the employer conducts the tests, the challenge concentrations of the gases and vapors should be at least 10 times the maximum use concentration of the respirator. The service life value

obtained from these tests should be used to determine how long a cartridge/canister could provide protection under actual use conditions. This information can be used to set up cartridge replacement schedules and should be used in conjunction with sensory warning properties. Workers should be trained to exit the contaminated area whenever they detect the odor of the contaminant. (See Subparagraph 6, page 26, for a discussion on service life testing for chemicals with poor warning properties.)

## **B. Restrictions and Requirements for All Respirator Usage**

The following requirements and restrictions must be considered to ensure that the respirator selected will provide adequate protection under the conditions of intended use:

1. A complete respiratory protection program should be instituted which includes regular worker training; maintenance, inspection, cleaning, and evaluation of the respirator; use of the respirator in accordance with the manufacturer's instructions; fit testing; and environmental monitoring. Whenever possible, quantitative evaluation of the protection factor in the workplace should be performed to confirm the actual degree of protection provided by the respirator to each worker. Minimum respiratory protection requirements for all contaminants can be found in the OSHA Safety and Health Standards, 29 CFR 1910.134, and in separate sections for specific contaminants (e.g., 1910.1001 for asbestos, 1910.1025 for lead, etc.).
2. Qualitative or quantitative fit tests should be provided as appropriate to ensure that the respirator fits the individual. Periodic evaluation of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection. When quantitative fit testing (QNFT) is used, the fit factor screening level should be chosen with caution and with the recognition of the uncertainty of its effectiveness since no studies have demonstrated what fit factor values provide adequate accept/reject criteria for quantitative fit screening.
3. Negative pressure respirators should not be used when facial scars or deformities interfere with the face seal.
4. No respirator (including positive pressure respirators) should be used when facial hair interferes with the face seal.
5. The respirators should be properly maintained, correctly used, and conscientiously worn.
6. The usage limitations of air-purifying elements, particularly gas and vapor cartridges, should not be exceeded.
7. The respirators must be approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (MSHA/NIOSH).

8. Workers should be instructed to leave the contaminated area immediately upon suspicion of respirator failure and then to determine the problem.

9. Workers are not exposed to a single unvarying concentration of a hazardous substance, rather individual exposures may vary throughout a workshift and between days. The highest anticipated concentration should therefore be used to compute the required protection factor for each respirator wearer.

10. Respirator wearers should be aware of the variability in human responses to the warning properties of hazardous substances. When warning properties must be relied on as part of a respiratory protection program, the employer should screen each prospective wearer for the ability to detect the warning properties of the hazardous substance(s) at exposure concentrations that are less than the REL for each given substance. (See Subparagraph 6, page 26, and Appendix C, page 48, for additional information.)

11. The assigned protection factors (APF's) that appear in this decision logic are based for the most part on laboratory studies. However, a few APF's have been validated and revised as necessary after consideration of data obtained from studies of workplace protection factors (WPF's). As more WPF testing of respirators is undertaken by NIOSH and others, the APF values may be further revised. For the present, the APF's should be regarded as approximate if they are not based on WPF's.

### **C. Respirator Decision Logic Sequence**

After all criteria have been identified and evaluated and after the requirements and restrictions of the respiratory protection program have been met, the following sequence of questions can be used to identify the class of respirators that should provide adequate respiratory protection:

1. Is the respirator intended for use during fire fighting?
  - a. If yes, only a self-contained breathing apparatus (SCBA) with a full facepiece operated in pressure demand or other positive pressure mode is recommended.
  - b. If no, proceed to Step 2.
2. Is the respirator intended for use in an oxygen-deficient atmosphere, i.e., less than 19.5% oxygen at sea level? (Refer to Subparagraph 1, page 21, for a discussion of oxygen deficiency.)
  - a. If yes, any type of SCBA or supplied-air respirator (SAR) with an auxiliary SCBA is recommended. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted. If additional contaminants are present, proceed to Step 3.

- b. If no, proceed to Step 3.
3. Is the respirator intended for use during emergency situations?
- a. If yes, two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.
- b. If no, proceed to Step 4.
4. Is the contaminant regulated by the Department of Labor as a potential occupational carcinogen or identified by NIOSH as a potential human carcinogen in the workplace, and is the contaminant detectable in the atmosphere?
- a. If yes, two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.
- b. If no, proceed to Step 5.
5. Is the exposure concentration of the contaminant, as determined by acceptable industrial hygiene methods, less than the NIOSH REL or other applicable exposure limit? (Whenever a worker is given a respirator to use on a voluntary basis when ambient levels are below applicable limits, OSHA requires the implementation of a complete respiratory protection program, which includes medical evaluation, training, fit testing, periodic environmental monitoring, and all other requirements in 29 CFR 1910.134.)
- a. If yes, a respirator would not be required except for an escape situation. Proceed to Step 7.
- b. If no, proceed to Step 6.
6. Are conditions such that a worker who is required to wear a respirator can escape from the work area and not suffer loss of life or immediate or delayed irreversible health effects if the respirator fails, i.e., are the conditions not immediately dangerous to life or health (IDLH)? (Refer to Subparagraph 3, page 22, for additional information on IDLH's.)

- a. If yes, conditions are not considered to be IDLH. Proceed to Step 7.
  - b. If no, conditions are considered to be IDLH. Two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. The auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.
7. Is the contaminant an eye irritant, or can the contaminant cause eye damage at the exposure concentration? (Refer to Subparagraph 4, page 23, for a discussion of eye irritation and damage.)
- a. If yes, a respirator equipped with a full facepiece, helmet, or hood is recommended. Proceed to Step 8.
  - b. If no, an orinasal respirator may still be an option, depending on the exposure concentration. Proceed to Step 8.
8. Divide the 8-hour time-weighted average (TWA) exposure concentration for the contaminant (or maximum exposure concentration for a contaminant with a ceiling limit) determined in Step 5 by the NIOSH REL or other applicable exposure limit to determine the minimum protection factor required. For escape respirators, determine the potential for generation of a hazardous condition caused by an accident or equipment failure. If a potentially hazardous condition could occur or a minimum protection factor has been calculated, proceed to Step 9.
9. If the physical state of the contaminant is a particulate (solid or liquid) during periods of respirator use, proceed to Step 10; if it is a gas or vapor, proceed to Step 11; if it is a combination of gas or vapor and particulate, proceed to Step 12.
10. Particulate Respirators
- 10.1. Is the particulate respirator intended only for escape purposes?
- a. If yes, refer to Subparagraph 5, page 24, for a discussion and selection of "escape only" respirators.
  - b. If no, the particulate respirator is intended for use during normal work activities. Proceed to Step 10.2.
- 10.2. A filter medium that will provide protection against exposure to the particulate in question is recommended. (Refer to Subparagraph 9, page 29, for a discussion on limitations of approvals for filter media.) Proceed to Step 10.3.

10.3. Respirators that have not been previously eliminated from Table 1 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors, and to Subparagraph 9, page 29, for a discussion on limitations of filter approvals.) Maximum airborne concentrations for each level of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

## 11. Gas/Vapor Respirators

11.1. Is the gas/vapor respirator intended for "escape only" purposes?

a. If yes, refer to Subparagraph 5, page 24, for a discussion on selection of "escape only" respirators.

b. If no, the gas/vapor respirator is intended for use during normal work activities. Proceed to Step 11.2.

11.2. Are the warning properties for the gas/vapor contaminant adequate at or below the NIOSH REL or other applicable exposure limit? (Refer to Subparagraph 6, page 26, and Appendix C, page 48, for additional information on requirements for adequate warning properties.)

a. If yes, proceed to Step 11.3.

b. If no, an air-purifying respirator equipped with an effective end-of-service-life indicator (ESLI), a supplied-air respirator, or a self-contained breathing apparatus is recommended. (Refer to Appendix A, page 43, for additional information on approval of air-purifying respirators with ESLI's.) Proceed to Step 11.4.

11.3. An air-purifying chemical cartridge/canister respirator is recommended that has a sorbent suitable for the chemical properties of the anticipated gas/vapor contaminant(s) and for the anticipated exposure levels. (Refer to Subparagraph 7, page 27, for the recommended maximum use concentrations of air-purifying chemical cartridge/canister respirators.) Proceed to Step 11.4.

11.4. Respirators that have not been previously eliminated from Table 2 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors.) Maximum airborne concentrations for each class of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. The calculated maximum use concentration limits should not exceed the limitations noted in Subparagraph 7, page 27. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

## 12. Combination Particulate and Gas/Vapor Respirators

12.1. Is the combination respirator intended for "escape only" purposes?

a. If yes, refer to Subparagraph 5, page 24, for a discussion and selection of "escape only" respirators.

b. If no, the combination respirator is intended for use during normal work activities. Proceed to Step 12.2.

12.2. Does the gas/vapor contaminant have adequate warning properties at or below the NIOSH REL or other applicable exposure limit? (Refer to Subparagraph 6, page 26, and Appendix C, page 48, for additional information on requirements for adequate warning properties.)

a. If yes, proceed to Step 12.3.

b. If no, either an air-purifying respirator equipped with an effective ESLI (Appendix A, page 43), a supplied-air respirator, or a self-contained respirator is recommended. Proceed to Step 12.4.

12.3. An air-purifying chemical cartridge/canister is recommended that has a particulate prefilter suitable for the specific type(s) of gas/vapor and particulate contaminant(s) and for the exposure concentrations. (Refer to Subparagraphs 7, page 27, and Subparagraph 9, page 29, for recommended maximum use concentrations and filter limitations.) Proceed to Step 12.4.

12.4. Respirators that have not been previously eliminated from Table 3 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors and Subparagraph 9, page 29, for a discussion on limitations of filter approvals.) Maximum airborne concentrations for each level of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. The calculated maximum use concentration limits should not exceed the limitations noted in Subparagraph 7, page 27. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

**Table 1.--Assigned protection factor classifications of respirators for protection against particulate exposures<sup>1</sup>**

Assigned protection factor	Type of respirator
5	Single-use (see definition in Glossary) or quarter mask <sup>2</sup> respirator
10	Any air-purifying half-mask respirator including disposable <sup>3</sup> (see definition in Glossary) equipped with any type of particulate filter except single use <sup>2,4</sup>
	Any air-purifying full facepiece respirator equipped with any type of particulate filter <sup>5</sup>
	Any supplied-air respirator equipped with a half-mask and operated in a demand (negative pressure) mode <sup>2</sup>
25	Any powered air-purifying respirator equipped with a hood or helmet and any type of particulate filter <sup>4</sup>
	Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode <sup>4</sup>
50	Any air-purifying full facepiece respirator equipped with a high efficiency filter <sup>2</sup>
	Any powered air-purifying respirator equipped with a tight-fitting facepiece and a high efficiency filter <sup>4</sup>
	Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode <sup>2</sup>
	Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode <sup>4</sup>

<sup>1</sup> Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m<sup>3</sup>.

<sup>2</sup> The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].

<sup>3</sup> An APF factor of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test.

<sup>4</sup> APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

<sup>5</sup> The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

Table 1.--Assigned protection factor classifications of respirators for protection against particulate exposures<sup>1</sup>--Continued

Assigned protection factor	Type of respirator
50 cont.	Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode <sup>2</sup>
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode <sup>2</sup>
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode <sup>2</sup>
10,000	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode <sup>2</sup>
	Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode <sup>2</sup>

- 1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m<sup>3</sup>.
- 2 The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 An APF of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test.
- 4 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].
- 5 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

Table 2.--Assigned protection factor classifications of respirators for protection against gas/vapor exposures

Assigned protection factor <sup>1</sup>	Type of respirator
10	<p>Any air-purifying half mask respirator (including disposable) equipped with appropriate gas/vapor cartridges<sup>2</sup></p> <p>Any supplied-air respirator equipped with a half mask and operated in a demand (negative pressure) mode<sup>2</sup></p>
25	<p>Any powered air-purifying respirator with a loose-fitting hood or helmet<sup>3</sup></p> <p>Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode<sup>3</sup></p>
50	<p>Any air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or gas mask (canister respirator)<sup>2</sup></p> <p>Any powered air-purifying respirator equipped with a tight-fitting facepiece and appropriate gas/vapor cartridges or canisters<sup>3</sup></p> <p>Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode<sup>2</sup></p> <p>Any supplied-air respirator equipped with a tight-fitting facepiece operated in a continuous flow mode<sup>3</sup></p> <p>Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode<sup>2</sup></p>
1,000	<p>Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode<sup>2</sup></p>

- 1 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
- 2 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

**Table 2.--Assigned protection factor classifications of respirators for protection against gas/vapor exposures--Continued**

Assigned protection factor <sup>1</sup>	Type of respirator
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode <sup>2</sup>
10,000	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode <sup>2</sup>
	Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode <sup>2</sup>

- 1 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
- 2 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

**Table 3.--Assigned protection factor classifications of respirators for protection against combination gas/vapor and particulate exposures<sup>1</sup>**

Assigned protection factor <sup>2</sup>	Type of respirator
10	<p>Any air-purifying half-mask respirator equipped with appropriate gas/vapor cartridges in combination with any type of particulate filter<sup>3</sup></p> <p>Any full facepiece respirator with appropriate gas/vapor cartridges in combination with a dust or mist or fume; dust and mist; or dust, mist, and fume filter<sup>4</sup></p> <p>Any supplied-air respirator equipped with a half-mask and operated in a demand (negative pressure) mode<sup>3</sup></p>
25	<p>Any powered air-purifying respirator equipped with a loose-fitting hood or helmet<sup>5</sup></p> <p>Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode<sup>5</sup></p>
50	<p>Any air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with a high efficiency filter or an appropriate canister incorporating a high efficiency filter<sup>3</sup></p> <p>Any powered air-purifying respirator with a tight-fitting facepiece equipped with appropriate gas/vapor cartridges in combination with a high efficiency filter or an appropriate canister incorporating a high efficiency filter<sup>5</sup></p> <p>Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode<sup>3</sup></p>

1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m<sup>3</sup>.

2 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.

3 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].

4 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

5 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

Table 3.--Assigned protection factor classifications of respirators for protection against combination gas/vapor and particulate exposures<sup>1</sup>--  
Continued

Assigned protection factor <sup>2</sup>	Type of respirator
50 cont.	<p>Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode<sup>5</sup></p> <p>Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode<sup>3</sup></p>
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode <sup>3</sup>
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode <sup>3</sup>
10,000	<p>Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode<sup>3</sup></p> <p>Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode<sup>3</sup></p>

- 1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m<sup>3</sup>.
- 2 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
- 3 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 4 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.
- 5 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

The Respirator Decision Logic Sequence is presented in Figure 1 in the form of a flow chart. This flow chart can be used to identify suitable classes of respirators for adequate protection against specific environmental conditions. Refer to the corresponding narrative section for additional information pertaining to a specific part of the flow chart.

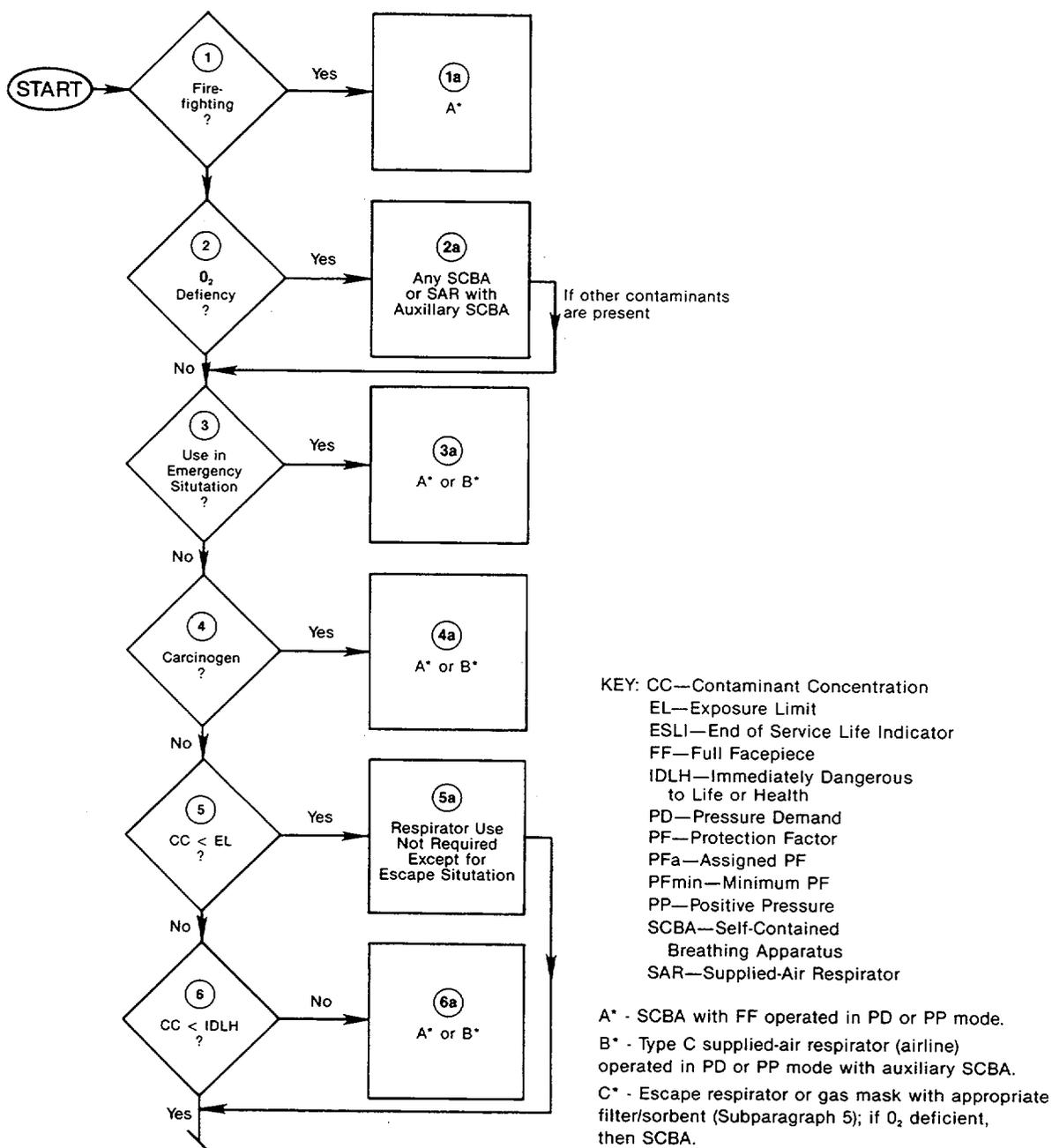


Figure 1. — Flow Chart of Respirator Decision Logic Sequence

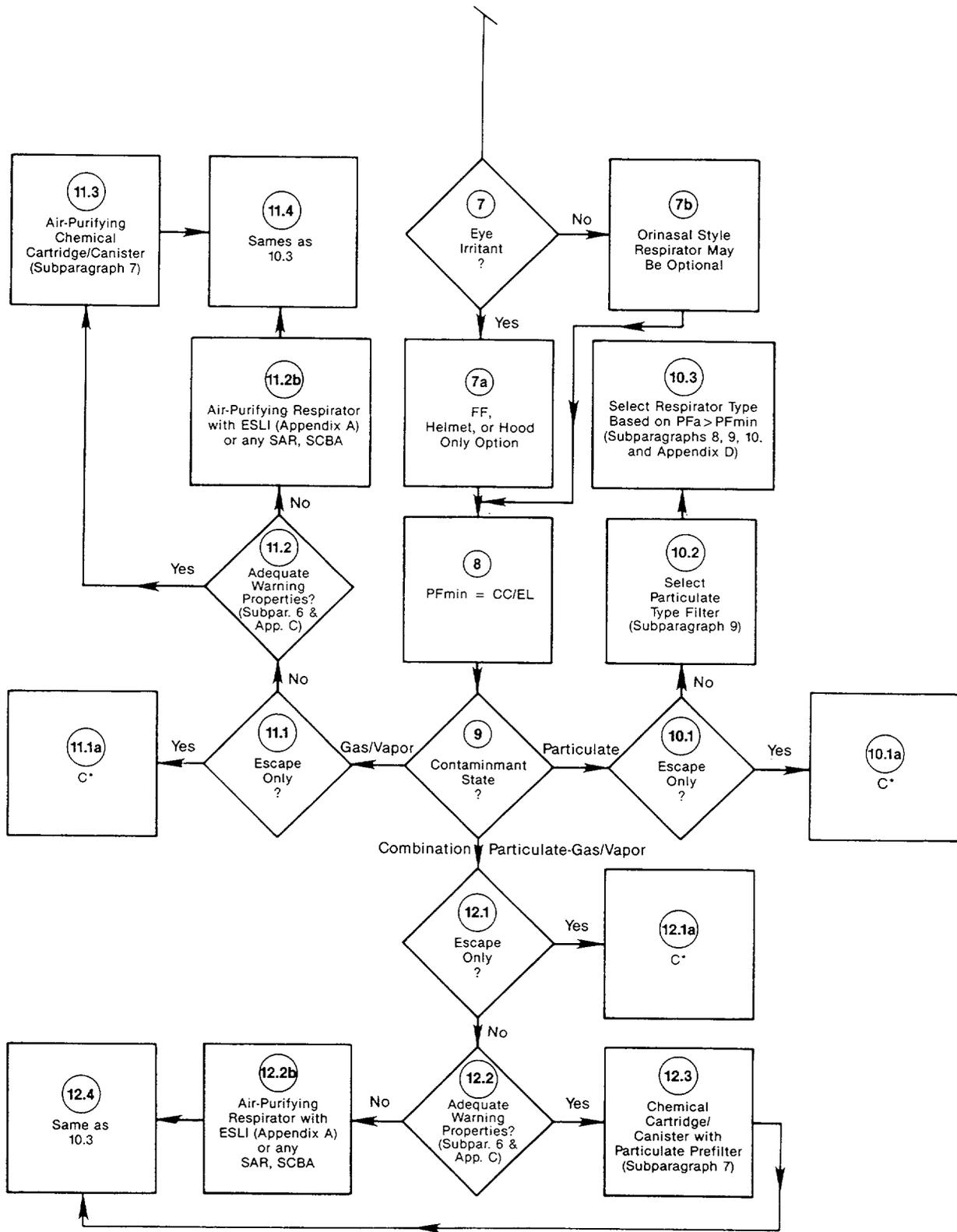


Figure 1. — Flow Chart of Respirator Decision Logic Sequence — Continued

#### **D. Subparagraphs**

The following subparagraphs provide additional information to assist the reader in using the Respirator Decision Logic Sequence:

##### **Subparagraph 1: Oxygen-Deficient Atmosphere**

The National Institute for Occupational Safety and Health (NIOSH) defines an oxygen-deficient atmosphere as any atmosphere containing oxygen at a concentration below 19.5% at sea level [1]. NIOSH certification of air-line or air-purifying respirators is limited to those respirators used in atmospheres containing at least 19.5% oxygen, except for those air-line respirators equipped with auxiliary self-contained breathing apparatus (SCBA).

The minimum requirement of 19.5% oxygen at sea level provides an adequate amount of oxygen for most work assignments and includes a safety factor. The safety factor is needed because oxygen-deficient atmospheres offer little warning of the danger, and the continuous measurement of an oxygen-deficient atmosphere is difficult.

At oxygen concentrations below 16% at sea level, decreased mental effectiveness, visual acuity, and muscular coordination occur. At oxygen concentrations below 10%, loss of consciousness may occur, and below 6% oxygen, death will result. Often only mild subjective changes are noted by individuals exposed to low concentrations of oxygen, and collapse can occur without warning [2,3,4].

Since oxygen-deficient atmospheres are life-threatening, only the most reliable respirators are recommended; the most reliable respirators are the self-contained breathing apparatus or the supplied-air respirators with auxiliary self-contained units. Because a high protection factor is not necessary to ensure an adequate supply of oxygen even in an atmosphere containing no oxygen, any certified self-contained unit is adequate. All aspects of a respiratory protection program must be instituted for these recommendations to be valid.

##### **Subparagraph 2: Exposure Limits**

The majority of the OSHA PEL's were adopted from the American Conference of Governmental Industrial Hygienists (ACGIH) TLVs® published in 1968. The difficulty in changing PEL's through promulgation of standards when new toxicologic information is identified has caused many standards to become outdated. The effectiveness of this decision logic is limited to the adequacy of the selected exposure limits in protecting the health of workers. Exposure limits based on a thorough evaluation of more recent or extensive data should be given priority.

For all chemicals that cause irritation or systemic effects but do not cause carcinogenic effects, it is currently believed that a threshold exposure

concentration exists such that virtually all persons in the working population (with the possible exception of hypersensitive individuals) would experience no adverse health effects.

For many carcinogenic substances, most available data provide no evidence for the existence of a threshold exposure concentration below which the substance would be safe. As with noncarcinogenic substances, there appears to be a dose-response relationship for carcinogenic substances. If no threshold exists for a carcinogen, then there is no safe exposure concentration; however, lower exposures would be associated with lower risks.

For some carcinogens, NIOSH attempts to identify the lowest REL on the basis of the quantitative detection limit for the method used to monitor exposures. For other carcinogens, NIOSH does not identify a precise exposure limit but recommends instead that the employer control worker exposures to the lowest feasible limit.

Regardless of the selected exposure limit for a carcinogen, the best engineering controls and work practices should be instituted. Respirators should not be used as a substitute for proper control measures. When respiratory protection is required to achieve the lowest exposure concentration, then only the most effective respirators should be used. Two types of respirators are recommended: a full facepiece SCBA operated in a pressure-demand or other positive pressure mode or a full facepiece supplied-air respirator (SAR) operated in a pressure-demand or other positive pressure mode in combination with a SCBA operated in a pressure demand or other positive pressure mode. The practicality of each situation must be assessed to determine the most technically feasible protection for the worker.

Other variables such as the specific situation, worker, or job may influence the selection of the appropriate exposure limit for a given contaminant. For example, the effects of some hazardous substances may be increased due to exposure to other contaminants present in the workplace or the general environment or to medications or personal habits of the worker. Such factors, which would affect the toxicity of a contaminant, would not have been considered in the determination of the specific exposure limit. Also, some substances are absorbed by direct contact with the skin and mucous membranes, thus potentially increasing the total exposure.

### **Subparagraph 3: Immediately Dangerous to Life or Health (IDLH)**

An IDLH exposure condition is defined in this decision logic as one that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment. The purpose of establishing an IDLH exposure level is to ensure that the worker can escape from a given contaminated environment in the event of failure of the respiratory protection equipment. The IDLH is considered a maximum level

above which only a highly reliable breathing apparatus providing maximum worker protection is permitted. Any appropriate approved respirator may be used to its maximum use concentration up to the IDLH concentration.

In establishing the IDLH concentration, the following conditions must be assured:

- a. The ability to escape without loss of life or immediate or delayed irreversible health effects. (Thirty minutes is considered the maximum time for escape so as to provide some margin of safety in calculating the IDLH.)
- b. The prevention of severe eye or respiratory irritation or other reactions that would hinder escape.

Sources of information for determining whether the exposure limit for a contaminant represents an IDLH condition are as follows:

- a. Specific IDLH guidelines provided in the literature such as the American Industrial Hygiene Association (AIHA) Hygienic Guides and the NIOSH Pocket Guide for Hazardous Chemical Substances (previous editions were published jointly by NIOSH and OSHA), and/or
- b. Human exposure and effects data, and/or
- c. Animal exposure and effects data, and/or
- d. Where such data specific to the contaminant are lacking, toxicologic data from analogous substances and chronic animal exposure data may be considered.

#### **Subparagraph 4: Eye Irritation**

Eye protection in the form of respirators with full facepieces, helmets, or hoods is required for routine exposures to airborne contaminants that cause any irritation to the mucous membranes of the conjunctivae or the cornea or cause any reflex tearing. Eye protection is required for contaminants that cause minor subjective effects as well as for those that cause any damage, including disintegration and sloughing of conjunctival or corneal epithelium, edema, or ulceration. NIOSH is not aware of any standards for gas-tight goggles that would permit NIOSH to recommend such goggles as providing adequate eye protection.

For escape, some eye irritation is permissible if the severity of irritation does not inhibit the escape and if no irreversible scarring or ulceration of the eyes or conjunctivae is likely.

When data on threshold levels for eye irritation are insufficient, quarter- or half-mask respirators can be used, provided that the worker experiences

no eye discomfort and no pathologic eye effects develop. Workers should be told that if any eye discomfort is experienced, they will be provided with respirators that have full facepieces, helmets, or hoods and that provide protection equivalent to the quarter- or half-mask respirators.

#### **Subparagraph 5: Escape Apparatus**

Escape devices have a single function: to allow a person working in a normally safe environment sufficient time to escape from suddenly occurring respiratory hazards.

Escape devices can be separated into two categories: air-purifying respirators and self-contained breathing apparatus. Air-purifying respirators remove contaminants from the air by sorbent and/or filter media, but because they do not provide air, these respirators cannot be used in an oxygen-deficient atmosphere. Air-purifying escape respirators include the escape gas mask (canister) respirator, the gas mask (canister) respirator, and the filter self-rescuer. The escape gas mask consists of a half-mask or a mouthpiece respirator. The mouthpiece respirator can be used for short periods of time to escape from low concentrations of organic vapor or acid gas. The escape gas mask, which utilizes a half-mask, filters contaminants from the air. These respirators may also be used to escape from low concentrations of organic vapor or acid gas. Escape gas mask respirators equipped with full facepieces can also be used for escape from IDLH conditions but not from oxygen-deficient atmospheres. No air-purifying device is suitable for escape from a potentially oxygen-deficient atmosphere. The filter self-rescue unit is the mouthpiece device, which is designed to protect specifically against less than 1% carbon monoxide.

A self-contained breathing apparatus (SCBA) provides air to the user for escape from oxygen-deficient environments. Escape SCBA devices are commonly used with full facepieces or hoods and, depending on the supply of air, are usually rated as 3- to 60-minute units. Self-contained self-rescuer (SCSR) devices have been approved by MSHA/NIOSH for escape from mines, but these devices may also have application in other similar environments. SCSR's are mouthpiece respirators that provide a source of oxygen-enriched air for up to 60 minutes. All SCBA devices can be used in oxygen-deficient atmospheres.

When selecting escape apparatus, careful consideration must be given to potential eye irritation. This consideration is important for determining whether a gas mask or SCBA equipped with a full facepiece should be selected rather than a device equipped with a half-mask or mouthpiece.

The majority of gas masks or escape gas masks can be used in situations involving gas(es), vapor(s), or particulates. For escape from particulate-contaminated environments, an air-purifying element must be selected that will provide protection against the given type of particulate. The information in Table 4 should be used to select the appropriate escape apparatus.

**Table 4.--Selection options for escape respirators**

Escape conditions	Type of respirator
Short distance to exit, no obstacles (no oxygen deficiency)	Any escape gas mask <sup>1</sup> (canister respirator) or gas mask <sup>2</sup> (canister respirator)
	Any escape self-contained breathing apparatus having a suitable service life <sup>3</sup>
	Any acceptable device for entry into emergency situations
Long distance to exit or obstacles along the way (no oxygen deficiency)	Any gas mask <sup>2</sup>
	Any escape self-contained breathing apparatus having a suitable service life <sup>3</sup>
	Any self-contained self-rescuer having a suitable service life
Potential oxygen deficiency	Any escape self-contained breathing apparatus having a suitable service life <sup>3</sup>
	Any self-contained self-rescuer having a suitable service life

- 1 An escape gas mask is a respirator designed for use during escape only from immediately dangerous to life or health (IDLH) or non-IDLH atmospheres. It may consist of a half mask facepiece or mouthpiece, appropriate air-purifying element for the contaminant, and associated connections. Maximum use concentrations for these types of respirators are designated by the manufacturer.
- 2 A gas mask consists of a full facepiece and either chin-style or front- or back-mounted canisters with associated connections. Maximum use concentrations for canister air-purifying elements are listed in Table 5.
- 3 Escape self-contained breathing apparatus can have rated service lives of 3 to 60 minutes. All acceptable devices for entry into emergency situations can also be used.

## **Subparagraph 6: Potential Warning Properties for Use With Cartridge/Canister Air-Purifying Respirators**

For the purpose of this decision logic, warning properties are defined according to odor, taste, eye irritation, or respiratory irritation. Adequate warning properties imply that the gas or vapor of interest has a persistent odor or irritant effect at concentrations at or below the OSHA PEL or NIOSH REL. Recognition of an odor depends on a person's sensory ability to detect it. Since the range of odor recognition thresholds within a population is very large, odor recognition should not be relied on as the only means for determining that a cartridge or canister is no longer effectively removing a contaminant from the air. A more detailed discussion of variability of odor detection within a population is provided in Appendix C.

NIOSH recommends that the employer ensure that each worker who is required to wear an air-purifying cartridge or canister respirator is capable of recognizing the odor of the substance of concern at a concentration at or below the applicable exposure limit. Such a determination will necessitate that an odor screening test be conducted on each individual for each substance of concern in the particular workplace.

It is recognized that existing screening tests are subjective in nature and not sufficiently sensitive and that conducting screening tests for a group of workers exposed to several substances may be impractical. Therefore, NIOSH knows of no compelling reason not to develop quantitative service life test data to supplement or replace odor screening test results if it can be demonstrated that such a procedure will afford the wearer a level of protection at least equivalent to that indicated by odor screening. Even when service life test data are used, the employer and the respirator wearer should not ignore the usefulness of sensory detection properties (for those who can detect the contaminant's presence) to serve as a warning that the cartridge/canister has failed or that the integrity of the respirator face seal has been compromised.

It is important to realize that 30 CFR 11 [specifically, 30 CFR 11.90(b) (note 4) for gas masks (canister respirators) and 30 CFR 11.150 (note 7) for chemical cartridge respirators], which provides for approval of air-purifying (organic vapor) devices, prohibits their approval for use against organic vapors with poor warning properties unless there is an OSHA standard which permits their use. A more detailed discussion appears in Appendix C.

A recent policy decision by NIOSH allows the use of respirators with effective end-of-service-life indicators for protection against contaminants with poor warning properties, provided that certain conditions are met. These conditions are described in that policy statement, which is reproduced in Appendix A.

### **Subparagraph 7: Limitations of Respirators for Gases and Vapors**

Air-purifying respirators cannot be used in IDLH atmospheres or in atmospheres containing less than 19.5% oxygen by volume. Gas masks (canister respirators) may be used for escape if the atmosphere is not oxygen-deficient.

If, after the APF is multiplied by the REL or other applicable exposure limit (APF X REL), the product exceeds the IDLH value, then the IDLH value shall be the maximum use concentration. (See Tables 1, 2, and 3.) In addition, there are maximum use concentrations associated with all gas and vapor air-purifying elements. (See Table 5.)

Air-purifying devices should not be allowed for either entry into or escape from hazardous environments when supporting evidence exists to demonstrate that unreasonably short service life would occur at the maximum use concentration.

Where there is reason to suspect that a sorbent has a high heat of reaction with a substance, use of that sorbent is not recommended. For such a substance, only non-oxidizable sorbents should be allowed.

Air-purifying respirators cannot be used for protection against gases and vapors with poor warning properties unless the respirator is approved with an effective ESLI. (See Appendix A.)

Although limited in number, there are specific air-purifying respirators that are approved by MSHA/NIOSH for protection against gases and vapors when respirators approved for a given class of contaminants (e.g., organic vapors) cannot be used due to sorbent deficiencies.

### **Subparagraph 8: Assigned Protection Factors (APF's)**

APF's (sometimes referred to in the literature as respirator protection factors), which appear in the 1975 and 1978 versions of the OSHA/NIOSH Respirator Decision Logic, in the 1980 American National Standards Institute (ANSI) standards for respiratory protection, and in all OSHA health standards, are based on quantitative fit testing (QNFT) of respirators [6]. (See definition of fit factors in Appendix D.) No data have been reported in the literature to demonstrate that the results of QNFT are sufficiently indicative of the protection that a given respirator provides in the workplace. Recent studies by NIOSH [7-9] and others [10-12] have suggested that fit factors do not correlate with the workplace protection factors provided by powered air-purifying respirators (PAPR's) and negative pressure half-mask respirators. (See definition of workplace protection factors in Appendix D.)

Table 5.--NIOSH recommended maximum use concentrations (expressed in ppm) for gas and vapor air-purifying elements

<u>Classification of gas and vapor air-purifying elements</u>			
Type of gas or vapor	Cartridge(s)	Chin-style canister	Front- or back-mounted canister
Organic vapors	1,000*	5,000†	20,000†
Acid gases			
Sulfur dioxide (SO <sub>2</sub> )	50	100	100
Chlorine (Cl <sub>2</sub> )	10	25	25
Hydrochloric (HCl)	50	100	100
Ammonia (NH <sub>3</sub> )	300	500	500
Methyl amine (CH <sub>3</sub> NH <sub>2</sub> )	100	--	--
Carbon monoxide (CO)	NA	NA	1,500

\* Maximum use concentration will be 1,000 ppm or the immediately dangerous to life or health (IDLH) value for the specific organic vapor, whichever is lower.

† Maximum use concentration for "entry into" will be limited to the value listed or to the IDLH value for the specific organic vapor, whichever is lower.

APF's that are still based on the fit factors determined by Los Alamos National Laboratories (LANL) can be used for those classes of respirators for which no WPF data or simulated workplace protection factor (SWPF) data are available. However, as WPF data are developed, these APF's will be revised, as have the current APF's for powered air-purifying respirators (PAPR's) [7-9,11,14-16]. It should be noted that a number of studies [17-20] on the workplace performance of respirators have appeared in the literature. However, the results of these studies are of little value for establishing APF's because their protocols did not require proper fit or correct use and conscientious wearing of the respirator while in-facepiece sampling was done. A notable exception is the study by Revoir (1974) [21].

When WPF data existed, NIOSH utilized the point estimate equation proposed by Myers et al. [13] to help establish the APF's recommended in this decision logic. The point estimate equation is as follows:

$$\text{protection factor (PF)} = \mu g / Sg Zp$$

where  $\mu g$  = the geometric mean of the measured WPF

$Sg$  = the geometric standard deviation of the measured WPF

$Zp$  = the value corresponding to the selected proportion (p) on the log-normal probability distribution

When WPF data existed, NIOSH selected a confidence limit of  $p=0.95$ . Thus for a given set of data and given class of respirators, NIOSH would expect that 95% of the WPF's would exceed the calculated point estimate value.

Despite the fact that some of the PF's have a statistical basis, they are still only estimates of an approximate level of protection. It must not be assumed that the numerical values of the APF's presented in this decision logic represent the absolute minimum level of protection that would be achieved for all workers in all jobs against all respiratory hazards. The industrial hygienist or other professional responsible for providing respiratory protection or evaluating respiratory protection programs is therefore encouraged to evaluate as accurately as possible the actual protection being provided by the respirator.

#### **Subparagraph 9: Particulate Filter Respirators**

MSHA/NIOSH particulate respirators are certified according to seven basic categories. These categories consist of the following types of exposures:

- Dusts: Airborne exposure limit not less than 0.05 mg/m<sup>3</sup> or 2 mppcf (see Appendix B);
- Fumes: Airborne exposure limit not less than 0.05 mg/m<sup>3</sup> or 2 mppcf;
- Mists: Airborne exposure limit not less than 0.05 mg/m<sup>3</sup> or 2 mppcf (see Appendix B);
- Dusts, Fumes, and Mists: Airborne exposure limit less than 0.05 mg/m<sup>3</sup> or 2 mppcf and radionuclides;
- Radon Daughters;
- Asbestos-Containing Dusts and Mists (see Appendix B); and
- Single-Use Dust and Mist Respirators (see Appendix B).

**Subparagraph 10: Suggested Medical Evaluation and Criteria for Respirator Use**

The following NIOSH recommendations allow latitude for the physician in determining a medical evaluation for a specific situation. More specific guidelines may become available as knowledge increases regarding human stresses from the complex interactions of worker health status, respirator usage, and job tasks. While some of the following recommendations should be part of any medical evaluation of workers who wear respirators, others are identified as being applicable for specific situations.

**a. A Physician Should Make the Determination of Fitness to Wear a Respirator by Considering the Worker's Health, the Type of Respirator, and the Conditions of Respirator Use.**

The recommendation above satisfies OSHA regulations and leaves the final decision of an individual's fitness to wear a respirator to the person who is best qualified to evaluate the multiple clinical and other variables. Much of the clinical and other data could be gathered by other personnel. It should be emphasized that the clinical examination alone is only one part of the fitness determination and that collaboration with foremen, industrial hygienists, and others may often be needed to better assess the work conditions and other factors that affect an individual's fitness to wear a respirator.

**b. A Medical History and At Least a Limited Physical Examination are Recommended.**

The medical history and physical examination should emphasize the evaluation of the cardiopulmonary system and should elicit any history of respirator use. The history is an important tool in medical diagnosis and can be used to detect most problems that might require further

evaluation. Objectives of the physical examination should be to confirm the clinical impression based on the history and to detect important medical conditions (such as hypertension) that may be essentially asymptomatic.

**c. While Chest X-Ray and/or Spirometry May Be Medically Indicated in Some Fitness Determinations, These Should Not Be Routinely Performed.**

In most cases, the hazardous situations requiring the wearing of respirators will also mandate periodic chest X-ray and/or spirometry for exposed workers. When such information is available, it should be used in the determination of fitness to wear respirators. (See Recommendation h, page 33.)

Routine chest X-rays and spirometry are not recommended solely as data for determining if a respirator should be worn. In most cases, with an essentially normal clinical examination (history and physical) these data are unlikely to influence the respirator fitness determination; additionally, the X-ray would be an unnecessary source of radiation exposure to the worker. Chest X-rays in general do not accurately reflect a person's cardiopulmonary physiologic status; and limited studies suggest that mild to moderate impairment detected by spirometry would not preclude the wearing of respirators in most cases. Thus it is recommended that chest X-ray and/or spirometry be done only when clinically indicated. (See Appendix E, page 52, for further discussion on the pulmonary effects of wearing respirators.)

**d. The Recommended Periodicity of Medical Fitness Determinations Varies According to Several Factors but Could Be as Infrequent as Every 5 Years.**

Federal or other applicable regulations shall be followed regarding the frequency of respirator fitness determinations. The guidelines for most work conditions for which respirators are required are shown in Table 6. These guidelines are similar to those recommended by ANSI, which recommends annual determinations after age 45 [22]. The more frequent examinations with advancing age relate to the increased prevalence of most diseases in older people. More frequent examinations are recommended for individuals performing strenuous work involving the use of SCBA. These guidelines are based on clinical judgment and, like the other recommendations in this section, should be adjusted as clinically indicated.

**e. The Respirator Wearer Should Be Observed During a Trial Period to Evaluate Potential Physiological Problems**

In addition to considering the physical effects of wearing respirators, the physician should determine if wearing a given respirator would cause extreme anxiety or claustrophobic reaction in the individual. This could be done during training, while the worker is wearing the respirator and

is engaged in some exercise that approximates the actual work situation.

Present regulations state that a worker should be provided the opportunity to wear the respirator "in normal air for a long familiarity period..." [23]. This trial period should also be used to evaluate the ability and tolerance of the worker to wear the respirator [24]. This trial period need not be associated with respirator fit testing and should not compromise the effectiveness of the vital fit testing procedure.

**Table 6.--Suggested frequency of medical fitness determinations\***

	<u>Worker age (years)</u>		
	<35	35 - 45	>45
Most work conditions requiring respirators	Every 5 yrs	Every 2 yrs	1-2 yrs
Strenuous work conditions with SCBA†	Every 3 yrs	Every 18 mos	Annually

\* Interim testing would be needed if changes in health status occur.

† SCBA = self-contained breathing apparatus

**f. Examining Physicians Should Realize that the Main Stress of Heavy Exercise While Using a Respirator Is Usually on the Cardiovascular System and that Heavy Respirators (e.g., Self-Contained Atmosphere Supplying) Can Substantially Increase this Stress. Accordingly, Physicians May Want To Consider Exercise Stress Tests with Electrocardiographic Monitoring When Heavy Respirators Are Used, When Cardiovascular Risk Factors Are Present, or When Extremely Stressful Conditions Are Expected.**

Some respirators may weigh up to 35 pounds and may increase workloads by 20 percent. Although a lower activity level could compensate for this added stress [25], a lower activity level might not always be possible. Physicians should also be aware of other added stresses, such as heavy protective clothing and intense ambient heat, which would increase the worker's cardiac demand. As an extreme example, firefighters who use SCBA inside burning buildings may work at maximal exercise levels under life-threatening conditions. In such cases, the detection of occult cardiac disease, which might manifest itself during heavy stress, may be important. Some authors have either recommended stress testing [26] or

at least its consideration in the fitness determination [22]. Kilbom [26] has recommended stress testing at 5-year intervals for firefighters below age 40 who use SCBA and at 2-year intervals for those aged 40-50. He further suggested that firemen over age 50 not be allowed to wear SCBA.

Exercise stress testing has not been recommended for medical screening for coronary artery disease in the general population [27,28]. It has an estimated sensitivity and specificity of 78% and 69%, respectively, when the disease is defined by coronary angiography [27,29]. In a recent 6-year prospective study, stress testing to determine the potential for heart attack indicated a positive predictive value of 27% when the prevalence of disease was 3 1/2% [30,31]. While stress testing has limited effectiveness in medical screening, it could serve to detect those individuals who may not be able to complete the heavy exercise required in some jobs.

A definitive recommendation regarding exercise stress testing cannot be made at this time. Further research may determine whether this is a useful tool in selected circumstances.

**g. An Important Concept Is that "General Work Limitations and Restrictions Identified for Other Work Activities Also Shall Apply for Respirator Use" [22].**

In many cases, if a worker is able to do an assigned job without an increased risk to health while not wearing a respirator, the worker will in most situations not be at increased risk when performing the same job while wearing a respirator.

**h. Because of the Variability in the Types of Respirators, Work Conditions, and Workers' Health Status, Many Employers May Wish to Designate Categories of Fitness To Wear Respirators, Thereby Excluding Some Workers from Strenuous Work Situations Involving the Wearing of Respirators.**

Depending on the various circumstances, there could be several permissible categories of respirator usage. One possible scheme would consist of three overall categories: full respirator use, no respirator use, and limited respirator use including "escape only" respirators. The latter category excludes heavy respirators and strenuous work conditions. Before identifying the conditions that would be used to classify workers into various categories, it is critical that the physician be aware that these conditions have not been validated and are presented only for consideration. The physician should modify the use of these conditions based on actual experience, further research, and individual worker sensitivities. The physician may wish to consider the following conditions in selecting or permitting the use of respirators:

- History of spontaneous pneumothorax;
- Claustrophobia/anxiety reaction;
- Use of contact lens (for some respirators);
- Moderate or severe pulmonary disease;
- Angina pectoris, significant arrhythmias, recent myocardial infarction;
- Symptomatic or uncontrolled hypertension; and
- Age.

It seems unlikely that wearing a respirator would play any significant role in causing lung damage such as pneumothorax. However, without good evidence that wearing a respirator would not cause such lung damage, it may be prudent to prohibit the individual with a history of spontaneous pneumothorax from wearing a respirator.

Moderate lung disease is defined by the Intermountain Thoracic Society [32] as being a forced expiratory volume in one second ( $FEV_1$ ) divided by the forced vital capacity (FVC) (i.e.,  $FEV_1/FVC$ ) of 0.45 to 0.60 or an FVC of 51 to 65% of the predicted FVC value. Similar arbitrary limits could be set for age and hypertension. It would seem more reasonable, however, to combine several risk factors into an overall estimate of fitness to wear respirators under certain conditions. Here the judgment and clinical experience of the physician are needed. Even many impaired workers would be able to work safely while wearing respirators if they could control their own work pace, including having sufficient time to rest.

## Conclusion

Individual judgment is needed in determining the factors affecting an individual's fitness to wear a respirator. While many of the preceding guidelines are based on limited evidence, they should provide a useful starting point for a respirator fitness screening program. Further research is needed to validate these recommendations and others currently in use. Of particular interest would be laboratory studies involving physiologically impaired individuals and field studies conducted under actual day-to-day work conditions.

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#### IV. GLOSSARY

The following definitions of terms are provided to assist in the understanding and application of this decision logic.

**ASSIGNED PROTECTION FACTOR (APF):** See **PROTECTION FACTOR**.

**BREAKTHROUGH:** The penetration of challenge material(s) through a gas or a vapor air-purifying element. The quantity or extent of breakthrough during service life testing is often referred to as the percentage of the input concentration.

**DISPOSABLE RESPIRATORS:** A respirator that is discarded after the end of its recommended period of use, after excessive resistance or physical damage, or when odor breakthrough or other warning indicators render the respirator unsuitable for further use.

**DUST:** A solid, mechanically produced particle with a size ranging from submicroscopic to macroscopic.

**EMERGENCY RESPIRATOR USE SITUATION:** A situation that requires the use of respirators due to the unplanned generation of a hazardous atmosphere (often of unknown composition) caused by an accident, mechanical failure, or other means and that requires evacuation of personnel or immediate entry for rescue or corrective action.

**ESCAPE GAS MASK:** A gas mask that consists of a half-mask facepiece or mouthpiece, a canister, and associated connections and that is designed for use during escape only from hazardous atmospheres (see Subparagraph 5).

**ESCAPE ONLY RESPIRATOR:** Respiratory devices that are designed for use only during escape from hazardous atmospheres.

**FILTERING FACEPIECE:** A particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium. (See **SINGLE-USE DUST** or **DUST** and **MIST RESPIRATORS** and **DISPOSABLE RESPIRATORS**.)

**FIT FACTOR:** A quantitative measure of the fit of a specific respirator facepiece to a particular individual. (For further discussion of fit factors, refer to Appendix D.)

**FUME:** A solid condensation particulate, usually of a vaporized metal.

**GAS:** An aeriform fluid that is in a gaseous state at standard temperature and pressure.

**IMMEDIATELY DANGEROUS TO LIFE OR HEALTH (IDLH):** Acute respiratory exposure that poses an immediate threat of loss of life, immediate or

delayed irreversible adverse effects on health, or acute eye exposure that would prevent escape from a hazardous atmosphere.

**MIST:** A liquid condensation particle.

**ORINASAL RESPIRATOR:** A respirator that covers the nose and mouth and that generally consists of a quarter- or half-facepiece.

**PLANNED or UNPLANNED ENTRY into an IDLH ENVIRONMENT, AN ENVIRONMENT OF UNKNOWN CONCENTRATION of HAZARDOUS CONTAMINANT, or an ENVIRONMENT of UNKNOWN COMPOSITION:** A situation in which respiratory devices are recommended to provide adequate protection to workers entering an area where the contaminant concentration is above the IDLH or is unknown.

**POTENTIAL OCCUPATIONAL CARCINOGEN:** Any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory, or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance that is metabolized into one or more potential occupational carcinogens by mammals (29 CFR 1990.103, OSHA Cancer Policy).

**PROTECTION FACTORS (See Appendix D):**

**ASSIGNED PROTECTION FACTOR (APF):** The minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users.

**SIMULATED WORKPLACE PROTECTION FACTOR (SWPF):** A surrogate measure of the workplace protection provided by a respirator.

**WORKPLACE PROTECTION FACTOR (WPF):** A measure of the protection provided in the workplace by a properly functioning respirator when correctly worn and used.

**RECOMMENDED EXPOSURE LIMIT (REL):** An 8- or 10-hour time-weighted average (TWA) or ceiling (C) exposure concentration recommended by NIOSH that is based on an evaluation of the health effects data.

**SERVICE LIFE:** The length of time required for an air-purifying element to reach a specific effluent concentration. Service life is determined by the type of substance being removed, the concentration of the substance, the ambient temperature, the specific element being tested (cartridge or canister), the flow rate resistance, and the selected breakthrough value. The service life for a self-contained breathing apparatus (SCBA) is the period of time, as determined by the NIOSH certification tests, in which adequate breathing gas is supplied.

**SINGLE-USE DUST or DUST AND MIST RESPIRATORS:** Respirators approved for use against dusts or mists that may cause pneumoconiosis and fibrosis.

**VAPOR:** The gaseous state of a substance that is solid or liquid at temperatures and pressures normally encountered.

## V. APPENDICES

### APPENDIX A. NIOSH POLICY STATEMENT ON APPROVAL OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Department of Health and Human Services  
Public Health Service  
Centers for Disease Control  
National Institute for Occupational Safety and Health

#### NIOSH/MSHA TESTING AND CERTIFICATION OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Agency: National Institute for Occupational Safety and Health (NIOSH)

Action: Notice of Acceptance of Applications for Approval of Air-Purifying  
Respirators with End-of-Service-Life Indicators

Summary: 30 CFR 11; Sec. 11.150 states that NIOSH and MSHA may, after a review of the effects on wearers' health and safety, approve respirators for gases and vapors not specifically listed in that section. The current regulations also permit the use of "window indicators" for gas masks to warn the wearer when the canister will no longer remove a contaminant [11.102-5(c)(2)]. Although indicators are not mentioned in Subpart L, Chemical Cartridge Respirators, there is nothing in the regulations which explicitly prohibits their use. A NIOSH policy to allow end-of-service-life indicators (ESLI's) on air-purifying respirators for gases and vapors with adequate warning properties has already been established (Letter to All Respirator Manufacturers from Dr. Elliott Harris, June 18, 1975).

Use of ESLI's on chemical cartridge respirators for use against gases and vapors with poor warning properties could also be approved, because 30 CFR 11; Sec. 11.150; footnote 7 states:

"Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor)...." Thus, air-purifying respirators with ESLI's could be approved for substances such as acrylonitrile, because the OSHA acrylonitrile standard permits the use of chemical cartridge respirators.

Under the present regulations, NIOSH can also require "any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres" [30 CFR 11; Sec. 11.63 (c)]. NIOSH must notify the applicants in writing of these additional requirements [30 CFR 11; Sec. 11.63 (d)].

The purpose of this notification is to inform respirator manufacturers and users of the NIOSH requirements for approving air-purifying respirators with

either effective passive or active ESLI's for use against gases and vapors with adequate warning properties or for use against gases and vapors with inadequate warning properties whenever there is a regulatory standard already permitting the use of air-purifying respirators.

For additional information, contact: Chief, Certification Branch, 944 Chestnut Ridge Road, Morgantown, WV 26505, (304) 291-4331.

### Supplemental Information

Because human senses are not foolproof in detecting gases and vapors and because many gases and vapors found in the workplace do not have adequate warning properties, NIOSH has been investigating alternate means of detection for respirator wearers. In 1976, NIOSH adopted its current policy which allows acceptance of applications for certification of air-purifying respirators, provided that the respirators are equipped with active ESLI's for use against gases and vapors with poor warning properties and are not specifically listed in 30 CFR 11.

An active ESLI is defined as an indicator that invokes an automatic and spontaneous warning signal (e.g., flashing lights, ringing bells, etc.). An active indicator does not require monitoring by the wearer although a passive indicator (normally color change indicator) does.

During the past several years, NIOSH has received notices of concern from respirator manufacturers, regulatory agencies, and general industry regarding the Institute's policy of accepting only active ESLI's for certification. At the October 1983 Mine Health Research Advisory Council (MHRAC) meeting, NIOSH presented a document briefing on "Consideration of Use of End-of-Service-Life Indicators in Respiratory Protective Devices," and requested that MHRAC provide recommendations to the Institute with regard to the appropriateness of the use of both active and passive ESLI's. MHRAC asked their Respirator Subcommittee to review the issue.

The Respirator Subcommittee held a public meeting in Washington, D.C., on December 19, 1983, to solicit comments from interested parties. The Subcommittee reviewed the comments and then reported back to the full committee at the February 2, 1984, MHRAC meeting. Based on the public comments, the Subcommittee also suggested a few additions or modifications be made to the NIOSH proposed evaluation criteria. NIOSH incorporated the recommendations. MHRAC also recommended that active and passive ESLI's are appropriate for use with respiratory protective devices provided that criteria are established for their certification and use to ensure that the user is not exposed to increased risk as a consequence of relying upon such ESLI's.

In order for NIOSH to determine the potential effects of ESLI's on user safety and health, NIOSH recommends that all applications for approval of gas and vapor respirators with ESLI's contain the following information:

## CRITERIA FOR CERTIFICATION OF END-OF-SERVICE-LIFE INDICATORS

An applicant for certification of an ESLI for use against substances with poor warning properties must provide NIOSH with the following information:

1. Data demonstrating that the ESLI is a reliable indicator of sorbent depletion ( $\leq 90\%$  of service life). These shall include a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are representative of actual workplace conditions where a given respirator will be used. A minimum of two contaminant levels must be utilized: the exposure limit (PEL, REL, TLV®, etc.) and the exposure limit multiplied by the assigned protection factor for the respirator type.
2. Data on desorption of any impregnating agents used in the indicator, including a flow-temperature study at low and high temperatures and humidities which are representative of actual workplace conditions where a given respirator will be used. Data shall be sufficient to demonstrate safe levels of desorbed agents.
3. Data on the effects of industrial interferences which are commonly found in workplaces where a given respirator will be used. Data should be sufficient to show which interferences could impair the effectiveness of the indicator and the degree of impairment, and which substances will not affect the indicator.
4. Data on any reaction products produced in the reaction between the sorbent and the contaminant gases and vapors, including the concentrations and toxicities of such products.
5. Data which predict the storage life of the indicator. (Simulated aging tests will be acceptable).

In addition to the foregoing, all passive ESLI's shall meet the following criteria:

1. A passive ESLI shall be placed on the respirator so that the ESLI is visible to the wearer.
2. If the passive indicator utilizes color change, the change shall be such that it is detectable to people with physical impairments such as color blindness.
3. If the passive indicator utilizes color change, reference colors for the initial color of the indicator and the final (end point) color of the indicator shall be placed adjacent to the indicator.

All ESLI's shall meet the following criteria:

1. The ESLI shall not interfere with the effectiveness of the face seal.
2. The ESLI shall not change the weight distribution of the respirator to the detriment of the facepiece fit.
3. The ESLI shall not interfere with required lines of sight.
4. Any ESLI that is permanently installed in the respirator facepiece shall be capable of withstanding cleaning and a drop from a height of 6 feet. Replaceable ESLI must be capable of being easily removed and shall also be capable of withstanding a drop from a height of 6 feet.
5. A respirator with an ESLI shall still meet all other applicable requirements set forth in 30 CFR 11.
6. If the ESLI uses any electrical components, they shall conform to the provisions of the National Electrical Code and be "intrinsically safe." Where permissibility is required, the respirator shall meet the requirements for permissibility and intrinsic safety set forth in 30 CFR 18, Subpart D. Also, the electrical system shall include an automatic warning mechanism that indicates a loss of power.
7. Effects of industrial substances interferences which are commonly found where a given respirator will be used and which hinder ESLI performance, shall be identified. Substances which are commonly found where the respirator is to be used must be investigated. Data sufficient to indicate whether the performance of the respirator would be affected must be submitted to NIOSH. The user shall be made aware of use conditions that could cause false positive and negative ESLI responses.
8. The ESLI shall not create any hazard to the wearer's health or safety.
9. Consideration shall be given to the potential impact of common human physical impairments on the effectiveness of the ESLI.

**APPENDIX B. NIOSH POLICY STATEMENT ON USE OF SINGLE-USE AND DUST  
AND MIST RESPIRATORS FOR PROTECTION AGAINST ASBESTOS**

June 21, 1984, OSHA Public Hearings

Under Title 30, Code of Federal Regulations, Part 11 (30 CFR 11), NIOSH is required to test and certify respirators within the categories specified therein when such devices are submitted to NIOSH by applicants. Currently, 30 CFR 11, Subpart K defines a number of dust, fume, and mist respirators which may be used for protection against certain hazardous particulate atmospheres. Among the respirators defined in Subpart K are single-use dust respirators designed as respiratory protection against pneumoconiosis-producing and fibrosis-producing dusts, or dusts and mists. Subpart K lists asbestos as one of the dusts against which the single-use dust respirator is designed to protect [Subpart K, Sec. 11.130(H)]. Although at the time of the promulgation of Subpart K, it may have been assumed appropriate to list asbestos as a fibrosis-producing particulate against which the single-use disposable respirator could be reasonably expected to provide adequate protection, NIOSH is no longer confident that such an assumption is reasonable because asbestos is also a potent carcinogen.

The current requirements as (specified in 30 CFR 11) for approval of a single-use dust respirator or dust and mist respirator do not include any tests with fibrous challenge aerosol. NIOSH is currently in the process of doing a comprehensive revision of 30 CFR 11 and intends to address the issue of appropriate respiratory protection for use against asbestos, and to require that any respirator for which such approval is sought be proven to provide effective protection against asbestos. NIOSH may change the regulations included in 30 CFR 11 only in accordance with procedures set forth in the Administrative Procedures Act. In the interim, NIOSH will continue to consider applications for approval of single-use and replaceable dust/mist respirators for use against asbestos only because of the legal requirement in the current approval regulations. However, NIOSH does not recommend the use of such respirators where exposures to asbestos may occur because such a recommendation would not be prudent based on the occupational health risk.

This policy position is contained in "The Statement of the National Institute for Occupational Safety and Health--The Public Hearings on Occupational Exposure to Asbestos."

## APPENDIX C. ODOR WARNING: BACKGROUND INFORMATION

It is important to realize that 30 CFR 11 prohibits the use of MSHA/NIOSH approved air-purifying (organic vapor) respirators for protection against organic vapors with poor warning properties unless there is an OSHA standard that permits such use. Specifically, 30 CFR 11, Section 11.90(b), footnote 4 gives the standards for gas masks (canister devices), while 30 CFR 11, Section 11.150, footnote 7 gives the standards for chemical cartridge respirators. Thus the "organic vapor respirator" shall be approved only for organic vapors with adequate warning properties. In addition, the requirement for adequate warning properties also applies to all MSHA/NIOSH-approved air-purifying respirators for protection against organic gases and vapors.

A recent policy decision by NIOSH allows the use of respirators for protection against contaminants with poor warning properties, provided that certain conditions are met. These conditions are outlined in the policy statement in Appendix A. MSHA/NIOSH approval may be granted for a respirator designed for use against gases and vapors with poor warning properties if the respirator incorporates an effective end-of-service-life indicator (ESLI).

However, unless the respirator incorporates an ESLI, wearers of air-purifying chemical cartridge/canister respirators must rely on adequate warning properties to alert them to the breakthrough of the sorbent in the cartridge or canister. Amoores and Hautala [33] have noted:

The ability of members of the population to detect a given odor is strongly influenced by the innate variability of different persons' olfactory powers, their prior experience with that odor, and by the degree of attention they accord to the matter.

Amoores and Hautala [33] found that on the average, 95% of a population will have a personal odor threshold that lies within the range from about one-sixteenth to sixteen times the reported mean "odor threshold" for a substance. That is, about 2.5% of a population will be able to detect a substance's odor at concentrations less than one-sixteenth of the "odor threshold" for a substance. Correspondingly, about 2.5% of the individuals will need to be exposed to concentrations exceeding by a factor of 16 the "odor threshold" in order to perceive the odor. Thus for many substances the width of distribution of personal odor threshold is over two orders of magnitude of concentration. The "odor thresholds" reported in the literature generally are the median values for wide population distributions. Also, 50% of prospective respirator wearers can detect a substance's odor only at levels that must exceed the reported "odor threshold," and about 15% cannot detect the odor at levels that exceed the "odor threshold" by fourfold [33].

OSHA incorporated into the lead standard a new isoamyl acetate qualitative fit test protocol, developed by Du Pont, which requires odor threshold

screening [29 CFR 1910.1025, Appendix D (I)(A)]. Du Pont realized that a qualitative fit test depending on odor recognition would be ineffective if every individual were not first screened for the ability to detect the odor of isoamyl acetate at some minimum concentration. This is also true for detection of the odor of the gas or vapor used to alert the wearer of sorbent element (cartridge or canister) breakthrough. Thus NIOSH recommends screening tests for workers who wear air-purifying gas or vapor respirators to determine their ability to detect the odor below the exposure limit for that gas or vapor.

## APPENDIX D. PROTECTION FACTOR: BACKGROUND INFORMATION

The U.S. Bureau of Mines referred to the term "Decontamination Factor" in their Approval Schedule 21B, first issued in 1965, and defined it to be "the ratio of the concentration of dust, fume, or mist present in the ambient atmosphere to the concentration of dust, fume, or mist within the facepiece while the respirator is being worn." The decontamination factor is now referred to as the respirator protection factor. The original definition and application given in schedule 21B has been somewhat generalized over the years.

The protection factor of a respirator is an expression of performance based on the ratio of two measured variables,  $C_1$  and  $C_0$ . The variable  $C_1$  is defined only as the measured concentration of a contaminant inside the respirator facepiece cavity, and  $C_0$  is defined only as the measured contaminant concentration outside the respirator facepiece. The relationship between these two variables can be expressed not only as the protection factor ( $C_0/C_1$ ) but also as the penetration ( $C_1/C_0$ ) or efficiency [ $(C_0-C_1)/C_0$ ].

The protection factor can be related to the penetration (p) and efficiency (E) as follows:

$$PF = C_0/C_1 = 1/p = 1/(1-E)$$

A further implicit condition on the PF function is that  $C_1 \leq C_0$ ; therefore, the PF will always be greater than unity.

Protection factor assessments are made almost exclusively on man/respirator systems, while penetration and efficiency assessments are made only on component parts of the respirator system. It is important to recognize that on a man/respirator system, the measured variable  $C_1$  becomes a complicated function of many individual sources of penetration (e.g., air-purifying element penetration, exhalation valve penetration, face seal penetration, and other inboard penetration) and those environmental conditions that would effect penetration. To deal with the multiple methods for determining and applying protection factors, a number of definitions have been proposed [13]. These definitions, described below in greater detail than in the Glossary, are as follows:

**ASSIGNED PROTECTION FACTOR (APF):** A special application of the general protection factor concept, APF is defined as a measure of the minimum anticipated workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to a percentage of properly fitted and trained users. The maximum specified use concentration for a respirator is generally determined by multiplying the exposure limit for the contaminant by the protection factor assigned to a specific class of respirators [13].

**SIMULATED WORKPLACE PROTECTION FACTOR (SWPF):** A surrogate measure of the workplace protection factor (WPF) of a respirator, SWPF differs from the WPF only in that it is measured in a laboratory simulation of a workplace setting rather than in the actual workplace. The definitions and restrictions of  $C_0$  and  $C_1$  are as described for the WPF. For laboratory protection factor testing to reliably estimate WPF's, a relationship must be demonstrated between the two tests. No such relationship has been identified in the literature. Until such a relationship can be shown to exist, the laboratory protection factor is of questionable use in determining or predicting the WPF [13].

**WORKPLACE PROTECTION FACTOR (WPF):** A measure of the actual protection provided in the workplace under the conditions of that workplace by a properly functioning respirator when correctly worn and used, WPF is defined as the ratio of the estimated contaminant concentration outside the respirator facepiece ( $C_0$ ) to the contaminant concentration inside the respirator facepiece ( $C_1$ ). The sampling restrictions placed on  $C_0$  and  $C_1$  are that both  $C_0$  and  $C_1$  should be TWA samples taken simultaneously while the respirator is being properly worn and used during normal work activities. In practice, the WPF would be determined by measuring the concentration inside and outside the facepiece during the activities of a normal workday [13].

**FIT FACTOR:** A special application of the protection factor ratio that represents a quantitative measure of the fit of a particular respirator facepiece to a particular individual, the fit factor is defined under the conditions of quantitative fit testing as the aerosol concentration in the test chamber ( $C_0$ ) divided by the penetration that occurs through the respirator face seal interface ( $C_1$ ) [34]. For  $C_1$  to reflect only face seal leakage, high efficiency filters [greater than 99.97% efficient against  $0.3 \mu\text{m}$  aerodynamic mass median diameter (AMMD) dioctylphthalate aerosol] are installed on the respirator. It is assumed that either no leakage or only a negligible amount of leakage into the facepiece occurs through the exhalation valve or any source other than the face seal. The fit factor is measured on a complete respirator worn by a test subject who follows a regimen of slow head movements, deep breathing, and talking; a polydispersed oil mist or sodium chloride aerosol is used that has an AMMD of approximately  $0.6 \pm 0.1 \mu\text{m}$  (with a geometric standard deviation of approximately 2 to 2.4).

## APPENDIX E. MEDICAL ASPECTS OF WEARING RESPIRATORS: BACKGROUND INFORMATION

In recommending medical evaluation criteria for respirator use, one should apply rigorous decision-making principles [35], using knowledge of screening test sensitivity, predictive value, etc. Unfortunately, many gaps in knowledge in this area exist. The problem is complicated by the large variety of respirators, their conditions of use, and individual differences in the physiologic and psychologic responses to them. For these reasons, the preceding guidelines (see Subparagraph 10) are to be considered as informed suggestions rather than established NIOSH policy recommendations. The following information is intended primarily to assist the physician in developing medical evaluation criteria for respirator use.

### Health Effects of Wearing Respirators

Brief descriptions of the health effects associated with wearing respirators are summarized below. Interested readers are referred to recent reviews for more detailed analyses of the data [36,37].

**Pulmonary:** In general, the added inspiratory and expiratory resistances and dead space of most respirators cause an increased tidal volume and decreased respiratory rate and ventilation (including a small decrease in alveolar ventilation). These respirator effects have usually been small both among healthy individuals and, in limited studies, among individuals with impaired lung function [38-42]. This generalization is applicable to most respirators meeting Federal regulations when resistances (particularly expiratory resistance) are low [1,43,44]. While most studies report minimal physiologic effects during submaximal exercise, the resistances commonly lead to reduced endurance and reduced maximal exercise performance [45-49]. The dead space of a respirator (reflecting the amount of expired air that must be rebreathed before fresh air is obtained) tends to cause increased ventilation. At least one study has shown substantially increased ventilation with a full-face respirator, a type which can have a large effective dead space [50]. However, the net effect of a respirator's added resistances and dead space is usually a small decrease in ventilation [39,45,46-48,51].

The potential for adverse effects, particularly decreased cardiac output, from the positive pressure feature of some respirators has been reported [52]. However, several recent studies suggest that this is not a practical concern, at least not in healthy individuals [53-55].

Theoretically, the increased fluctuations in thoracic pressure while breathing with a respirator might constitute an increased risk to subjects with a history of spontaneous pneumothorax. Few data are available in this area. While an individual is using a negative pressure respirator with relatively high resistance during very heavy exercise, the usual maximal peak negative oral pressure during inhalation is about 15-17 cm of water [53]. Similarly, the usual maximal peak positive oral pressure

during exhalation is about 15-17 cm of water, which might occur with a respirator in a positive pressure mode, again during very heavy exercise [53]. By comparison, maximal positive pressures, such as those during a vigorous cough, can generate 200 cm of water pressure [56]. The normal maximal negative pleural pressure at full inspiration is -40 cm of water [57], and normal subjects can generate -80 to -160 cm of negative water pressure [56]. Thus while vigorous exercise with a respirator does alter pleural pressures, the risk of barotrauma would seem to be substantially less than that of the cough maneuver.

In some asthmatics, an asthmatic attack may be exacerbated or induced by a variety of factors including exercise, cold air, and stress, all of which may be associated with wearing a respirator. While most asthmatics who are able to control their condition should not have problems with respirators, a physician's judgment and a field trial may be needed in selected cases.

**Cardiac:** The added work of breathing from respirators is small and could not be detected in several studies [38,39]. A typical respirator might double the work of breathing from 3 to 6% of the oxygen consumption, but this is probably not of clinical significance [38]. In concordance with this view is the finding of several studies that at the same workloads heart rate does not change with the wearing of a respirator [39,54,58-60].

In contrast, the added cardiac stress due to the weight of a heavy respirator may be considerable. A self-contained breathing apparatus (SCBA), particularly one that uses compressed air cylinders, may weigh up to 35 pounds. Heavier respirators have been shown to reduce maximum external workloads by 20% and similarly increase heart rate at a given submaximal workload [46]. In addition, it should be appreciated that many uses of SCBA (e.g., for firefighting and hazardous waste site work) also necessitate the wearing of 10-25 pounds of protective clothing.

Raven et al. [40,58] found significantly higher systolic and/or diastolic blood pressures during exercise for persons wearing respirators (although increases were minimal, i.e.,  $\leq 10$  mmHg systolic, 0-2 mmHg diastolic). Arborelius et al. [54] did not find significant differences for persons wearing respirators during exercise.

**Body Temperature:** Proper regulation of body temperature is primarily of concern with the closed circuit, self-contained breathing apparatus that produces oxygen via an exothermic chemical reaction. Inspired air within these respirators may reach 120°F (49°C), thus depriving the wearer of a minor cooling mechanism and causing discomfort. Obviously this can be more of a problem with heavy exercise and when ambient conditions and/or protective clothing further reduce the body's ability to lose heat. The increase in heart rate due to increasing temperature represents an additional cardiac stress.

Closed-circuit breathing units of any type have the potential for heat stress since warm expired gases (after exothermic carbon dioxide removal with or without oxygen addition) are rebreathed. Respirators with large dead space also have this potential problem, again because of partial rebreathing of warmed expired air [50].

**Diminished Senses:** Respirators may reduce visual fields, decrease voice clarity and loudness, and decrease hearing. Besides the potential for reduced productivity, these effects may result in reduced industrial safety. These factors may also contribute to a general feeling of stress [61].

**Psychologic:** This important topic is discussed in recent reviews by Morgan [61,62]. There is little doubt that virtually everyone suffers some discomfort when wearing a respirator. The large variability and the subjective nature of the psycho-physiologic aspects of wearing a respirator, however, make studies and specific recommendations difficult. Fit testing obviously serves an important additional function in providing a trial to determine if the wearer can psychologically tolerate the respirator. General experience indicates that the great majority of workers can tolerate respirators and that experience aids in this tolerance [62]. However, some individuals are likely to remain psychologically unfit for wearing respirators.

**Local Irritation:** Allergic skin reactions may occur occasionally from wearing a respirator, and skin occlusion may cause irritation or exacerbation of preexisting conditions such as pseudofolliculitis barbae. Facial discomfort from the pressure of the mask may occur, particularly when the fit is unsatisfactory.

In addition to the health effects associated with wearing respirators (described above) specific groups of respirator wearers may be affected by the following factors:

**Perforated Tympanic Membrane:** While inhalation of toxic materials through a perforated tympanic membrane (ear drum) is possible, recent evidence indicates that the airflow would be minimal and rarely if ever of clinical importance [63,64]. In highly toxic or unknown atmospheres, use of positive pressure respirators should ensure adequate protection [63].

**Contact Lens:** Contact lenses are generally not recommended for use with respirators, although little documented evidence exists to support this viewpoint [65]. Several possible reasons for this recommendation are noted below:

- a. Corneal irritation or abrasion might occur with the exposure. This would, of course, be a problem primarily with quarter- and half-face masks, especially with particulate exposures. However, exposures could occur with full-face respirators due to leaks or

inadvisable removal of the respirator for any reason. While corneal irritation or abrasion might also occur without contact lenses, their presence is known to substantially increase this risk.

b. The loss or misplacement of a contact lens by an individual wearing a respirator might prompt the wearer to remove the respirator, thereby resulting in exposure to the hazard as well as to the potential problems noted in "a." above.

c. The constant airflow of some respirators, such as powered air-purifying respirators (PAPR) or continuous flow air-line respirators, might irritate a contact lens wearer.



SEP 28 1998

DOCKET NUMBER  
PROPOSED RULE PR 20  
(63FR 38511)

9

Comments on  
Respiratory Protection and Controls To Restrict Internal Exposures 63 FR 38511

Disclaimer: The opinions expressed below are my own, and have not been reviewed or approved by Battelle, the Pacific Northwest National Laboratory, or the U.S. Department of Energy.

Daniel J. Strom, Ph.D., CHP  
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OFFICE OF  
RULEMAKING  
ADJUDICATION AND  
HEARING  
98 SEP 29 P 2:49  
DOCKETED  
USMRC

Introduction

The choice of the phrase "restrict internal exposures" confounds the concepts of restricting intakes and restricting dose equivalents. Restricting *intakes* of radioactive materials will restrict *dose equivalent*, but it is only one method of doing so. Enhanced decorporation through decontamination, emesis, chelation, purgatives, and competitive mass action may also limit *dose equivalent* after intake.

Comments

1. The phrase "internal exposure" should be abandoned in favor of clearer terminology that communicates to non-experts and scientists outside of health physics. "Internal exposure" is an oxymoron that confuses workers, educated lay persons, physicians, toxicologists, and industrial hygienists. The NRC should avoid "internal exposure;" NRC should use "intake" or "dose from internal radioactive material" depending on context. A confusion exists between the use of "exposure" to mean the process of encountering an agent or energy field (the meaning understood by workers, educated lay persons, physicians, toxicologists, and industrial hygienists), and the use of "exposure" as a generic term for absorbed dose or dose equivalent. There is also a confusion between the *process of exposure* and the *process of irradiation*. For radiation sources outside of the body, exposure and irradiation are simultaneous. For doses from intakes of radioactive material, *exposure* to the material is completely distinct from subsequent *irradiation* by the material in the body. By using "internal exposure," the NRC perpetuates the confusion of *exposure* with *irradiation*. See figure, tables and discussion below.

2. The NRC should avoid the phrase "internal dosimetry;" NRC should use "intake dosimetry."

3. The NRC should use "deposition" only for the process of deposition, and use "retained quantity" for an *amount* of activity. Tritium, <sup>14</sup>C, <sup>85</sup>Kr, <sup>137</sup>Cs, etc. do not "deposit" in the body in the sense of radium or strontium translocating to bone and being largely retained there (even

though much remodeling occurs) over decades.

## **Discussion**

Following are several comments supporting the above-referenced clarifications in language.

## **Definitions**

The word *expose* is a transitive verb with several related meanings, two of which are confused in health physics. One meaning of *expose* is *to submit, subject or allow to be subjected to an action or an influence*; for example, to expose people to fine arts, to expose someone to a disease, to expose a worker to dust. Another distinct and specific meaning is *to subject something (e.g., photographic film) to the action of radiant energy or light*.

The word *exposure* is a noun meaning *the act, condition, or instance of being exposed*. A related meaning of *exposure* is *the amount or quantity of the agent to which something is exposed*, such as the amount of light reaching film. Exposure has taken on two special meanings in radiological physics. The first is the quantity of charge liberated per unit mass in air by photons between the energies of 10 keV and 3 MeV. The second is the product of potential alpha energy concentration (*PAEC*) and time, expressed in  $\text{J}\cdot\text{h}\cdot\text{m}^{-3}$  or working level months (WLM).

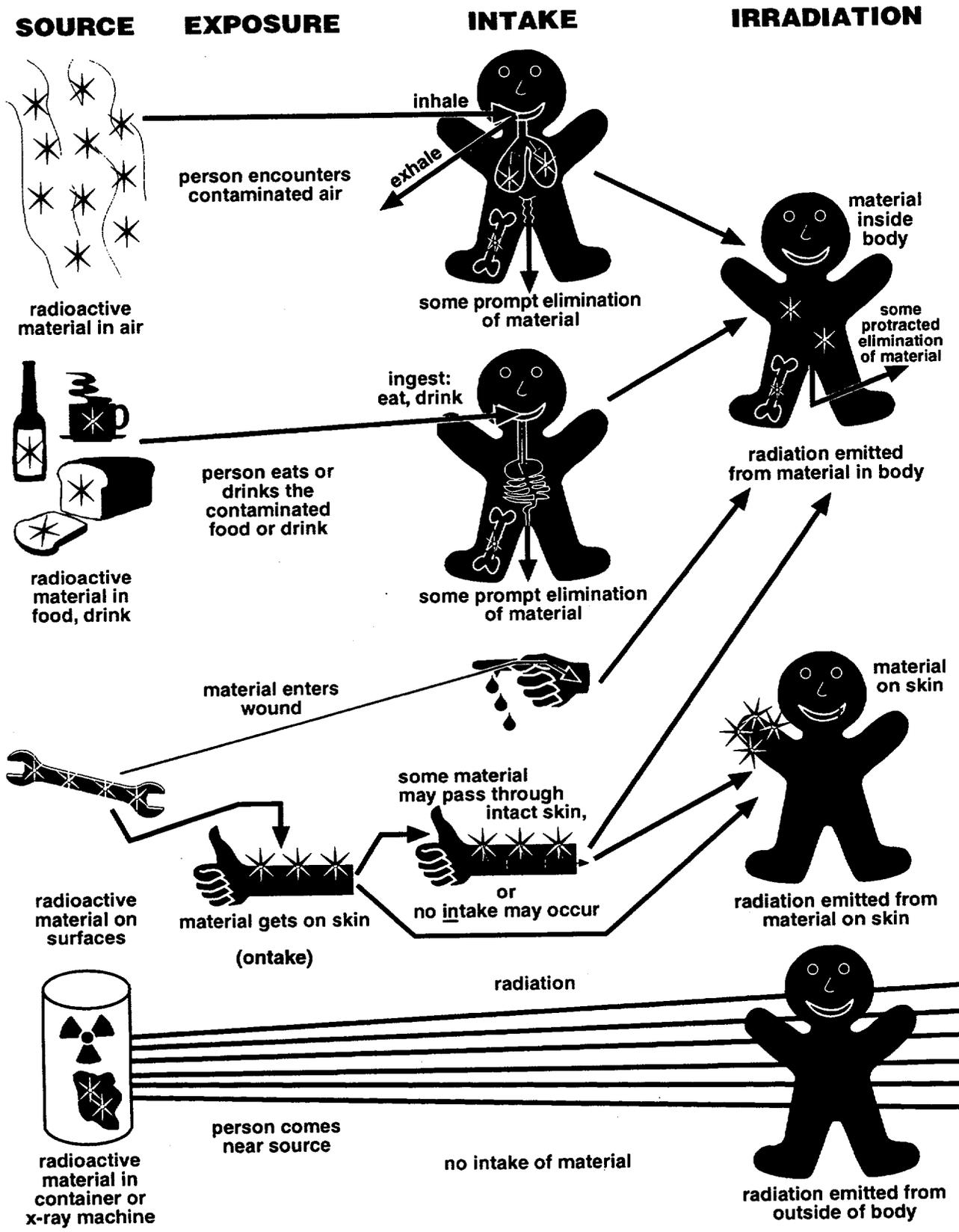
## **The Phrase “Internal Exposure” Is Confusing**

- *All* sources of radiation start EXTERNAL to body
- *All* irradiated organs are INTERNAL to the body
- Exposure to a non-health physicist means uncovering, being exposed to an agent (microbe, chemical, radionuclide, energy field) outside the body

## Irradiation: Where And When

	External Source	“Ontakes” of Radioactive Material (Skin Contamination)	Intakes of Radioactive Material
Irradiation Source Is Outside of Body	✓	✓	
Irradiation Source Is On Body (Topical)		✓	
Irradiation Source Is Inside of Body			✓
Exposure and Irradiation	Simultaneous	Sequential (?)	Sequential
Course of Irradiation Can Be Altered after Exposure		✓	✓

Source	Exposure	Intake or Ontake	Irradiation and Fate of Source	
1. Airborne radioactive material (radioactive gas or aerosol)	1. Person encounters contaminated air	1. Intake by inhalation: airborne radioactive material enters respiratory tract (R tract)	<b>Irradiation by Internal Source</b> 1, 2, 3a & 3b. <ul style="list-style-type: none"> <li>• Material emits radiation from within body</li> <li>• Source stays with person for some period of time</li> <li>• Material irradiates "while passing through"</li> <li>• Some or all material eliminated from body by decay and/or by natural or enhanced decorporation</li> </ul>	
2. Food-borne radioactive material: Radioactive material in or on food, drink, cigarette, gum, cosmetics, etc.	2. Person eats or drinks contaminated food or beverage, or has oral contact with other contaminated items	2. Intake by ingestion: radioactive material enters the gastrointestinal tract (GI tract)	2. Material irradiates GI tissue and body from GI tract <ul style="list-style-type: none"> <li>• Insoluble material passes through (essentially remains "outside" of the body, in the contents of the GI tract)</li> <li>• Some material may be absorbed systemically from GI tract</li> </ul>	
3. Surface-borne radioactive material: Radioactive material on surfaces, in environment	3a. Person's skin broken by contaminated surface or object	3a. Intake by entry through wound or injection	3a. Material irradiates body from wound site <ul style="list-style-type: none"> <li>• Some material may be absorbed systemically from wound site</li> <li>• Some material may translocate via lymphatic system</li> <li>• Some material may remain at wound site indefinitely</li> </ul>	
	3b & 3c. Person comes in contact with contamination or contaminated surface	3b. Ontake followed by intake: partial or total absorption of material in contact with skin through intact skin	3b. Some material may be absorbed systemically from skin	
		3c. Ontake <i>not</i> followed by intake: material remains on skin, in contact	<b>Irradiation by Topical Source</b> 3b & 3c. <ul style="list-style-type: none"> <li>• Material emits radiation while in contact with skin</li> <li>• Source stays with person for some period of time</li> <li>• Material removed by decay and/or sloughing</li> </ul>	
4. Radiation-generating device or radioactive material that remains outside of the body	4. Person comes near a source of penetrating radiation	4. No intake or ontake of source itself	<b>Irradiation by External Source</b> 4. Machine or material remains outside of body	
			4. Machine or material emits radiation which penetrates body, irradiating tissues	



The figure illustrates the distinction between “exposure” to radioactive material and the subsequent, perhaps protracted, “exposure” to radiation emitted by that material while some of it is retained in and/or on the body. Communication clarity is enhanced if the latter “exposure” is called “irradiation.”

## Conclusions

- “Internal exposure” is an oxymoron that confuses workers, educated lay persons, physicians, toxicologists, and industrial hygienists.
- Communication is enhanced if we distinguish between exposure and irradiation:
  - Being near radioactive materials or radiation generating machines that emit penetrating radiation may result in *irradiation by an external source*. Exposure to the source and irradiation by the source are simultaneous. There is no intake of material. Irradiation ceases when exposure ceases.
  - Exposure to air-, food-, drink-, and surface-borne radioactive materials may result in intake or ontake of material, with subsequent *irradiation by a topical source* or *irradiation by an internal source* or both. Exposure to the material and irradiation by the material occur at different places and different times. Following ontake or intake, material may remain on or in a person for an extended period of time. Irradiation usually continues after exposure ceases, and irradiation patterns change over time.

**From:** <Mike\_Benjamin@wastemanagement.com>  
**To:** TWD2.TWP6(CAG)  
**Date:** 9/30/98 9:44am  
**Subject:** Comments - Respiratory Protection

DOCKETED  
USNRC

'98 SEP 30 P2:54

OFFICE OF THE SECRETARY  
RULEMAKING AND ADJUDICATION  
OFFICE

Mike Benjamin@WMI  
09/30/98 08:44 AM

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

Michael J. Benjamin, RRPT  
403 West Main Street  
Williston, SC 29853  
803.541.5014 (work)

September 30, 1998

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attention: Rulemakings and Adjudication Staff

Subject: Comments on "Respiratory Protection and Controls To Restrict Internal Exposure"

The NRC published proposed changes to 10 CFR 20, Respiratory Protection and Controls to Restrict Internal Exposures, in the July 17 Federal Registrar (Volume 63, Number 137, page 38511 - 38521) and requests comments which are due by Sept. 30, 1998.

"The NRC staff specifically requests comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a simple performance-based rule with a Regulatory guide endorsing ANSI standards to permit a more rapid regulatory response by the NRC to future technical developments and changes in industry standards."

Comment:

The OSHA recently published, as a final rule, 29 CFR 1910.134, "Respiratory Protection" with an effective date of Oct. 5, 1998. This standard requires employers to establish and maintain a respiratory protection program that includes selection, medical evaluation, fit testing, use, maintenance and care, training, record keeping and program evaluation. NRC licensees are required to meet this OSHA standard and the NRC should recognize this standard

as a basis for Part 20's Respiratory Protection standard. If the NRC recognized and referenced 29 CFR 1910.134 licensee's would have one common standard for respiratory protection not two (both the OSHA standard and the NRC standard) providing some administrative relief.

The NRC proposes in Section 20.1003, Definitions, to add definitions that are provided in the OSHA Respiratory Protection standard (1910.134 (b)).

Comment:

Terms such as "Fit Check" proposed by the NRC tend to confuse and conflict with the OSHA term "User Seal Check" and should be consistent. By referencing the OSHA standard employers providing and employees using respirator protection would stay better informed with a common set of respiratory protection definitions.

In Section 20.1703 (c)(6) the NRC proposes to change the frequency of fit tests from annual to "not to exceed 3 years" placing the requirement to perform continual physiological evaluations of employees on the licensee (employer).

Comment:

Changing the frequency of fit tests from annually to "not to exceed 3 years" appears to be an unnecessary burden on the licensee and a requirement that could be subjectively enforced. The proposed standard does not provide clear direction for the documentation of the employee evaluations performed to ensure that licensee has met the Commissions expectations for these evaluations.

Thank you for the opportunity to submit comments and recommendations.

Sincerely,

Michael J. Benjamin, RRPT

September 30, 1998

NOTE TO: Emile Julian  
Chief, Docketing and Services Branch

FROM: Carol Gallagher  
ADM, DAS



SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULEMAKING - RESPIRATORY  
PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE

Attached for docketing is a comment letter related to the subject proposed rulemaking.

This comment was received via e-mail on September 30, 1998. The submitter's name is Michael J. Benjamin, 403 West Main Street, Williston, SC 29853. Please send a copy of the docketed comment to Alan Roecklein (mail stop O11-F-1) for his records.

Attachment:  
As stated

cc w/o attachment:  
A. Roecklein

DOCKET NUMBER  
PROPOSED RULE PR 20  
(63FR38511)

DOCKETED  
USNRC

'98 OCT -1 P 4:01

September 30, 1998

OFFICE OF SECRETARY  
RULEMAKING AND  
ADJUDICATION STAFF

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Attn: Rulemakings and Adjudications Staff

Re: Mallinckrodt Inc.'s Comments on NRC's Proposed Rule for "Respiratory Protection and Controls to Restrict Internal Exposures"

Gentlemen:

Attached please find Mallinckrodt Inc.'s comments on NRC's proposed rule for the "Respiratory Protection and Controls to Restrict Internal Exposures." This proposed rulemaking was issued in the Federal Register, Volume 63, number 137, pages 38511-38521, dated July 17, 1998.

Mallinckrodt Inc. operates under several NRC licenses at various sites.

With respect to NRC's request for specific comments on the "alternate approaches" for the proposed rule, Mallinckrodt Inc. strongly recommends that a simple "performance-based" rule be implemented to minimize the regulatory burden upon licensees. NRC does not need to establish a new set of regulations. Instead, the NRC should endorse the ANSI standard, and NRC may wish to issue an Information Notice (IN) for any additional clarification. The performance-based approach would be compatible with the NRC's strategic assessment and re-baselining initiative of performance-based, risk-informed strategy.

Other comments from Mallinckrodt Inc. are provided in the attachment.

Mallinckrodt Inc. appreciates the opportunity for commenting on this proposed rulemaking.

If you have any questions, or need any clarification, please contact me at 314.654.7960.

Sincerely yours,

Ashok K. Dhar  
Manager, Radiological Affairs  
Regulatory Compliance Department

Attachment

**MALLINCKRODT INC.**

**Comments on**

**Proposed Rulemaking on "Respiratory Protection and Controls to Restrict Internal Exposure"**

1. A simple performance based rule should be implemented to minimize the regulatory burden upon licensees. Having only one reference to establish a program would greatly simplify the NRC's replication. Endorsing ANSI standards when they are released can be followed by an IN from the NRC for any additional clarification. If the ANSI standard changes in a way that is not commensurate the NRC's philosophy, the NRC can reestablish the full amended rule.
  
2. If number 1 above is not adopted, please make the following recommended changes.
  - (a) Pages 38515 and 38516 reference the use of half-face disposable respirators without the need for medical screening and fit testing. When referring to the NRC's Third Set of Questions and Answers to new 10 CFR Part 20 dated July 23, 1992, question number 91 states that the requirements in 10CFR20.1703(a) must be met to utilize respiratory protection whether or not credit is taken for the device. Is this a change in philosophy by the NRC? We agree with the new rule allowing flexible application of disposable respirators if no credit is taken for their use.
  
  - (b) Fit testing requirements in the suggested rule call for achieved fit factors that are ten times the APF for the specific negative-pressure air-purifying device. This new requirement should have some indication as to how this may be achieved. Can a qualitative test be used or will a quantitative test be required?

September 30, 1998

NOTE TO: Emile Julian  
Chief, Docketing and Services Branch

FROM: Carol Gallagher  
ADM, DAS



SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULEMAKING - RESPIRATORY  
PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE

Attached for docketing is a comment letter related to the subject proposed rulemaking.

This comment was received via e-mail on September 30, 1998. The submitter's name is Ashok K. Dhar, Mallinckrodt, Inc. Please send a copy of the docketed comment to Alan Roecklein (mail stop O11-F-1) for his records.

Attachment:  
As stated

cc w/o attachment:  
A. Roecklein

Innsbrook Technical Center  
5000 Dominion Boulevard  
Glen Allen, Virginia 23060

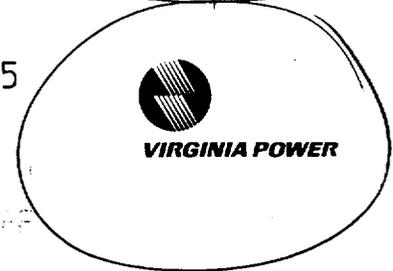
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USNRC

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

'98 OCT -5 A11:35

OFFICE OF THE  
GENERAL COUNSEL  
ADJUDICATIONS

12



September 30, 1998

Serial No. GL98-021

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20055-0001  
Attention: Rulemakings and Adjudications Staff

Gentlemen:

**10 CFR PART 20; RESPIRATORY PROTECTION AND  
CONTROLS TO RESTRICT INTERNAL EXPOSURES,  
63 FEDERAL REGISTER, NO. 137, JULY 17, 1998**

Virginia Power has reviewed the subject entry in the Federal Register and offers the comments in the attached table.

Thank you for your consideration of our comments. If you need further information, please contact Gwen Newman at (804) 273-4255, [Gwen\\_Newman@vapower.com](mailto:Gwen_Newman@vapower.com) or Tom Szymanski at (804) 273-3065, [Tom\\_Szymanski@vapower.com](mailto:Tom_Szymanski@vapower.com).

Respectfully,

A handwritten signature in dark ink, appearing to read "J. McCarthy".

FOR:

James H. McCarthy, Manager  
Nuclear Licensing & Operations Support

Attachment

**VIRGINIA POWER COMMENTS**  
**10 CFR PART 20; RESPIRATORY PROTECTION**  
**AND CONTROLS TO RESTRICT INTERNAL EXPOSURES**  
**SEPTEMBER 30, 1998**

Reference	Comment
20.1703(c) (6)	The benefit of three year fit testing may not be realized since annual (or more frequent) testing would be done for industrial respiratory protection and current common practice is to use one fit test for both programs. This would mean two separate fit test programs or remaining with the one-year frequency.
20.1703(e)	The requirement to make provision for "adequate communication" may be open to various opinions of what is adequate. Depending on the definition of adequate, it may be hard to meet this requirement due to the limited communication options available with respiratory devices.
20.1703(f)	The requirement for direct communication between the standby person and worker may force the standby person to remain in a high dose rate area since respiratory devices make communications difficult and wire/wireless means of communication may not be practicable. The radiological conditions requiring the worker to wear these levels of protective equipment may preclude the standby person from being in direct communication and immediately available without being so dressed themselves. This type of situation may be inconsistent with the concept of keeping total TEDE ALARA.
20.1703(h)	The wording of the regulation does not convey the intent discussed on page 38514 in the Summary of Proposed Changes. The supporting discussion is quite specific concerning the intention of the NRC relative to the preventing of the presence of anything that may interfere with the respirator seal (i.e. facial hair, cosmetics, spectacle earpieces, surgeons caps, etc.). We feel that since fit testing proves the ability to properly maintain a seal, employees should not categorically be required to wash their face and hands prior to using a tight-fitting respirator.
Appendix A Footnote c.	"Air purifying respirators with APFs < 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs < 100 must be equipped with particulate filters that are at least 99.97 percent efficient." The inequalities used above appear to conflict.
Appendix A Footnote d.	"gasses" should be "gases"
Appendix A Footnote f.	The word "part" should be capitalized.
Inconsistent Standards	It would be beneficial for the NRC and OSHA to establish commonality between the proposed revision to 10 CFR 20 and 29 CFR 1910. We will be unable to take advantage of provisions such as the relaxed fit test frequency because we also provide the fit tests for industrial respirator usage (29 CFR 1910) for which the frequency has not been relaxed.

**VIRGINIA POWER COMMENTS**  
**10 CFR PART 20; RESPIRATORY PROTECTION**  
**AND CONTROLS TO RESTRICT INTERNAL EXPOSURES**  
SEPTEMBER 30, 1998

Reference	Comment
NRC specific request on technical aspects of the proposed rule	Public Law 104-113 states "all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments." An exception is allowed if compliance would be "inconsistent with applicable law or otherwise impractical". Virginia Power supports this position, therefore we would support a performance-based rule with an associated Regulatory Guide (8.15) endorsing an ANSI standard (Z88.2).
NRC specific request on NUREG-0041	The proposed revision to NUREG-0041 will include a lot of needed detail, such as how heat, discomfort, and reduced vision affect efficiency and additional guidance regarding the application and limitation of APFs. If all of this pertinent data were included in ANSI Z88.2, then there would be no need to continue maintaining NUREG-0041.

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USNRC

'98 OCT -5 P2:19



October 1, 1998

OFFICE OF THE  
PUBLIC UTILITIES  
ADJUDICATOR GENERAL

Secretary  
U. S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001  
Attention: Rulemakings and Adjudications Staff

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

Subject: Comments on Proposed Rulemaking, "Respiratory Protection and Controls to Restrict Internal Exposures"

Reference: Volume 63, Federal Register, Page 38511 (63FR38511), dated July 17, 1998.

This letter provides the Commonwealth Edison (ComEd) Company comments on the subject Nuclear Regulatory Commission (NRC) proposed rulemaking published in 63FR38511. ComEd generally supports the proposed changes with the exceptions discussed in the comments below.

**General** In the proposed rule's Federal Register summary, the NRC requested comments on whether the technical aspects of the rule should be addressed through other approaches. In response to that request, ComEd does endorse the development and use of simple risk-informed, performance-based rules. ComEd supports development of regulations and Regulatory Guides that directly endorse industry standards. These nuclear industry standards, in turn, need to be developed through nuclear industry participation.

Regarding the planned revision to NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials," consideration should be given to elimination of the NUREG. The information contained in the current NUREG-0041 is in many cases redundant with the type of information found in other industry documents such as American National Standards Institute (ANSI) Standard Z88.2-1992, "American National Standard for Respiratory Protection." If certain aspects of the NUREG are considered crucial by the NRC in terms of respiratory protection-related guidance, then those few items should be added to the Proposed Revision 1 to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." ComEd believes this approach would be consistent with the strategy of formulating a more simple regulatory oversight process, that is,

having two regulatory-related documents on respiratory protection rather than three such documents.

Some specific comments on the proposed rule are provided below.

**20.1703**

- (c) (5) Per the proposed rule, non-face sealing respirators do require a medical evaluation before the first field use, except as noted for single-use disposable respirators in Note e. to Appendix A. However, this exemption is inconsistent with Occupational and Safety Health Administration (OSHA) 29 CFR 1910.134(e), which requires a medical evaluation prior to use for all respirators. Since the use of this type of respirator would not normally be used for protection against airborne radioactive material, NRC regulations should not provide an exemption for these medical evaluation requirements.
- (c) (6) The proposed Fit Factor of  $\geq 100$  for any positive pressure, continuous flow, and pressure demand devices is different than OSHA 29 CFR 1910.134. Since quantitative fit tests are performed in the negative pressure mode, the fit factor of a full facepiece cartridge respirator could be the same as the half-mask cartridge respirator, i.e., 100. OSHA 29 CFR 1910.134 requires a minimum fit factor of 500 for full facepiece respirators. It is recommended that OSHA regulations and NRC regulations be the same regarding this issue.

**Appendix A to Part 20**

- Note c. There is an apparent typographical error in the note. The second use of the "less than or equal" sign should actually be a "greater than" sign.
- Note e. The medical evaluation exemption may be inappropriate due to the fact that a medical exemption is inconsistent with OSHA 29 CFR 1910.134(e) as was discussed in the comments to the proposed 10 CFR 20.1703(c)(5) above.

October 1, 1998  
U. S. Nuclear Regulatory Commission  
Page 3

Some models of single-use respirators are equipped with seal enhancing material, and, therefore, in those cases, there should be no difficulty in achieving a facial seal. This is in conflict with the blanket statement in the note that it is difficult to perform an effective fit check on these devices.

Respectfully,

A handwritten signature in black ink, appearing to read "R.M. Krich". The signature is written in a cursive style with a large, sweeping initial "R".

R.M. Krich  
Vice President - Regulatory Services

**TSI Incorporated**  
**Health and Safety Instruments**  
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DOCKETED  
USMRC



'98 OCT -8 AM 11:26

9/30/98

U.S. Nuclear Regulatory Commission  
Attn: Rulemakings and Adjudications Staff  
Washington DC 20555-0001

OFFICE OF THE  
RULEMAKING  
ADJUDICATIONS

Re: Proposed revisions to 10 CFR Part 20  
as described in F.R. vol. 63, no. 137, July 17,1998

DOCKET NUMBER  
PROPOSED RULE **20**  
**(63FR38511)**

Dear NRC:

There are three issues concerning the proposed revisions to respirator fit testing requirements that TSI Inc. would like to bring to your attention. Both specifically involve paragraph 20.1703( c )( 6 ). The proposed paragraph reads:

(6) Fit testing, with a fit factor of 10 times the APF for negative pressure devices, and a fit factor 100 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 3 years.

Issue 1 - fit factor for positive-pressure full-face respirators:

A fit factor requirement of only 100 is too low for full-face tight-fitting masks regardless of their use with negative-pressure or positive-pressure respirators. TSI is in close contact with many of the thousands of organizations that have been using QNFT to fit test full-face masks. This experience spans more than a decade. We have never come across an organization that had difficulty achieving a fit factor above 1000 on most individuals. A fit factor of 100 on a full-face mask represents a very poor fit. The NRC should not allow anyone to wear a poor fitting mask under any circumstances. Positive-pressure is intended to elevate the protection level provided by a good fitting mask. It is not intended to compensate for the deficiencies of poor fitting equipment.

Issue 2 - fit testing frequency:

The proposal to replace the annual fit test requirement with one that allows up to 3 years between fit tests is based on the assumption that physical change to an individuals face is the only parameter that justifies a retest more frequently than every 3 years. In our experience, and the experience shared with us by our customer base, the primary benefit of an annual fit test is to refresh an individual's training. Having the proper size respirator is of little value if the equipment is not donned properly. Given the potential health hazard, annual fit testing can easily be justified based on the training issue alone.

Issue 3 - fit testing positive-pressure masks in negative- pressure mode:

It is an undisputed technical requirement that positive-pressure tight-fitting masks be fit tested in negative-pressure mode. This requirement needs to be added into the document. See ANSI Z88.2-1992 and OSHA 29 CFR 1910.134 for details.

Sincerely,

Jeff Weed  
Senior Product Specialist  
Member ANSI Z88.10 Respirator Fit Test Methods

October 5, 1998

DOCKET NUMBER  
PROPOSED RULE **PA 20**  
**(63FR38511)**

OFFICE OF  
RULEMAKING  
ADJUDICATION

'98 OCT -9 A9

DOCKETED  
USNRC

Rulemakings and Adjudications Staff  
Secretary, U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

RE: Comments of ISEA, The Safety Equipment Association regarding 10 CFR Part 20, Respiratory Protection and Controls to Restrict Internal Exposure to Radioactive Material.

Dear Secretary:

ISEA represents the leading manufacturers of safety and health equipment. ISEA members manufacture more than 95% of all NIOSH certified respirators. We offer the following comments to the proposed revision of 10 CFR Part 20.

**Section 20.1003, Definitions**

To make the terminology of the revised NRC standard consistent with current OSHA and proposed ANSI standard wording, change the word "disposable respirator" to read "filtering facepiece" and "Fit Check" to read "User Seal Check fit check".

The definition for fit test should be changed to "Fit test means a test, quantitative or qualitative, to evaluate the fit of a respirator on an individual and, in the case of quantitative testing, to determine a fit factor".

**Section 20.1702, Use of other controls**

ISEA believes that guidelines for ALARA analysis need to be better defined. Currently, there is a wide range of assumptions used in the industry when estimating the loss in efficiency resulting for the use of respirators. Recent studies indicate that these assumptions are incorrect. An EPRI study, "Effects of respiratory protection on worker efficiency", demonstrated that the loss of worker efficiency did not exceed 7%. This is contrary to current assumptions of 10% or more. We recommend that this standard require justification on ALARA programs that assume losses of worker efficiency greater than 5%. This will assure worker safety and is consistent with the NRC's desire to keep exposures ALARA.

**Section 20.1703 Use of individual respiratory protection equipment**

This section discusses the removal of "facelets" in 20.1703 which we believe is logical. However, the NRC should provide a detailed description of products that meet the intent of the standard as well as a discussion as to how they differ from

other forms of respiratory protection. If the wording is not changed, there is the opportunity for "facelets" to be used that cause significant reduction in worker efficiencies, without the appropriate ALARA discussion. Many styles of facelets resemble respirators in every feature, with the one exception that are not approved by NIOSH as respiratory protection. In the absence of a third party approval, the NRC should take some responsibility to assure that these products have some minimum performance and quality standards.

**Sec. 20.1703 ( c ) (6) and Preamble page 38513**

NRC states the licensee shall implement and maintain a respiratory protection program that includes, "Fit testing, with fit factor greater than or equal to 10 times the APF for negative pressure devices, and a fit factor of greater than or equal to 100 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 3 years."

ISEA believes that the frequency of fit testing should be at least once per year. Although, we understand that in the case of protection from radioactive substances there are accurate means to determine exposure of an individual and therefore respirator fit is actually determined through a very indirect method, we maintain that the fit test must still be evaluated annually. Indirect means of determining fit and/or exposure should not take the place of fit testing. Taking such an approach diminishes the importance of respiratory protection in individuals and thereby engenders little confidence in their use.

Although we agree that the use of respiratory protection should only be used as a secondary means of protection, and that engineering and administrative controls should be the primary means of protection, when respirators are used they should be used with the intent of them providing the maximum level of protection afforded to them. By not performing yearly fit tests one cannot ensure that they are in fact providing the maximum level of protection they are intended to provide. An individual's condition can change substantially in a year or less and could dramatically effect the efficacy of a respirator. Such conditions are weight change, use of dentures, use of corrective lenses, psychological conditions, etc. A supervisor or even the individual wearer either may not be aware or consider that such changes may effect the fit and ultimately the efficacy of the respirator.

In addition, fit testing on an annual basis provides the wearer an opportunity to be retrained and reminded of the proper use of respiratory protection and also allows management to ensure that the respirator is being used properly. We therefore recommend that fit testing be conducted on an annual basis.

**Section 1703 (g) and Preamble page 38514**

NRC states, Whenever atmosphere-supplying respirators are used, they must be supplied with respirable air of grade D quality or better as defined by the

Compressed Gas Association and endorsed by ANSI, in publication G-7.1, "Commodity Specification for Air," 1989, (ANSI-CGA G-7.1, 1989).

ISEA requests that the most current standard of ANSI-CGA be used. This is ANSI-CGA G-7.1, 1997.

**Appendix A to Part 20**

**Air Purifying Respirators** says "Single use disposable." NIOSH no longer has a designation for single use respirators. This should be changed to "Filtering facepiece".

**Footnote d Appendix A to Part 20 and Preamble page 38514**

In footnote d of the Assigned Protection Factors for Respirators, NRC states that "The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g. radioiodine)."

ISEA believes that there is no justification why an APF comparable to what is provided for particulate respirators, cannot be assigned to radioactive gases or vapors with good warning properties when a chemical cartridge exists that is appropriate for that contaminant.

**Footnote c of Appendix A Part 20 and Preamble page 38516**

Footnote c states, "Air purifying respirators with APF less than or equal to 100 must be equipped with particulate filters at least 99 percent efficient. Air purifying respirators with APF less than or equal to 100 must be equipped with particulate filters that are at least 99.97 percent efficient."

We believe that the footnote is in error and should read, "Air purifying respirators with APF of less than or equal to 100 must be equipped with particulate filters at least 99 percent efficient. Air purifying respirators with APF greater than 100 must be equipped with particulate filters that are at least 99.97% efficient.

NRC also requires "at least 99 percent efficient". NRC offers no justification as to why 95% efficiency filters should not be used. ISEA believes 95% efficiency filtering respirators should be allowed and given an APF of 10, as this what is allowed by ANSI for any half mask respirator with a minimum filter efficiency of 95%. We see no reason to only allow a minimum of 99% efficiency since if a wearer passes a fit test with a 95% efficiency respirator they must achieve a fit factor of at least 100, and therefore can assume to have a protection factor of at least 10.

**Footnote f of Appendix A Part 20 and Preamble page 38515 and 38516**

Footnote f states "Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains

some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 99 percent efficient and all other requirements of this part are met.”

ISEA believes that quarter chin masks should not be categorically eliminated for use by the NRC. If a respirator meets all requirements including NIOSH certification and it has been determined that a particular device fits on an individual (through fit testing) then that device should be permitted for use. General statements as found in the preamble that a particular type of device exhibits “erratic” face sealing characteristics should not be made. The efficacy of a particular device on a specific individual can only be determined on a case by case basis through a comprehensive respiratory protection program. Those elements which include training a fit testing will determine whether or not a particular device is appropriate for an individual.

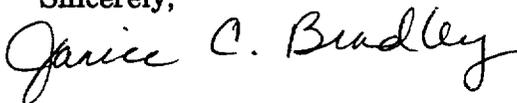
Additionally, ISEA believes that a half face piece disposable respirators without seal enhancing elastomeric components and are not equipped with two or more adjustable suspension straps should not be categorically discounted and effectively given an APF of 1. These respirators are half masks and provide the same level of protection as an elastomeric half face piece respirator with the required features.

If a respirator meets all requirements including NIOSH certification and it has been determined that a particular device fits on an individual (through fit testing) then that device should be allowed for use and given the appropriate credit for protection. general statements as found in the preamble that “NRC believes that without these components it is difficult to maintain a seal in the workplace” should not be made.

The efficacy of a particular device on a specific individual can only be determined on a case by case basis through a comprehensive respiratory protection program. Those elements which include training and fit testing will determine whether or not a particular device is appropriate for an individual. We don note that the NRC does give credit for those respirators that are fit tested to an APF level of 100 when the licensee performs the appropriate fit test. We do not understand why the NRC differentiates between these filtering facepieces and other half mask respirators when the result is the same. We believe that these respirators should not be treated in a different manner from other half face piece respirators.

ISEA appreciates the opportunity to comment on the proposed changes to the rule. Please call me if I can provide additional assistance.

Sincerely,



Janice Comer Bradley, CSP  
Technical Director



NUCLEAR ENERGY INSTITUTE  
98 OCT 19 AM 10:05

Lynnette Hendricks  
DIRECTOR,  
PLANT SUPPORT  
NUCLEAR GENERATION DIVISION

OFFICE OF  
RULEMAKING AND  
ADJUDICATIONS STAFF

October 9, 1998

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

Mr. John C. Hoyle  
Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**ATTENTION:** Rulemakings and Adjudications Staff

**SUBJECT:** Proposed Rule—10 CFR Part 20, “Respiratory Protection and Controls to Restrict Internal Exposures” (63 *Federal Register* 38511-July 17, 1998) and Draft Regulatory Guide GG-8022, Proposed Revision 1 to Regulatory Guide 8.15, “Acceptable Programs for Respiratory Protection” (63 *Federal Register* 40141-July 27, 1998)

Dear Mr. Hoyle:

The Nuclear Energy Institute (NEI)\* submits these comments on behalf of the nuclear energy industry in response to the subject notices.

The Commission has specifically requested comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a performance-based rule with a regulatory guide endorsing ANSI standards. We support such an approach because it will provide greater flexibility to licensees and permit more efficient and effective regulatory response by NRC to future technical developments and changes in industry consensus standards.

This approach also better reflects the direction of NRC policy on performance-based approaches to regulation and the mandate of the Technology Transfer Act of 1996

\* NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

Mr. John C. Hoyle

October 9, 1998

Page 2

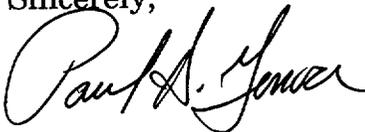
(Public Law 104-113), than does the proposed prescriptive rule. On the same basis, we recommend that draft regulatory guide (DG-8022) be revised to simply endorse relevant ANSI standards, noting exceptions being taken to the standards by NRC, and to retain guidance on assuring that exposures will be maintained as low as reasonably achievable (ALARA).

The proposed rule does not resolve inconsistencies between the regulatory requirements of the NRC (10 CFR Part 20) and the Occupational Health and Safety Administration-OSHA (29 CFR Part 1910) with regard to respiratory protection. We recommend that the final rule clarify that licensee respiratory protection programs that comply with OSHA requirements also will be considered to be in compliance with NRC requirements with regard to the basic elements of an acceptable respiratory protection program. This will provide increased flexibility for licensees desiring to implement a single, common respiratory protection program to address radiological and non-radiological airborne contaminants and hazards.

With regard to NRC's planned revision to NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials," we suggest that NRC consider eliminating the NUREG. Most, if not all, of the scope of the current NUREG contains information that is redundant with what should be contained in the rule, the regulatory guide, and the relevant ANSI standards. The final regulatory guide and referenced ANSI standards should contain all of the relevant information needed by the licensee to implement an acceptable respiratory protection program.

We have enclosed specific comments intended to help improve the usefulness and clarity of the proposed rule and the draft regulatory guide. If you have any questions regarding these comments, please contact Ralph Andersen of our staff at 202-739-8111.

Sincerely,



 Lynnette Hendricks

Enclosure

RLA/tnb

**NEI Comments on Proposed Rule - 10 CFR Part 20,  
 “Respiratory Protection and Controls to Restrict Internal Exposures”  
 (63 Federal Register 38511 - July 17, 1998)**

<u>Section</u>	<u>Comment</u>
<p>General</p>	<p>The Commission has specifically requested comment on whether the technical aspects of the rule should be addressed through alternative approaches other than the proposed rule, such as a performance-based rule with a regulatory guide endorsing ANSI standards.</p> <p>We endorse such an approach because it will provide greater flexibility to licensees and permit more efficient and effective regulatory response by NRC to future technical developments and changes in industry standards. This approach also better reflects the direction of NRC policy on performance-based approaches to regulation and the mandate of the Technology Transfer Act of 1996 (Public Law 104-113), than does the proposed prescriptive rule.</p> <p>Specifically, we suggest section 20.1703 should be revised to require that “the licensee shall implement and maintain a respiratory protection program consistent with ANSI Z88.2-1992, <i>American National Standard for Respiratory Protection</i>, as endorsed with exceptions in Regulatory Guide 8.15” (or similar wording). Much of the technical details in this section of the proposed rule regarding a respiratory protection program could be deleted because they are redundant to the criteria and the standards in the regulatory guide.</p> <p>The final rule should retain provisions specific to protection against radiation and radioactive materials that are not within the scope of the ANSI standard and provisions that address application for use of higher assigned protection factors.</p>
<p>General</p>	<p>The proposed rule does not resolve inconsistencies between the regulatory requirements of the NRC (10 CFR Part 20) and the Occupational Health and Safety Administration - OSHA (29 CFR Part 1910) with regard to respiratory protection. We recommend that the final rule clarify that licensee respiratory protection programs that comply with OSHA requirements will also be considered to be in compliance with NRC requirements with regard to the basic elements of an acceptable respiratory protection program. This will provide increased flexibility for licensees desiring to implement a single, common respiratory protection program to address protection against radiological and non-radiological airborne contaminants and hazards.</p>

Note: The following comments on the proposed rule should be applied within the context of Revision 1 to Regulatory Guide 8.15, if the cited sections are removed from the final rule consistent with our general comments on developing a performance-based rule.

20.1701	Change "practicable" to "practical" to be consistent with other sections of Part 20.
20.1703(a)	The phrase, "except as otherwise noted in this Part" (or similar wording) should be added to this section. This will help clarify, for example, that the use of continuous-flow, supplied-air suits is authorized as described in Appendix A.
20.1703c(5)	Change "physician" to "physician or licensed health care professional" as defined in 29 CFR 1910.134. This help achieve consistency between NRC and OSHA requirements and eliminate unneeded restrictiveness in the regulation.
20.1703(f)	The requirement that "standby rescue persons shall observe or otherwise be in direct communication with the workers" is unnecessarily prescriptive and may lead to adverse results. For example, such a requirement may lead to standby rescue workers having to be positioned in radiation areas that result in excessive exposure. The provision already includes a sufficient performance basis, i.e., "[standby rescue persons] must be immediately available to assist [the workers]..." The prescriptive detail on how to accomplish this is unneeded and should be deleted.
Appendix A	"Single-use disposable" respirators are included without an assigned protection factor. Footnote e clarifies that this type of respirator may be used under conditions in which no credit is taken for their use in estimating intake or dose. It is not clear if respirators used under these circumstances must be certified by NIOSH per 20.1703(a). This should be clarified in the final rule.
Appendix A	The assigned protection factor 10,000 for self-contained breathing apparatus (SCBA) used in the pressure-demand (PD) or positive pressure, recirculating (RP) modes differs from that included in the ANSI standard. ANSI Z88.2-1992, Table 1, does not include assigned protection factors for SCBA used in these modes because "a limited number of recent simulated workplace studies concluded that all users may not achieve protection factors of 10,000." The ANSI standard suggests that for emergency planning purposes, "an assigned protection factor of no higher than 10,000 should be used." NRC should include a discussion of its rationale for departure in the proposed rule from the ANSI standard, or change or clarify the use of the assigned protection factors (e.g., in a footnote).

Appendix A/ Footnote c	Footnote c contains an apparent typo that should be corrected. The second sentence should be changed to reflect "APF > 100" to be congruent with the first sentence.
Appendix A/ Footnote h	The wording in Footnote h should be changed to "immediately dangerous to life or health" for consistency with wording in ANSI standards and OSHA regulations.

**NEI Comments on Draft Regulatory Guide GG-8022, Proposed Revision 1  
to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection"  
(63 Federal Register 40141 - July 27, 1998)**

Page/Section	Comment
General	Much of the guidance in the draft regulatory regarding the basic elements of an acceptable respiratory protection program simply restates what is in ANSI standard ANSI Z88.2-1992. The guide should endorse the ANSI standard with noted exceptions and redundant material should be deleted from the guide. Guidance should be retained that addresses protection against radiation and radioactive material that is outside the scope of the ANSI standard.
General	The guide should clarify that compliance with OSHA requirements with regard to the basic elements of a respiratory protection program will be acceptable to the staff as compliance with comparable NRC requirements.

Note: Many of the comments below would not apply if the two "General" comments on the guide are adopted. These comments are provided in the event that the current scope of the guide is retained (i.e., in case the "General" comments are not adopted).

8/2.3	The last paragraph in this section allows for licensees issuing respirators to workers upon request in accordance with applicable State OSHA regulations. The guide should that an ALARA evaluation need not be performed and documented under such circumstances.
8/2.3 and 11/3.6	The guidance given in sections 2.3 and 3.6, regarding whether the use of respirators is appropriate for contamination control purposes, appears contradictory. The wording in these sections should revised to clarify intent. We believe that the approach taken in section 2.3, allowing for such use, provides better flexibility to address worker comfort, health and safety concerns, and should be retained.

10/3.3	The intent of this section is unclear. As written, the guidance appears to be inconsistent with requirements in Part 20 for monitoring, assessing, and recording individual dose from intakes, for example, 10 CFR 20.1502. This section should be revised to more clearly reflect Part 20 requirements, or it should be deleted.
12/4.3	This guidance given in this section is for <u>routine use respirator facepieces</u> stored in clear plastic bags is that they be handled and examined monthly. It is not clear what is intended by such a cursory inspection. Respirators that are cleaned, sanitized, inspected for defects, repaired (as needed), and then sealed in a plastic bag and stored properly (i.e., in accordance with ANSI Z88.2-1992, section 10.4) are unlikely to be damaged or deteriorate to any significant degree over time -certainly not to the degree that would be apparent in a cursory "handling and examination." Also, when issued, the respirator will be inspected and checked by the wearer prior to use. We suggest that the guidance be that such respirator facepieces in storage sealed in plastic bags "be inspected periodically." The period for inspection should be established by the program administrator based on experience.
12/4.3	<p>This guidance given in this section is <u>emergency respiratory protection equipment (SCBA)</u> "be donned and operationally tested frequently (at least quarterly)."</p> <p>Adequate operational testing of the equipment, e.g., as described in ANSI Z88.2-1992 (section 10.2), does not necessitate "donning" the equipment. Donning the respirator facepiece would likely require that it subsequently be cleaned, sanitized, and re-inspected, resulting in excessive wear on the equipment and unnecessary burden.</p> <p>The suggested inspection frequency, at least quarterly, is inconsistent with ANSI Z88.2-1992 (section 10.2) and OSHA requirements (1910.134(h)(3)(b) which require inspection of emergency equipment monthly. Emergency use equipment (SCBA) has the high potential quick donning and use in IDLH areas. Therefore, we suggest that the frequency for inspection be changed to be "monthly."</p>
21/5.3	Coaching and assistance may form an integral part of the fit-testing, which is recognized in the OSHA protocols referenced in this section of the guide. The purpose of the fit-test is to confirm the size and type of respirator needed by the wearer and the ability to obtain a proper fit and face-seal with regard to the assigned protection factor. This paragraph is not relevant (and may be contradictory) to that purpose and we suggest that this paragraph be deleted.

21/5.3	The next-to-last paragraph on page 21, beginning with the wording, "During training or operation..." appears to be out of place within the guide, i.e., it does not directly relate fit-testing, the topic of the respective section. We suggest that it be relocated to a more appropriate section of the guide.
23/6.3	For clarity, this section should be revised to reflect its applicability to "suspect" areas. As written, the guidance may be inferred to apply to all areas that have not been assessed, including a large number of areas for which there is no reason to assume that hazards may be present, e.g., due to process or historical knowledge. We suggest that the section be retitled as "Unknown and Unassessed Areas," and that the first sentence be revised to read "...the level of hazard is unknown and unassessed..."

# RESPIRATOR SUPPORT SERVICES

2028 Virts Lane Jefferson, MD 21755-8801 Tel: (301) 834-6008 Fax: 301-682-3731 Email: jph@radix.net

October 22, 1998

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
**(63FR38511)**

OFFICE OF  
RULEMAKING  
ADJUDICATION  
STAFF

98 OCT 28 P 3:18

DOCKETED  
USNRC

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attn: Rulemakings and Adjudications Staff

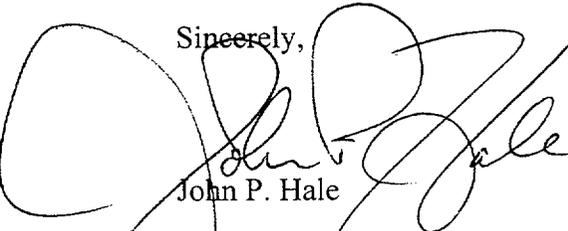
Though unfortunately late, this is to provide you with my comments on the proposed rule change to 10 CFR Part 20 as published in the Federal Register, Volume 63, Number 137 on Friday, July 17, 1998 regarding "Respiratory Protection and Controls to Restrict Internal Exposures", in hopes that you will still be able to consider them.

Also enclosed are my comments on the draft revision of Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection" which is related to this rulemaking.

I have taken the liberty of enclosing a copy of my curriculum vitae for your review.

Thank you in advance for your consideration of these comments. If I may provide any further information, please advise.

Sincerely,

  
John P. Hale

- Enclosures: Curriculum Vitae
- Comments on 10 CFR 20 - 2 pages
- Comments on Reg Guide 8.15 - 2 pages
- Respiratory Protection Update - Volume 8, Number 1*

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# RESPIRATOR SUPPORT SERVICES

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2028 Virtis Lane Jefferson, MD 21755-8801 Tel: (301) 834-6008 Fax: 301-682-3731 Email: [jph@radix.net](mailto:jph@radix.net)

## CURRICULUM VITAE

### *JOHN P. HALE*

Established the consulting firm: RESPIRATOR SUPPORT SERVICES, in August 1989 offering training, technical services, and consulting in occupational respiratory protection on a nationwide wide basis.

### PROFESSIONAL ACTIVITIES

International Society for Respiratory Protection Board of Directors  
American Industrial Hygiene Association Organizational member  
American Society of Safety Engineers member  
National Fire Protection Association member  
American Association of Occupational Health Nurses Patron member  
AIHA Respiratory Protection Committee member  
American Standards Institute member  
ANSI Z88.2 subcommittee member - 1992 edition & current rewrite  
ANSI Z88.10 subcommittee chairperson - current

### EDUCATION & TRAINING

"Radiation Protection and Control" - Health Physics Services, Inc.  
"In-Place Filter Testing Workshop" - Harvard School of Public Health  
"Quantitative Fit Testing Apparatus Using Oil Mist Test Aerosols" - Dynatech Frontier  
"In-House Respirator Cleaning System Training" - Hydro Nuclear Services, Inc.  
Factory Authorized Service Training on SCBA Regulators - Mine Safety Appliances  
Factory Authorized Service Training on SCBA Regulators - Scott Aviation  
"Respiratory Protection at Nuclear Power Plants" - Radiation Safety Associates, Inc.  
"Respirator Programs" - University of North Carolina / Duke University / NIOSH  
"Occupational Respiratory Protection #134", "Advanced Occupational Respiratory Protection", "Respiratory Protection for the Nuclear Industry", "Hazardous Waste Operations and Emergency Response", "Current Topics in Respiratory Protection",  
"Respirator Fit Testing". "Self-Contained Breathing Apparatus" - DBA, Inc.  
"Respiratory Protection 222A" - OSHA Training Institute  
"Confined Spaces" - National Safety Council / John F. Rekus

Undergraduate college courses at Frederick Community College in Maryland, Louisiana State University in New Orleans, and Monroe Community College in Michigan

**PREVIOUS EXPERIENCE**

1988-1989 Director, Respirator Programs - Radiation Safety Associates, Inc., Hebron, Connecticut. Responsible for organizing, developing and expanding the respiratory protection services offered. Supervised contract activities, conducted training courses and served as Associate Editor of the Radiological Respiratory Protection Newsletter. Developed and wrote complete set of Respirator Program procedures for client facility, Babcock & Wilcox / Naval Nuclear Fuel Division. Primarily responsible for obtaining contract with the Nuclear Regulatory Commission for the rewrite of NUREG 0041.

1985-1988 Director of Respiratory Protection Programs - Darell Bevis Associates, Inc., Chantilly, Virginia. Responsible for coordinating all training and consulting activities in the nuclear field. Served as instructor in all respiratory protection training courses offered by the company for government, general industry, and nuclear industry clients. Coordinated and supervised services in qualitative and quantitative respirator fit testing. Developed several new courses. Assisted in research projects related to respiratory protection. Conducted complete respirator program reviews and audits for client facilities.

1983-1985 Supervisor, Respiratory Protection Program - under contract to Detroit Edison Company, Fermi 2 Nuclear Power Station, Newport, Michigan. Responsible for entire development, setup and implementation of the respirator program, procedures and facilities.

1980-1983 Senior Health Physics Technician - under contract to various nuclear power plants; Three Mile Island, Dresden, Connecticut Yankee, Hatch, Rancho Seco, San Onofre, Pilgrim, Vermont Yankee. McGuire, providing radiation protection and respiratory protection technical services.

1976-1980 Operations Manager, Neutron Products, Inc. Managed a new division of the company offering field service for the inspection and integrity testing of high efficiency laminar airflow devices on a nationwide basis. Also served as Manager for the Cobal-60 Irradiator facility which utilized over a half-million curies of radioactive Cobalt-60 for sterilization and chemical processing of various materials.

# RESPIRATOR SUPPORT SERVICES

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10/22/98

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Comments on Proposed Rule 10 CFR Part 20, FR VOL.63, NO. 137, 7/17/98

by: John P. Hale, Respirator Support Services

re: **20.1003 Definitions**

*Disposable respirator* should be called *filtering facepiece*.

*This will conform to the terminology used by OSHA in their revision to 29 CFR 1910.134 and the agreed upon name for these products in the next revision to Z88.2. The term disposable is not descriptive nor useful. Any respirator can be disposable if cost is of no concern, or if the cost of decontamination and/or repair exceed the cost of a new device, then any respirator may be considered disposable. (this comment applies throughout the proposed rule)*

*Fit check (user seal check) should be called User Seal Check (formerly called fit check).*

Again, this will conform with the new term used by OSHA and the next revision to ANSI Z88.2. It has been agreed that we should use the new term because it may help remove any confusion about a 'fit check' being a type of 'fit test' because of the word 'fit'. Performed properly, a user seal check will provide as much information about the integrity of the facepiece as it will the facepiece to face seal.

re: **20.1703 (c)(6)**

Fit testing of positive pressure facepieces should have the same acceptance criteria as negative pressure facepieces. Since fit testing must always be done in a negative pressure mode, the acceptance criteria (required fit factor) should be at least 10 times the APF of the facepiece being tested in. Though I recognize that ANSI Z88.2-1992 says that facepieces used on positive pressure respirators only need an acceptance criteria of 100 - that provision is being changed in the revision, the subcommittee has already debated this issue and have reached a consensus in agreement of a minimum of 10 times the APF of the facepiece being tested in.

Of all the facepieces worn, those that are used with respirators that operate in a positive pressure mode, especially SCBA, are the ones that need to fit the best. Anybody that has experience with quantitative fit testing knows, beyond a shadow of doubt, that a fit factor of 100 on a full facepiece is a terrible fit - it is very

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# RESPIRATOR SUPPORT SERVICES

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Comments on Proposed Rule 10 CFR Part 20, FR VOL.63, NO. 137, 7/17/98

by: John P. Hale, Respirator Support Services

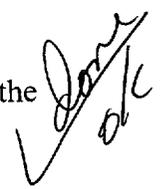
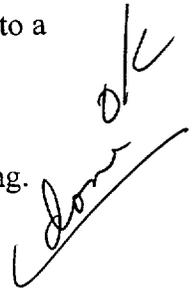
typical to see fit factors in the thousands or even ten thousands on facepieces that fit well. Almost without exception, the higher fit factors are associated with more comfortable facepieces - helping ensure that they will be worn properly in the workplace.

The issue of required frequency for fit testing is one where there is little agreement and not much real data. As you discussed in the preamble, there is anecdotal evidence at licensee facilities that suggests unlikely change in facepiece make, model, style, or size from year to year. However, nobody has really qualified that experience or put the data to scientific scrutiny. I believe part of the reason for seeing little change in that community is because the acceptance criteria that are used are too low. If we were to raise the required fit factor to a more meaningful level, I believe more year to year change would be seen - especially with the aging population now at work in licensee facilities.

Both OSHA and ANSI continue to require and recommend annual fit testing. Introducing this variable does little to help licensees that are going to be committed to following these documents anyway.

re: 20.1703 (g)

Though I agree with the reference to the CGA G7.1 standard, it should be to the most recent revision which is 1997.



# RESPIRATOR SUPPORT SERVICES

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Comments on Proposed Revision to Reg. Guide 8.15, July 98

by: John P. Hale, Respirator Support Services

re: Page 3, Line 4: "...unless the device is clearly and exclusively used for protection against nonradiological hazards."

Why does it have to be exclusively used? What if radiological and non-radiological respiratory hazards exist? In many cases, the non-radiological hazards may pose more of a health risk, but the NRC should still be concerned insofar as it may also be used to limit intakes of airborne radioactive materials. It is unclear just what was meant by this statement.

*addressing  
"limit intake"  
defining*

re: Page 7, 3rd paragraph: "For ALARA evaluations, a respirator-induced worker efficiency factor of up to 15% may be used without further justification."

Where is the scientific basis for the 15% number. There is no number that can be given. Each case must be estimated based on the circumstances and merits of a given operation. It is wholly unacceptable to allow the use of a fictitious number like this. There needs to be some justification for any number used. Can we expect this number to increase along with amount of acceptable gratuity on dining out?

*Done*

I have enclosed a copy of the Feature Article I published in my newsletter, *Respiratory Protection Update, Vol.8, No.1 (1st Qtr 1997)*, entitled, "Going Once, Going Twice. Sold - to the Industry with the Highest Person-Rem Price" that addresses this issue more fully and ask that it be considered as part of my comment.

re: Page 19, **5.3 Fit Testing** (same as comment regarding 10 CFR 20 proposal) *500*

Fit testing of positive pressure facepieces should have the same acceptance criteria as negative pressure facepieces. Since fit testing must always be done in a negative pressure mode, the acceptance criteria (required fit factor) should be at least 10 times the APF of the facepiece being tested in. Though I recognize that ANSI Z88.2-1992 says that facepieces used on positive pressure respirators only need an acceptance criteria of 100 - that provision is being changed in the revision, the subcommittee has already debated this issue and have reached a consensus in agreement of a minimum of 10 times the APF of the facepiece being tested in.

*Did*

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# RESPIRATOR SUPPORT SERVICES

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10/22/98

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**Comments on Proposed Revision to Reg. Guide 8.15, July 98**

by: John P. Hale, Respirator Support Services

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The issue of required frequency for fit testing is one where there is little agreement and not much real data. As you discussed in the preamble, there is anecdotal evidence at licensee facilities that suggests unlikely change in facepiece make, model, style, or size from year to year. However, nobody has really qualified that experience or put the data to scientific scrutiny. I believe part of the reason for seeing little change in that community is because the acceptance criteria that are used are too low. If we were to raise the required fit factor to a more meaningful level, I believe more year to year change would be seen. Especially with the aging population now at work in licensee facilities.

Both OSHA and ANSI continue to require and recommend annual fit testing. Introducing this variable does little to help licensees that are going to be committed to following these documents anyway.

re: Page 21, 5th paragraph

The use of a "containment chamber around the head and torso of the fit test subject to contain the smoke" is not safe practice nor was this fit test method validated this way.



# RESPIRATORY PROTECTION UPDATE

A NEWS LETTER • ISSN 1048-6658 • VOLUME 8, NUMBER 1

## FEATURE ARTICLE

### **GOING ONCE, GOING TWICE, SOLD - TO THE INDUSTRY WITH THE HIGHEST PERSON-REM PRICE**

Respirators of virtually every description have been used extensively in many industries for several decades to help protect workers by reducing their exposure to a variety of airborne contaminants. In the past, it could be argued that nowhere had this practice been more vigorous than in the nuclear industry. Commercial nuclear power plants have been recognized as having exceptionally well established programs, facilities and equipment to support the use of respirators. And use them they did, thousands of respirators were used at many of the sites as an effective way of decreasing worker inhalation of airborne radioactive contaminants and also for non-radiological purposes.

Though I have held radiological respirator programs up as a model for others to follow, I have also criticized for many years the seeming rush to use respirators in nuclear plants, there were many, many jobs that were just automatic respirator jobs with little or no real evaluation of the possibility of using various forms of engineering and/or administrative controls. But not much happened, thousands of respirators were being used as a matter of routine in situations that really did not warrant them.

Then something happened, people in the industry started talking about the possibility of dramatically reducing the number of respirators based on TEDE ALARA principles. Unfortunately, one aspect of this new thinking was based on some flawed information: specifically, the numerical assumptions about the effect of respirators on a worker's efficiency, or how much more time it may take to perform a given task with a respirator versus without a respirator.

Early in this recent history, a presentation was given by Ron Cardarelli on the effect of respiratory protection on worker efficiency and ALARA considerations at the 31st Annual Meeting of the Health Physics Society meeting in Pittsburgh, PA in 1986. In this presentation the author stated that many people were assuming a 25% loss of worker efficiency from using respirators, and that these assumptions were based on anecdotal information. The presenter went on to report that a study done at Three Mile Island nuclear station did not show any significant difference.

This remark, though I believe well intentioned, was perhaps the single most misquoted comment and the piece of information that was used out of context more than any other.

*(continued on page 6)*

**RESPIRATORY PROTECTION UPDATE** is published quarterly by Respirator Support Services, 2028 Virts Lane, Jefferson, MD 21755, (301) 834-6008, FAX: 301-682-3731, E-mail: "jph@radix.net" as part of an information update subscription service for \$280/calendar year. The News Letter alone, is available by subscription for \$90/calendar year. Editor: John P. Hale

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## **REGULATIONS UPDATE**

### **NIOSH**

The National Institute for Occupational Safety and Health (NIOSH) is looking for a few good N-series respirators. Their request for your help in their project is detailed in the January 6, 1997 letter on pages 3 & 4 of this newsletter.

### **OSHA**

Latest word from a source at the Occupational Safety and Health Administration (OSHA) is that the finishing touches are being actively worked on for the revision to 29 CFR 1910.134 - the General Industry standard for Respiratory Protection. They hope to be done with it by the end of April. The document then goes to the Office of Management and Budget where they are expected to take 60 to 90 days in their review. Therefore publication of the final rule is entirely possible by early July, 1997. Naturally, that is all subject to change.

## **CALENDAR OF EVENTS**

### **AMERICAN INDUSTRIAL HYGIENE CONFERENCE (AIHC)**

May 17-23, 1997

Dallas, Texas

Contact: AIHC Registration, Suite 250  
2700 Prosperity Avenue  
Fairfax, VA 22031-4307  
(703) 849-8888  
FAX# 703-207-3561

#### Future Convention Locations:

1998 - Atlanta, Georgia  
1999 - San Diego, California  
2000 - Orlando, Florida

### **INTERNATIONAL SOCIETY FOR RESPIRATORY PROTECTION**

8th Conference / September 22-26, 1997

Amsterdam

Contact: Lawrence Livermore National Labs  
Attn: James S. Johnson, L-379  
ISRP Conference  
P.O. Box 808  
Livermore, CA 94550

### **INTERNATIONAL CONFERENCE ON OCCUPATIONAL RESPIRATORY DISEASES**

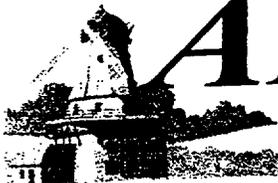
October 13-16, 1997

Kyoto, Japan

Contact: 9th ICORD, Secretariat  
c/o Japan Industrial Safety  
and Health Association  
5-35-1, Shiba, Minato-ku  
Tokyo 108, Japan  
+81-3-3452-6841 ext. 525

## **PUBLICATIONS**

The International Society for Respiratory Protection (ISRP) has issued a *Call for Papers*, which appears on the next page, for its upcoming Eighth Conference, September 22-25, 1997 in Amsterdam.



# AMSTERDAM '97

Eighth Conference Of The  
International Society For Respiratory Protection



## CALL FOR PAPERS

SHEET 1

### ISRP

The International Society for Respiratory Protection (ISRP) is a non profit organisation which aims to help maintain the health and safety of those who wear respiratory protective devices.

The Society, established in 1982, has members in over 28 countries divided into four sections.

Every two years a four day conference is organised to provide a venue for technical presentations on respirator research, standards, equipment, protection programmes and use.

It provides an opportunity for all section members and others to exchange information on aspects of respiratory protection.

Previous conferences have been held in St Paul, USA (1983), York, UK (1985), Toronto, Canada (1987), San Francisco, USA (1989), Winchester, UK (1991), Tokyo, Japan (1993) and Vancouver, Canada (1995).

The venue and date for the next ISRP conference is :-

**Eighth ISRP Conference**  
**KRASNOPOLSKY GRAND HOTEL**  
**22-25 September 1997**

Further information can be obtained by contacting Peter Steel the 1997 ISRP Conference Co-ordinator :

Address : PO Box 7228  
Tadley  
Hampshire  
RG26 3WQ  
England

U.K Phone : (0118) 9826522  
U.K Fax : (0118) 9824813

Papers on any aspect of respiratory protection will be considered for the 1997 ISRP Conference for which a list of suggested topics is given below. Submission of an abstract will be required before May 31st 1997. It will also be helpful to receive a notification of an 'intent to present' before December 31st 1996 to aid in the design of the conference agenda. All material submitted will be viewed before being accepted, and will be selected on the basis of quality, relevance and originality.

### Suggested Topics :

- ♦ Effective respiratory protection programmes.
- ♦ Implementation of respiratory programmes.
- ♦ Evaluation of programmes.
- ♦ Standards for respiratory devices.
- ♦ International regulations.
- ♦ Respiratory protection research.
- ♦ Air filtering and air supplied respirators / Breathing apparatus.
- ♦ Physiology and Bioenvironmental concerns.
- ♦ Workplace protection factor studies.
- ♦ Asbestos.
- ♦ Terminology.
- ♦ Firefighting.
- ♦ Assigned protection factors.
- ♦ Chemical defence.
- ♦ Nuclear installations.
- ♦ Mining industry.
- ♦ In space and under water.
- ♦ ISO 9000 considerations.

### Intent To Present :

If you would like to present a paper on one of the topics listed here or any other relevant subject area then please notify the 1997 Conference Co-ordinator. This can be done simply by completing your details on the reverse of this Information Sheet, indicating your intent to present and then sending the 'ready to Fax' page to the number given.

If you don't have access to a Fax machine then copy the page details and send to the address provided.

### Submission Of Abstract :

If you intend to present a paper you will need to provide the 1997 Conference Co-ordinator with an abstract by May 31st 1997 for inclusion in the conference booklet. However, if you are not currently in a position to provide an abstract then a simple outline of your intent to present on the form overpage will suffice until a suitable abstract is available for inclusion by this date.

### Request For Further Information :

Further details of the 1997 ISRP Conference will be sent to you on receipt of your 'intent to present'. If you are interested in attending the conference but do not intend or are unsure about presenting then indicate with a 'tick' in the box overpage to receive further information on cost, bookings, accommodation and other information sheets that are available.

This is one of a number of information sheets which cover aspects of the 1997 ISRP Conference, such as booking, accommodation, sponsorship, exhibition, etc. A sheet, giving a simple overview of the conference and a full list of the available information sheets can be obtained from the 1997 ISRP Conference Co-ordinator. Further sheets will be made available as and when the need arises.



Centers for Disease Control  
and Prevention (CDC)  
National Institute for Occupational  
Safety and Health - ALOSH  
1095 Willowdale Road  
Morgantown, WV 26505-2888

PHONE: (304) 285-5907  
FAX: (304) 285-6030  
January 6, 1997

John Hale  
Respirator Support Service  
2028 Virts Lane  
Jefferson, Maryland 21755

Dear Mr. Hale:

The National Institute for Occupational Safety and Health (NIOSH) is conducting a user survey of N-series respirators certified under Title 42 Code of Federal Regulations, Part 84 (also referred to "Part 84"). The goals of this survey are to identify workplace environments and contaminants that may be degrading to the filtration efficiencies of these filters. This is a research effort and in no way will be used for enforcement purposes.

This survey will involve collecting used N-series respirators from a variety of workplaces and testing their efficiencies under the conditions of the Part 84 certification test. This may provide some insight into the effects of specific aerosols on respirator filtration efficiencies.

Along with the filters, we will be asking participants to provide the following information:

1. The make, manufacturer, and model of the N-series respirator.
2. A description of the work that was performed while wearing the respirator.
3. The duration of respirator wear.
4. A description of the materials (such as aerosols, liquids, vapors and gases) that may have challenged the respirator.

Only N-series filters certified under Part 84 will be accepted for this survey. All three filter efficiency classes (95%, 99% and 99.97%) will be accepted. I emphasize that NIOSH is not

Page 2 - Mr. John Hale

asking anyone to collect respirators at this time. I will notify participants in writing when it is time to do so.

Please share this information with your industrial hygiene associates and have anyone who is interested in participating contact me. My telephone number is (304) 285-5970 and my E-mail address is [vzb3@niosr1em.cdc.gov](mailto:vzb3@niosr1em.cdc.gov).

Sincerely yours,



Michael Bergman  
Air Purifying Respirator Section  
Certification and Quality  
Assurance Branch  
Division of Respiratory Disease Studies

(continued from page 1)

Whether it has been an intentional attempt to fabricate and mislead by falsifying information for the benefit of cost savings, or whether it has just been a natural rumor-like evolution fueled by a common interest in being able to reduce respirator use for worker comfort and safety, it has happened.

I happen to believe there has been a little of all of it - but that doesn't really matter. In the end, we have not had many serious exposures, there has not been a life threatening incident. So why all the hoopla and complaining? Well, it is simply an attempt to set the record straight and maybe to get people to go back and look at how respirator use determinations are made. And surely, it is an attempt to get people to stop arbitrarily using numbers like 20% and 30% for assumptions about respirator wearer efficiency reduction. They are bogus!

One of the earliest published articles I found on this topic was *A Method for Optimizing the Use of Respiratory Protection in Radiation Areas* authored by Steven E. Merwin and Jerome B. Martin of Battelle - Pacific Northwest Laboratories, and Roger C. Brown of Westinghouse Hanford Company as published in Radiation Protection Management (Vol.6, No.1, pp 64-71, January/February 1989). Under the heading "Respirator Use Is Not ALARA" the authors state:

When possible, the sum of external and internal exposures should be optimized to ensure that the total effective dose

equivalent is as low as reasonably achievable (ALARA).

I agree 100%, indeed this sentence might even be strengthened by making the "should" a "shall" or "must":  
..."exposures must be optimized"... The article continues:

Emphasizing total prevention of internal exposures is contrary to ALARA principles because steps taken to reduce internal exposures may cause higher internal exposures.

Here, I disagree with the way the sentence is worded and the resultant influence it may have had. I contend that it should have read: ...Emphasizing total prevention of internal exposures **may** be contrary to ALARA principles'... There is a big difference in the wording. The authors continue this discussion with an assumption:

...if the worker's efficiency is reduced by 10% or more due to wearing the respirator, the external dose equivalent will be increased ...

Where does the number 10% come from? No clue is given. The implication I see is that the authors apparently felt that was a reasonable guess. I find the next step in the thinking written about in this article more than a little disturbing:

An equally important factor in the decision on issuing respirators is cost. Costs associated with respirator use include those of cleaning and maintaining the respirators and replacing consumables and those associated with worker training, fit testing, and medical evaluations. Costs associated with not using respiratory protection equipment include increased

bioassay frequencies, increased health physics support, and potentially higher administrative costs for documentation and reporting.

Sure, I understand virtually everything has a cost/benefit aspect to it - it is not justifiable to spend \$50 billion on shielding to reduce exposure rates by 1 mr/hr- but I simply fail to understand the assumptive transition the authors make that something in the conceivable cost range of a respirator use is of any significance or can be used a factor in a formula to calculate whether or not a respirator should be worn. I cannot think of any other workplace or industry where this type of rational is used - or should be. What this implies here is that radiation exposure (internal or external, or both combined - TEDE) below established annual legal limits is of no consequence whatsoever, or at least that it is not worth the cost associated with minimizing or eliminating it. How expensive is too expensive? Why should we ever issue respirators if their use costs anything? Yes, I read the rest of the article and I think I understand it - I just think that this is classic example of the "ends justifying the means."

I would be remiss if I did not cite at least one more passage from this article, near the end of a section they call "The Optimization Method":

Another factor that may be difficult to quantify is Eff, the relative efficiency experienced by workers using respiratory protection. In practice, the actual efficiency would be specific to each task and could only be accurately determined by thorough (and costly) simulations of these tasks.

Here, a simple truth is stated, but the article goes on to describe how in the face of no scientific data, and prohibitive costs to obtain such data, you should proceed to just pick numbers that seem reasonable to you.

Even the lofty Health Physics Society Journal (Vol.59, No.6, pp 925-929, December, 1990) published a paper that builds an article entitled, *Optimizing Radiation Worker Protection: The Practical Application of Risk Analysis*, written by Michael C. Williams of the Union Electric Company, on the anecdotal 25% number mentioned by Cardarelli in his presentation at the 31st Annual Meeting of the Health Physics Society in 1986.

The 25% increase in work time is a typical value used to account for the decrease in worker efficiency due to use of respiratory protective equipment.

Another discussion appeared in Radiation Protection Management (Vol.9, No.4, pp 22-29, July/August 1992) written by Regis A. Greenwood, CHP and Thomas J. O'Dou, CHP of Toledo Edison Company. In the section of their article entitled, *Determination of the Dose Due to Wearing a Respirator* they express the following:

Wearing respiratory protective devices (filter respirators, supplied air respirators, or self-contained breathing apparatus - SCBA) slows the worker in the performance of the job. This is due to discomfort, reduced ability to breathe freely, reduced visual acuity, tunnel vision, and reduced communication ability. Over the past 28 years working in various parts of the nuclear industry, we have seen estimates of this increase

in work time within the following ranges:

Filter respirator: 10-50 percent  
Supplied air respirator: 20-100 percent  
SCBA: 50-200 percent.

For the purpose of this article, and for future planning, an increase in work time of 20 percent in a radiation field was chosen. This was chosen arbitrarily without documented evidence purely as an estimate, based on experience.

I couldn't have said it better myself, the number was plucked out of the air. But, that doesn't keep them from proceeding to use it and justify their position:

We assumed the stay time in the area increased by 20 percent due to wearing a respirator. The dose without respirator use was estimated. This was calculated to be 66.34 person-rem, demonstrating that 13.27 of the 79.61 person-rem received were *as a result of wearing respirators*.

Yet another discussion of this issue appeared in same issue of Radiation Protection Management, (Vol.9, No.4, pp 44-48, July/August 1992) written by Jack N. Earley of Radiation Safety Associates, Inc. entitled, *Professional Suicide: Disregarding the Respiratory Protection Realities of the Revised 10 CFR 20*. Much of this discussion is sound thinking, but once again, near the end of the article the author repeats the 25% number without any basis:

What would be the cost if you decided to put this worker in respiratory protection equipment to save that 50 mrem? I've heard estimates of greater than 25 percent loss of efficiency (you will want to perform your own tests for typical work in characteristic stressful environments - heat, radiation, etc. - in

your facility) from wearing respirators (see "Dose Expansion from Using Respirators," pages 22-29, in this issue). At 25 percent, that means our break-even point is 50 mR/hr; anything higher is going to cost our worker more than 12.5 mrem each hour. In that case, you'll have violated ALARA, and if you have a particularly politically active worker, you may find yourself with a lawsuit, as well, for costing that person unnecessary radiation dose and unwarranted physical and psychological stress.

In a paper dated September 24, 1992, prepared for presentation at the 1992 REM Seminar by Benjamin W. Morgan, Project Specialist - Health Physics, Carolina Power & Light Company, entitled *Guidelines for the Optimization of Radiation Worker Protection*, the author once again reinforces a number that has no real basis in scientific fact.

When considering the effect of respirator use on external dose the most important factor is the impact on worker efficiency. There is not a lot of data available yet on the effect of respirators on radiation worker efficiency and values in the literature vary from 3% [Kahn and Baum] to 25% [Williams]. This impact can be expected to vary depending on the type of work, the work environment, and the ability of the individual worker to cope with respirator usage. If time and facilities are available, performing the job on a mock-up both with and without respirators may be the best way to determine this factor.

The 'Williams' reference quotes Cardarelli's anecdotal mention of as high as 25%. But Morgan's article references Williams as if the 25% came from a valid scientific study. This, as we know now, is not true - it was merely mentioned as anecdotal information.

Once a number appears in print and begins to get repeated, it sometimes takes on the appearance of real data. Interestingly enough, the 3% number did come from a good scientific study that was done at Ontario Hydro about 1990. It was done on workers in a form of supplied air suit - so that data was discounted and ignored.

On January 1, 1994, the rules of game officially changed for respirator use under jurisdiction of the Nuclear Regulatory Commission (NRC). Some licensees implemented the changes made to 10 CFR 20 earlier than that. Significant among the changes was the charge to licensees to ensure that they maintained total effective dose equivalent (TEDE) as low as is reasonably achievable (ALARA) while working in airborne radioactivity areas. This was certainly a good thing.

Part of the basis for this change was discussed by the NRC in section 04.03.d of their Temporary Instruction 2515/123 (NRC Inspection Manual) which was issued on March 15, 1994 and entitled, "Implementation of the Revised 10 CFR Part 20".

04.03 TEDE/ALARA and Respiratory Protection

...  
d. Review the licensee's implementing procedures.

...  
In the process of balancing the external and internal worker risks, licensees will usually assume some loss of worker efficiency when wearing a respirator. While changes in worker efficiency are ideally determined empirically by the use of realistic mockups (this is not required), literature searches of workplace respirator studies designed to

determine loss (or gain) in worker efficiency show expected findings. That is, the effect of wearing a respirator varies with a number of variables -- environmental conditions, type of respirator, level of work (effort), work duration, type of work, individual worker differences, etc.

Therefore, it cannot be assumed that worker efficiency will increase if workers stop using respirators.

Because of the many variables associated with respirator use for specific jobs, licensees may be found using a range of efficiency factors. However, in the absence of specifically applicable factors, licensees may use default factors for each type of respirator. The following worker efficiency improvements resulting from removing respirators are documented in the literature (chiefly from military, and non-nuclear workplace studies):

| <u>RESPIRATOR TYPE</u>       | <u>RANGE (%)</u> |
|------------------------------|------------------|
| Negative pressure, full-face | 5 -- 30          |
| Supplied air, hoseline       | 15 -- 60         |
| SCBA                         | 40 -- 200        |

The use of an efficiency factor higher than those above should be technically justified by the licensee.

Everything about that is correct except the numbers cited for respirator worker inefficiency. As it turns out, the basis for these numbers is only anecdotal. There is no hard documentation of scientifically produced numbers in the ranges cited in the literature - from any source.

Associated with this change was a major culture shock for many of the so-called "radiation workers" who, along with much of the entire workforce in this

country are aging - they have been around for quite awhile now. Lots of workers, both utility employed and contractor have been working for a long time. And, for the previous several decades had become very accustomed to wearing respirators and other protective clothing as a matter of routine in areas of nuclear power plants where known or suspected surface or airborne radioactive contamination may have been.

Along with the aging process, I can tell you from my own perspective, it becomes harder to accept any change - especially when it seems to contradict everything we have been told and have experienced. So, perhaps some of the resistance to change is just organic. In this case, where workers were told, almost overnight in some cases, that jobs that always required respirators now all of a sudden do not - there was resistance. Another facet was perhaps that of employees tending to be a little leery of anything employers say or do, especially when it relates to some activity that is going to save the employer money - and especially when it is a health and safety related matter.

One of the situations that arose occurred at the Dresden Nuclear Station in Dresden, Illinois. The Commonwealth Edison plant was the subject of a feature aired by WFLD-TV, Fox 32 News in Chicago. The following is a transcript from part of the April 18, 1994 broadcast:

Walter Jacobson, anchor:

Tonight, the Nuclear Regulatory Commission is taking a closer look at the state's most troubled

nuclear power plant. Federal inspectors say that a pipe burst at the Dresden plant last January, spilling fifty-five thousand gallons of water into the basement of the building that houses the reactor. (Visual of Commonwealth Edison plant in Morris, Illinois.) The reactor has been shut down since 1978, and the NRC says the leak did not pose any health dangers to anyone. The commission is faulting Commonwealth Edison for not paying closer attention to the plant's stability.

And Dresden is not the only plant in the news tonight. There are new and pretty serious questions being raised about the nuclear plant in Zion. How safe is it? Fox News has learned exclusively that the federal government is right now investigating charges by some workers in that plant that Con Ed may unnecessarily exposing them to radioactive contamination.

David Johnson (Zion Plant Employee): Commonwealth Edison is practicing the policy of forcing the people to go into an environment that they feel that their health is risked. (sic)

Jacobson: David Johnson works at Zion. He says he is afraid for his life. The same for Mike Nabbitt, afraid enough, he says, to be thinking about quitting.

Mike Nabbitt (Zion Plant Employee): I don't want to work somewhere where my health is put at risk, in the first place. So if it's going to cost me my job, so be it.

Jacobson: He's also afraid of being fired for talking about being afraid. What they are worried about are these respirators that the company is now taking away from them. (Visual of respirator) A new policy to restrict the use of respirators because, says Con Ed, "it is possible a respirator may decrease efficiency, cause you to work more slowly, and thereby, in fact, increase

your exposure to radiation." (Graphic of quote) Not so, says Mike.

Nabbitt: Without a respirator on, you can't see, smell or taste radiation. And a person that doesn't know what's going on or can't see, they're going to be moving slower and more cautious to make sure they're not going to stir up the contamination and receive it internally. A person wearing a respirator won't have that concern, they'll just move about freely.

Jacobson: Johnson and Nabbitt have complained to the NRC, the Nuclear Regulatory Commission in Washington. And a few weeks ago, NRC officials came here to Zion to talk to Johnson and Nabbitt and others. (Visual of Zion plant)

Nabbitt: They looked into it right away. Told me I had a legitimate complaint, and that, that was a concern.

Jacobson: Concern that working without respirators in there may be dangerous, and the NRC has other concerns as well: Is Con Ed being honest with its workers at Zion; how did Con Ed determine the respirators decrease efficiency?

Johnson: They never once consulted with the workers, never once. And to me, that's the worst thing. We're the experts on the job. Why not come and ask us, "Will the respirators slow you down or not?" Before now we could go in, work as fast as we want, we didn't have to worry about airborne contamination, because the respirator protected you. To me, it's a piece of safety equipment. We have signs around saying, "you are responsible for your own safety," and why not let us be responsible for our own safety.

Jacobson: "Let us wear these respirators," they say, "or at least talk to us about our fear of not wearing them."

Johnson: It's gotten to the point of domination, "You'll do it or we'll get somebody else to do your job." In fact, that's - those were the words of my general foreman.

Jacobson: They both say that's how it works at Zion, and from their point of view, it's becoming increasingly dangerous in there.

Johnson: In fact, I can remember in the old days, remember seeing people up there, and it was, you know, big gossip to hear that somebody got internally contaminated. Where now, it's, you know, we're talking two or three people a week that I know of.

Nabbitt: Yeah, you're talking zero in eight years to two dozen in two months.

Jacobson: It is important to add some perspective to this story now, which is that a clear and present danger of contamination at the Zion plant has not been proved by those workers there. Con Ed says it would not take away the respirators if that were dangerous. The NRC says it's checking it all out, and will have a judgment later this week.

Now, on the matter of how Con Ed is handling its workers fears about those respirators? It's fair to say there's no need to check that all out. In the three weeks I've been working on the story, I've discovered that when it comes to the fears about the respirators, Con Ed just couldn't care less.

Pretty dramatic stuff, eh? Well, such television spots are sometimes - well, you know. However, the point is that the *change* that was taking place was met with resistance. Each power plant had its own experience. I personally heard reports from respirator program supervisors from dozens of facilities and their experience ranged from having a transition as smooth as butter to major

revolt. All agreed though that the key to making the change was through training and educating the workers and through time.

In the July/August 1994 (Vol.11, No.4, pp 70-74) issue of Radiation Protection Management, in an article entitled, *Respiratory Protection and Worker Efficiency - A Review* the author, Gary S. Kephart of Clinton Power Station, continues the rumor about the number 25%. First, in the Abstract:

... This article summarizes some aspects of the industrial hygiene literature which 1) suggest that 25 percent loss of efficiency is typical...

Next, in the article itself, under the heading *The Best Guess of Better Health Physicists*:

Several recent articles in the health physics literature [1,2,3] have discussed this "inefficiency factor" or "respirator decrement" and recommended estimates of 20 to 25 percent increase in task performance duration.

Ironically, reference 3 cited above is an article from the July/August 1989 (Vol.6, No.4, pp 49-53) issue of Radiation Protection Management that I co-authored while employed by the magazine's new publisher. The following excerpt comes from that article:

The use of respiratory protection equipment can be a serious strain on the wearer. There are a few ways to combat some of this stress, as well as a few considerations to avoid it entirely.

All regulations and guidance tell us to avoid the use of respirators wherever

feasible or practicable. We are supposed to use process or other engineering controls, increase surveillance, and limit worker exposure times before assigning respiratory protection devices. More emphasis should be given to actually trying to comply with this directive. Limit the use of respirators and employ engineering or process controls wherever possible. If airborne levels permit, consider doing the job without respirators. In some cases, such as high radiation areas, avoidance of respirator use may lead to a more rapid task completion, thereby limiting the total exposure (both internal and external) to the worker. The small amount of internal dose received may be offset by the reduction in time spent and subsequent dose received from exposure in a high radiation area.

Again, there is no mention of numbers like 20% or 25% or any other specific values.

A little further on in the 1994 article, the author states:

The purpose of this review article is to encourage pursuit of these efforts with an awareness of the previously published research on this subject. These days all of us seat-of-the-pants health physicists are often asked to produce the documented technical bases [sic] for our actions. In this environment, it might be hard to implement and initial 25 percent inefficiency estimate (pending its refinement through experience) if its only basis was "tribal knowledge." Fortunately, there is abundant published literature that suggests the 25 percent estimate for respirator induced inefficiency is entirely reasonable and defensible.

Interesting choice of words - "suggests...estimate".

In Kephart's *Epilogue* (give me a break, *Epilogue*?) the stage is set for another irony in this soap opera:

While this article was in the review-publication cycle, the author became aware of a utility-sponsored effort through the Electric Power Research Institute (EPRI) to evaluate respirator impacts on worker efficiency. The mock-up study, targeted for the fall of 1994, will utilize an environmental chamber and nuclear workers at General Public Utilities, and build upon a previous study performed by Yankee Atomic Electric. Both the proposed EPRI study and its YAE predecessor are outgrowths of the Three Mile Island study mentioned in this article - in that Ron Cardarelli of YAE has been a primary investigator in all three. The article has cautioned that there are innumerable variables and potential confounding factors affecting the design of a mock-up experiment. Nevertheless, this third-iteration study, with EPRI backing and a multi-utility steering committee, is the industry's best hope for quantification of the inefficiencies attributed to respirator usage in the nuclear occupations.

Isn't it odd that there was such anticipation that this study would produce the numbers needed to get people out of respirators - numbers in the 20% to 50% range. And then, when it turned out that the study showed a small decrease in worker efficiency - the study is downplayed as being flawed in its design - therefore not producing usable numbers because of the non-representative conditions.

The study, "Effects of Respirators on Worker Efficiency" (EPRI TR-105350, Project 3099, Final Report June 1995) which was sponsored by the Electric

Power Research Institute (EPRI) to evaluate the effect on worker efficiency while wearing full facepiece air-purifying respirators did indeed get done. The study showed that workers' performed the tasks from 1% faster to 7% slower when wearing respirators.

In a June 1996 *Nuclear News* article entitled, "Respirators, internal dose, and Oyster Creek" there appeared a pretty typical presentation on this subject matter. Some of what was said in this article is troubling.

It is worth noting up front that I have personally had the experience of having been interviewed by telephone for an article written by a staff writer at one of the major industry publications that resulted in no end of misery. The quality of such articles, technically, is subject to the whim and subject familiarity of the given writer. There are often misquotes and misinformation - it happens all the time. Some English major that couldn't get any other job goes to work for an editor and gets a writing assignment. They get on the phone and find "experts" on their assigned topic, sometimes they actually make a site visit and do investigative reporting, they plug in a few file photos (often with problems of their own) - and they bang out an article to fill a space and meet a deadline. Rarely, do the interviewed parties have an opportunity to review the article before it gets published. So I do not point the finger of blame at the gentlemen that was interviewed - I have no way of knowing what he actually said or thought.

Nevertheless, this article did get published, and presumably people in the

industry read it and may have used the information it contained. The article (like all other articles, including mine), with all of its good points and its bad points, its insightful passages and its misinformation is now "out there" - it is published "in the literature" - it may be used in research by another writer and bits and pieces culled and cited and built upon (just like the article you are now reading does). And it certainly is available for others in positions of responsibility to look to for guidance.

Well, specifically, in the article the author talks about the respirator reduction effort at Oyster Creek. He also talks about a study that had been done on-site in the previous year by the Electric Power Research Institute (EPRI) - the one in which Ron Cardarelli was the principal investigator. The article revolves around an apparent interview with Oyster Creek's Director of Radiological Controls, Roger Shaw. In part, the article states:

While the premise of not wearing respirators to save dose is sound, the analysis to do so shows it is still a difficult decision. A study done last year by the Electric Power Research Institute has shown that dose savings in the respirator versus nonrespirator debate may not always be as great as thought. Nuclear plants have often calculated an expected dose number for a typical job. In the past, that estimate might have said, for example, "If you do the specific job without a respirator, the job will run approximately 25 percent faster than with a respirator, thus a dose savings."

Here is a perfect example of how this 25% number keeps getting mentioned without any basis in fact. Also,

interestingly enough - when the author did not have anyone to quote on this statement - he just created a statement in quotes and attributed it to commonspeak. The article continues:

But EPRI's study, "Effects of Respirators on Worker Efficiency," which was conducted last year at Oyster Creek in an environmentally controlled chamber to quantify estimates for the industry, showed that for two maintenance tasks - bolt torquing and a manual dexterity test - the savings in dose and time was less than anticipated when comparing respirator wear to nonrespirator wear. The results of 20 workers performing the maintenance tasks showed that "the mean percentage difference in time to complete a strenuous task with a respirator was between one percent faster to five percent slower," the study said.

As EPRI pointed out several times in the text of its study, however, the two specific maintenance tasks were conducted in controlled and safe conditions, and they were not designed to be representative of work performed by teams where worker communication was essential for task completion. Actual plant conditions and tasks can skew the results, said Shaw, who was on hand to view the EPRI tests at Oyster Creek. "There are variables involved," he said. "You have to take into consideration the time involved for a job, the accessibility to the workplace, if it has a high dose rate, and, very important, the physical impact that wearing a respirator will have on an individual."

Another media account, this time a small article that recently appeared in *The Boston Globe* on November 13, 1996 was headlined: *2 at Conn Yankee to be tested for exposure:*

Two workers at Connecticut Yankee nuclear power plant may have inhaled more than their annual limit of radiation in just 20 minutes earlier this month when they stirred up highly contaminated paint dust.

Northeast Utilities, owner of the Haddam Neck, Conn., plant, has hired two health physicists from the University of Massachusetts at Lowell to determine how much radiation the workers absorbed on Nov. 2 when they collected radioactive paint chips by hand and did not wear respirators.

"They shouldn't have been doing some of the work they were doing and at least one of them was walking in an area he shouldn't have been," said spokesman Neil Sheehan of the Nuclear Regulatory Commission. He said respirators would have greatly reduced the amount of radiation the workers ingested.

The NRC estimated the workers could have inhaled enough alpha particles of radiation to expose their bones to 50 rems of radiation over 50 years as the particles pass slowly through their bodies. Such exposure would increase their lifetime risk of cancer. However, Clayton French, one of the Lowell health physicists, said the workers showed no signs of radiation sickness and predicted the increased risk would be small.

The workers were exposed when they entered a part of the reactor containing loose surface radioactive contamination, NRC officials said. They scraped paint and debris from the surfaces, stirring radioactive dust into the air.

Exposure-measuring devices they wore showed less than one third of a rem of radiation on their skin, far below the 5 rems per year limit set by the NRC. But what they had ingested can't be measured so easily, prompting an NRC investigation.

And of course, there have been other incidents that have occurred not mentioned here - some insignificant, some not so insignificant. The point is, people are being exposed internally in many cases where there is not TEDE ALARA justification.

Another ramification of this change has been the variety of ways people have found to deal with facial contamination. In the absence of respirators, the workers' faces are now exposed to contamination as they were not before. If surface (smearable) radioactively contaminated material contacts the face there is some risk of direct ingestion and/or inhalation. When we had people in respirators this potential was typically not a concern. However if something brushes against the face, or splashes on, or just deposits on from airborne activity, or through what we characterize as poor work practice - the worker touches his own face with a contaminated hand or arm, facial contamination may result. This may or may not be a real problem. Most instances of facial contamination are readily dealt with and are of no consequence. There can however, be some very troublesome cases.

Various power stations have been very creative in coming up with "facial PCs" or protective clothing for the face. The list of contraptions is long: ninja hoods with goggles, ski masks, disposable face shields with dust masks, full face shields, painters masks, surgical masks w/ safety glasses, bubble hoods modified with filtered air blowers, etc., etc. In cases where respirators are modified or non-NIOSH approved respirators (some dust masks and surgical masks) are used

in this application, I believe it is bit of a stretch of the imagination. What are they being used for? Some would say just to protect the face from contamination. Well, yes I see that this would be the case - but, isn't it also true that some of these devices are also providing respiratory protection? Certainly they are. Then the argument comes that since a respirator is not required, you do not have to use NIOSH approved equipment. Only the NRC and DOE have yielded on this point. OSHA has stated many times that whenever respirators are provided or used they must be NIOSH approved.

This article is not written with the intent of damning the net effect of what has taken place or anybody involved in that effort. Blame is not the motive. It is written in the spirit of continuing assessment of what the right thing to do is - related to respirator use in radiological environments. It is not this author's belief that we should return to the old ways of issuing respirators - far from it. Most of what has happened is a good thing. Contrary to my obvious bias of being in the business of providing training and consulting services in support of respirator use, I have always felt that there has been a rush to use respirators and too little effort made at avoiding their use through engineering controls of all description. However, I do not believe that we should stop using respirators based on misinformation or with the primary motive being cost savings.

Where we use to see thousands of respirators used per year at a nuclear power generating station, we may now see less than 50. Is this article written in

an attempt to get the numbers back up? No! Not at all. It simply is an appeal to make sure that these numbers and the cost savings associated with them are not unduly influencing decisions about when to wear respiratory protection.

I cannot argue against the fact that dose is dose - it surely is, whether external or internal. However, I can argue against internal deposition, whether ingestion or inhalation when it is avoidable and is still consistent with the ALARA concept.

If, for example, an operator has to walk into a room or area with a given external dose rate, where there is known or suspected potential for airborne exposure of radioactive material to make an observation, can we really justify claiming that his time in the area will be increased by 25%, or any other assumed number? I would argue that examples like this (and I believe there are many of them) are cases where the industry has become a little overzealous in keeping people out of respirators. Is it really ALARA to allow someone to breathe in radioactive material (no matter how miniscule) because it saves money? Where is the scientific evidence that shows that walking into a room and taking gauge readings or observing the operation of a pump or system will be measurably hindered or slowed while wearing a respirator. In fact, a recent study published in the American Industrial Hygiene Association Journal (Vol.58, No.2, February 1997, pp 105-109) by David M. Caretti of the U.S. Army Edgewood Research, Development and Engineering Center showed no cognitive effects from

respirators for low stress jobs performed for up to 10 hours.

The results of this study suggest that respirator wear over a relatively long time period in the absence of other stressors should not significantly inhibit cognitive functions as measured by reaction time. Therefore, decreased performance of workers wearing respirators while executing tasks such as display monitoring, computer operation, or surveillance - tasks requiring minimal physical activity - does not appear to be caused by detrimental cognitive effects imposed by a respirator. Whether observed cognitive performance during mask wear would be observed in wear trials of longer than 10 hours still needs to be determined. However, in practice it seems unlikely that continuous respirator wear of longer than 10 hours would occur for operations other than military engagements.

It is a little troubling to see how the dramatic respirator reduction has been bragged about just like the number of days it takes to complete an outage. The feeling conveyed by some in the industry is that it's "fashionable" to reduce the number of respirators used in an outage - it's like a competition between utilities - just like with outage duration. I have not seen it or heard of it, but it would not surprise me to learn that there have been signs erected along site access roads rejoicing the low number of respirator hours maintained much like the number of days without an accident or the number of days till outage completion. I am sorry, but this is not the appropriate mentality.

Well if what has been done is so wrong, why haven't we seen more problems? I believe that there are a number of

reasons. But I believe that most significant of all has been the dramatic decrease, industry wide, of contamination levels and areas in nuclear power plants, in some cases by more than tenfold. I believe that the cleanup that has taken place over the last ten to fifteen years is extremely commendable and is primarily responsible for the success of the respirator use reduction effort.

The bottom line is, if an entire industry - especially the nuclear industry, is going to take such dramatic and sweeping action related to occupational exposure of employees, then it should not have a significant part of the basis for that action a multiplier in a formula that has such little basis in scientific fact. There is not a single study, of any credible quality that provides respirator wearer efficiency reductions anywhere near the values that have been talked about and are in use today. **SHOW ME THE NUMBERS!** We need more research - a tired but true statement.

That's just my opinion, I could be wrong.

## **EDITORIAL**

### **Let One Slip By!?**

Sometimes in the business of occupational health and safety consulting, it happens that something of significance slips by you - well, I have become aware of one of those events.

Applicable for activities that fall under the requirements of 29 CFR 1910.146, OSHA's Permit-Required Confined Spaces (PRCS) Standard, there is a peculiar twist on the requirements for respiratory protection. I am embarrassed to say that I was completely unfamiliar with it. A recent telephone inquiry from a client brought me up to speed. Questions about the need for a specific type of respirator involved with a confined space situation ensued. At first, I did not have a clear understanding of exactly what their concern was, nor which document they were referring to, so they faxed me a portion of it.

Unbeknownst to me, way back on May 5, 1995, the Directorate of Compliance Programs issued OSHA Instruction 2.100, *Application of the Permit-Required Confined Spaces (PRCS) Standard, 29 CFR 1910.146* with its stated purpose:

This instruction established enforcement policy and provides explanation of the standard to ensure uniform enforcement.

And a scope that says:

This instruction applies OSHA-wide.

This 7 page document has an additional 39 pages of appendices covering a range of interpretations including some on respiratory protection.

A portion of Appendix E: *Questions and Answers for PRCS Standard Clarification*, Section K - *Rescue Service*, containing question 3 and its answer/discussion are reprinted on the next two pages (19 & 20). (Readers may find that the rest of this commentary makes more sense upon first reviewing those two pages.)

I was very surprised to see that OSHA was apparently allowing the use of a respirator in a situation for which it may not be NIOSH approved.

I believe that the position in this interpretation was taken in light of the fact that there are many entranceways to confined spaces that are very small and otherwise restricted - making it difficult, if not impossible, to pass through them while wearing a self-contained breathing apparatus (SCBA) with a standard 30 or 60 minute cylinder. Though my reaction is generally, "make the hole bigger", I do understand that this is often not possible. Something must be done to do the job.

One way that I have heard that people are dealing with this difficulty, that is absolutely unacceptable, is to allow entry without the cylinder and/or SCBA on and have it passed through the opening behind you. Nor is acceptable to just carry or drag the cylinder with you instead of wearing it in its harness.

Assuming that the physical circumstances necessitate it - what is suggested in this OSHA interpretation seems reasonable from a practical standpoint, provided all three of the stated minimum conditions are complied with - **AND** - that people understand that you cannot use any respirator in violation of its NIOSH approved

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Directorate of Compliance Programs

3. Would a rescuer entering an Immediately Dangerous to Life and Health (IDLH) atmosphere using a supplied-air respirator in combination with SCBA (escape bottle), be in violation of OSHA regulations?

Yes, however, under the conditions addressed below, the violation can be considered as de minimis.

The PRCS standard because of its performance nature does not specify the personal protective or rescue equipment necessary for rescue. The OSHA standard for respiratory protection is 1910.134. Currently paragraph 1910.134(e)(3)(iii) requires, when an IDLH atmosphere exists, . . . . A standby man or men with suitable self-contained breathing apparatus shall be at the nearest fresh air base for emergency rescue.

The 1910.134 standard published in the June 27, 1974 issue of the Federal Register was derived from a now out-of-date voluntary standard (ANSI consensus standard Z88.2-1969). The most recent (1992) version of this same ANSI standard for respiratory protection for working in IDLH conditions has been changed. The new change specifies either a SCBA or a combination supplied-air respirator with SCBA for IDLH conditions.

It is OSHA policy to accept compliance with a provision in a current national consensus standard (ANSI) which provides an equivalent or greater level of protection from the hazards.

A rescue service can employ the use of supplied-air respirators in combination with self-contained breathing apparatus (SCBA) when conducting rescue operations. If a rescue service employer chooses to use combination supplied-air respirator with SCBA over the SCBA specified in the respiratory protection standard 1910.134(e)(3)(iii), for permit-required confined space rescue, the violation will be considered as de minimis as long as the following minimum conditions are also employed:

1. An evaluation of the permit space to be entered has been done to determine which appropriate respiratory protection (SCBA or Supplied-air with SCBA) is best suited for the rescue.
2. The rescuer's respirators and air source meet the requirements of the 1910.134 standard.

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3. The air source for the rescuer's respiratory protection is independent from that which is being used by the authorized entrants.

We also would recommend the following policies and work practices for the rescue services which choose the supplied-air respirators with SCBA option:

- a. Establish a policy requiring immediate withdrawal from the space whenever a respiratory protection problem develops.
- b. Establish a policy for use and training on emergency air line sharing "buddy breathing".
- c. Ensure that the rescuers wear full body harness and use life lines whenever practical.
- d. Establish a policy requiring a minimum capacity of the source air to be twice (2X) the volume of the total needs of all rescuers connected to it for the anticipated duration of the rescuer's entry.
- e. Establish a policy which mandates a minimum team of two rescuers for all permit space rescue entries.

conditions of use. This point is not expressly clear in the OSHA document.

It is noteworthy that OSHA does not state that this practice is limited to those situations where a small opening necessitates something that is smaller than a standard SCBA - it seems to allow such practice for any confined space rescuers. And please note that all of this applies only to rescuers - not the original entrants.

If I am interpreting this compliance directive correcting, OSHA has based its position on changes in language that appeared in ANSI Z88.2 - 1992 regarding respirator use under IDLH conditions:

7.3.2 Respirators for use under IDLH conditions at normal atmospheric pressure.

The required respiratory protection for IDLH conditions caused by the presence of toxic materials or a reduced percentage of oxygen as described in conditions (a), (b), (c) in 7.3.1 is a positive-pressure SCBA or a combination of supplied-air respirator with SCBA.

When respirators are worn under IDLH conditions, at least one standby person shall be present in a safe area. The standby person shall have the proper equipment available to assist the respirator wearer in case of difficulty. Communications (visual, voice, signal line, telephone, radio, or other suitable means) shall be maintained between the standby person and the wearer.

That does not say what I see OSHA saying in their Instruction. Though, I admit that the language in the ANSI standard leaves the door open to some

questions. For example, What type of combination supplied-air respirator with SCBA? I believe, when this was written, we assumed that it was understood that the conditions of approval of such devices would be adhered to. That is, that such devices with less than a 15 minute service life rating on the self-contained air cylinder could not be used for entry into IDLH while breathing from the cylinder. And further, that devices with a self-contained air cylinder having a service life rating of 15 minutes or longer were limited to entry while breathing from the cylinder for no more than 20% of the cylinder's rated service life.

Also, though the ANSI language is admittedly open for interpretation, I do not believe it was intended that the standby person(s) had the same options for respirator use as the primary respirator wearer (the entrant).

But be assured, I will bring this issue up at our next meeting of the current subcommittee working to revise the Z88.2 document once again.

Well, I was a little puzzled and concerned about what OSHA was saying in their instruction - and the way it may be interpreted, so I telephoned John Steelnack at OSHA and queried him about this issue. He advised that prior to the issue of this document, in their work on revising 29 CFR 1910.134, they were anticipating language that would allow such practice - without any restriction on the service-life rating of the breathing air cylinder which would be part of such a combination respirator. I expressed my dismay and concern that such an anticipated use would be in contradiction

of the devices' NIOSH approval unless the cylinder had a service-life rating of 15 minutes or longer and that it would not be anticipated that more than 20% of that rated service-life would be consumed during the entry portion of the rescue. He seemed to agree that this would have to be fixed. Unfortunately, since there was no comment submitted regarding this issue during the period that the docket was open to receive such comments on the revision to .134, it may be difficult to change it. We will have to wait and see what they do.

Bottom line - I believe both Z88.2 - 1992 and OSHA Instruction CPL 2.100 could be clearer on this issue. It must be understood that NIOSH approval conditions must take precedence in any respirator selection or use.

\*\*\*\*\*

Respirator Support Services welcomes any materials for publication in **RESPIRATORY PROTECTION UPDATE**. Feature Articles, Technical Notes, Editorials, Letters to the Editor, News Releases, Calendar of Events items, Training Topics, or any other materials related to the subject are requested. Your input is needed.

\*\*\*\*\*

## **EXTRA FEATURE**

### **JUST ANOTHER RESPIRATOR?**

Where there is a will there is a way.  
Where there is a need, there is a product.  
That is that way it seems with an increasing number of products making their way into the marketplace.  
Nowhere is this more true perhaps than with devices being called RPEDs, Respiratory Protection Escape Devices.

Because the National Institute for Occupational Safety and Health's (NIOSH) existing testing and certification regulation, 42 CFR 84, does not have provision for evaluating or certifying such products - they cannot become NIOSH "approved". This does not necessary mean that they are not good products, it simply means that they do not fit into any existing category. My guess is that some of the products on the market are good, some are adequate, and some are not so.

In some cases, the marketing and sales of some of the RPEDs seems to have at least bordered on 'selling to the fears' that people have about fire. Not that fire isn't something to be afraid of - it is just that fear is not always the best incentive or basis for purchases. The fear of being unable to escape from a smoky burning high-rise, airplane, train, cruise ship, nursing home, or any building or structure. There is a convincing argument to be made about the number of people who might have survived any number of incidents over the years where smoke inhalation was the primary cause of death. I have heard, anecdotally, numbers as high as 90%.

This author's earliest encounter with this type of product was about 10 to 12 years ago at the annual American Industrial Hygiene Conference. There was actually an exhibitor set up in a booth at the trade show demonstrating a "plastic" bag that was being sold as an escape respirator. This bag was rather large, and was supposed to be made out of flame resistant material. It was simply a bag with a draw string incorporated. The salesman demonstrated one for me. He tore open its storage pouch, unfolded the bag, snapped it vigorously so as to fill it full of room air and then placed the bag over his head and pulled the draw string to close the bag securely around his neck. This product was being sold to employers in, and owners of, high-rise office buildings for their office workers to use.

The next product encountered was from the Jalypso Marketing Company. I saw it featured in the *New Products* section on page 47 of the May 1992 issue of **Professional Safety** (the official publication of the American Society of Safety Engineers).

*The Jalypso Smoke Filter, a safety-orange cloth bag that, when worn over the face, filters smoke as it passes through. The filter is filled with specially coated materials that trap smoke particulates, making it easier to breathe. An elastic strap holds the bag in place to free hands during escape from smoke-filled areas.*

Sometime later, yet another product came to my attention: the **EVAC-U8 Emergency Escape Smoke Hood**. I was really quite impressed with the cleverness of the name. Upon receiving a sample of the product I was also quite

intrigued - this thing actually looked like it had the potential for working. The sales literature offered the following description:

*Why wait for a fire? Take control of your own safety now with the EVAC-U8 Emergency Escape Smoke Hood. It is the smoke and toxic fumes that kill in 80% of the 10,000 fire-related deaths each year. In less than 60 seconds, your home can become impossible to breathe in. And in an airplane, there is no safety device to put on. So, bring it with you.*

*The EVAC-U8 gives you breathable filtered air for up to 20 minutes, keeping smoke and deadly gases like carbon monoxide out of your lungs. Its Kapton hood also protects your head and eyes. You can see all around you. Kapton resists 1500°F.*

*EVAC-U8 is as small as a soda can, lightweight, easy to put on in seconds, and its glow-in-the-dark bottom helps you find it and others find you. Replaced free if ever used in a fire. Five year guarantee.*

*Price...\$59.95 + \$5.00 shipping and handling*

Another product is called, "Smoke Escape Emergency Respirator" and is described as follows on the internet.

*A self-rescue device, allows users to escape fire or smoke emergencies. The transparent, heat-resistant hood unfolds from a matchbook size package to protect users' eyes, nose, and mouth from lethal smoke. A special ionized filter blocks soot and smoke particles 0.1 micron or larger. Hoods are constructed of .002 mil optically clear random copolymer UL-rated VTM-O. The filter features patented tri-layer ionized construction. Buyers and distributors sought.*

Another offering found on the information highway:

*The "Xcaper Smoke Filter" is an internationally patented, laboratory tested product that can eliminate over 95 percent of smoke particulates caused by common fires. The firm says that smoke particulate inhalation accounts for over 70 percent of all fire-related deaths. The filter is tested and certified safe and saleable by the U.S. Department of Defense, NATO, the American Bureau of Shipping, and other organizations. Buyers, distributors, agents are sought.*

A catalog that was received via bulk mail called the Self Care Catalog, along with bug bite proof shirts and UV ray protection clothing offers an "Emergency Escape Smoke Hood".

*More than 80% of fire-related deaths actually are caused by smoke and chemically-poisoned air. Give yourself and family 20 minutes of evacuation time with this smoke hood - its transparent, heat-resistant shield is gas-impermeable, with a 360° charcoal filter and a rubber seal at the neck. Proven to protect from smoke and 98% of toxins created by fire, including chlorine, ammonia, hydrogen chloride, hydrogen sulfide, and acrolein. Compact, lightweight, sealed package can easily be kept in briefcase, desk drawer, or handbag. One size. Made in England. Price...\$69.00*

Frequent Flyer magazine (July 1994, pg 62) featured the exact same hood:

*There's a new smoke hood on the market that could buy precious time in the event of an air crash. The Provita smoke hood, distributed by Santa Barbara-based Euro Marketing, Inc., claims to protect the lungs for up to 20*

*minutes from 98 percent of the toxic gasses created by fire, including chlorine, ammonia, hydrogen sulphide [sic] and acrolein. One potentially deadly gas that Provita, which sells for \$59.95 including shipping and handling, doesn't protect against, however, is carbon monoxide.*

This same product is offered in another mail-order catalog, Magellan's Essentials for the Traveller. The descriptive text is a little different however:

*"Until airlines are compelled to provide smoke hoods for passengers...you will have to bring your own." (Ralph Nader, Collision Course).*

*You know how we feel about the value of emergency escape hoods for our customers who fly or stay in high-rise hotels (see page 10 in our annual catalog). So we have added a third hood to our line - the new instant wear smoke hood from Provita. With 360° visibility, there's no pausing to find the "front or "back", so donning it is a simple matter of tearing open the clear vinyl carrying pouch and pulling it over your head. Automatically forms a snug seal at its neck opening - no straps or ties to slow you down. Made of heat-resistant Kapton™ polyimide film that extends protection to the wearer's full neck and shoulders, with a special three-layer filter to remove hazardous byproducts of fire (including the eye-irritating smoke particles themselves). Gives you those extra few minutes to escape that could save your life (or the life of someone you love). A compact 5 x 6-1/2 x 3/4" in its pouch, it'll fit in purse, pocket or briefcase. For one-time use. 5 oz. Made in England. Price...\$59.00*

From page 10 of Magellan's annual catalog:

*We feel very strongly about the value of emergency escape smokehoods for all who fly. It comes from studying as many of the reports on aircraft "incidents" as we have, reading again and again how many lives might have been saved if passengers would've had just a few extra minutes to evacuate from the smoke and fumes that claim far more lives than impact or flames. So please think very seriously about making a compact smokehood a permanent part of your travel gear, never taking it out of your carry-on bag.*

*We introduced the Israeli-made Duram Escape Hood in our Summer '93 Newsletter. It was an instant hit. Its price, its compact size and the confidence the traveling public placed in it soon made it a very popular item here at Magellan's. The hood itself is constructed of a heat-resistant polychloroprene latex material, soft and flexible, with a large, clear visor of a special polyimide film (also extremely resistant to heat), and a unique, multi-layer filter that removes the hazardous levels of such combustion by-products as cyanide, hydrogen chloride, acrolein, smoke particles, and other toxic components. It is vacuum-packed in a very compact 4 x 5 x 1/2" easy-opening pouch, easy to remove and slip over your head if ever needed, forming a snug seal around your neck. A veteran of many live-fire demonstrations that we at Magellan's have witnessed ourselves. For one-time use. (5 oz) Price...\$59.00*

This product (which has been updated and upgraded) is now being marketed under the name **QUICKMASK** as a **Respiratory Protective Escape Device** and is recommended for *Self Rescue, Victim Rescue, and Health Risk Reduction* for Military, Civilian, Law Enforcement, Security, Fire, Rescue, EMS, and HazMat. It is available from

Fume Free Inc., P.O. Box 1680, Stuart, FL 34995-1680, (800) 386-3373 and is feature on an internet website: <http://www.quickmask.com>. Single unit price is now at \$80.00.

Surely, there must be a number of other similar products out there as well. And obviously there must be a market for them. Consumers are of course free to purchase whatever they wish. There are no government restrictions on using this type of product or any other respirator-like product.

One of the serious concerns with consumer use is that they may not take the time to read or adequately understand, or always remember the important restrictions and limitations for using such products. Sometimes the product manufacturer does a good job of providing these instructions - and sometimes they do not. Regardless, we consumers don't always do such a good job of paying attention to such things.

These products are not intended for entry into hazardous environments. What will happen to the person who, say, escapes from a burning structure with this product on and then decides to go back in and look for others - or perhaps the family cat. What if they decide that: "if the product can protect me in such a hostile environment as a smoke fire, then why wouldn't it protect me against any other toxic gas or substance?"

Without NIOSH certification, employers who may be interested in utilizing any of these devices are faced with a bit of a quandary. All of the health and safety regulatory agencies for all workplaces (OSHA, MSHA, DOE and the NRC)

require that when respirators are provided that they be either NIOSH "approved" or otherwise [specifically] "accepted" by that enforcement agency. Even if there is a legitimate need for such a product, the employer likes its features and wants to purchase and provide it - it is a violation of Federal (and perhaps State) regulation without such approval or acceptance.

The issues of design, materials, construction, performance, and quality control in the manufacturing of these products are of concern. If indeed the product is made well and will serve a useful purpose, there should be a system under which it can be recognized as such and will be able to help ensure that there is a known minimum level of performance and quality.

The rest of the world seems to have recognized this and done something about it a lot quicker than we have. There is already a European standard (N403) covering these products. Also, the Japanese and Australians have their standards in place.

In this country, within the "respirator industry" specifically, some of the larger, conventional respirator manufacturers, the firefighters union, and others in this business have been interested in these things and some of the same problems discussed above. They have gotten together and have been drafting a consensus standard to help establish minimum criteria for RPEDs. Apparently, the committee is essentially done with their writing and are in the process of trying to find a home for it - perhaps with the American National Standards Institute (ANSI). There is

some speculation that a finished standard may be out in about two years. In fact, I am told that this group is meeting in Vancouver on April 2 & 3, 1997 to put the finishing touches on. A point of contact regarding this effort is:

Bruce Teele  
NFPA  
P.O. Box 9101  
Quincy, MA 02269-9101  
(617) 770-3000

There certainly is good reason to have some type of performance standard for these products, they are currently being used and likely will be a very hot product for American consumers, employees, security forces, and military personnel. There is an increasing awareness of the potential for having to face the hazards associated with smoky fires but also with chemical releases and unfortunately chemical and biological terrorism.

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**THANK YOU!**



Department of Energy  
Germantown, MD 20874-1290

January 29, 1999

DOCKETED  
USNRC

'99 FEB -5 P3:16

OFFICE OF  
ADMINISTRATIVE  
PROCEDURES

Secretary  
U.S. Nuclear Regulatory Commission  
ATTN: Rulemaking and Adjudications Staff  
Washington, D.C. 20555-0001

DOCKET NUMBER  
PROPOSED RULE **PR 20**  
(63FR38511)

Dear Secretary:

The U.S. Department of Energy (DOE), with over 120,000 Federal and contractor employees, is a significant user of respirators. Over 20 percent of DOE contractors use a respirator at some time in their career. Our contractors follow Occupational Safety and Health Administration (OSHA) respiratory regulations and American National Standards Institute (ANSI) Z88.2-1992. Each of our sites has a defined respiratory protection program and administrator. In addition, our Federal workforce comes under OSHA regulation. Paducah and Portsmouth, former DOE sites, also come under OSHA regulation.

DOE is quite concerned over potential conflicts between current OSHA and the proposed amendment to the Nuclear Regulatory Commission (NRC) respiratory protection regulations because in the near future DOE sites may be regulated by both OSHA and NRC. As written, the proposed NRC amendment to title 10, Code of Federal Regulations, part 20 (10 CFR 20) (63 Federal Register 38511, July 17, 1998), could result in DOE having to implement two distinct respiratory protection programs (one for each agency's regulations). This could adversely impact worker safety and lead to additional unnecessary program costs.

DOE recommends that the NRC standard and supporting guidance be as consistent as possible with the OSHA standard. DOE provides the following reasons for this recommendation:

- o Executive Order (EO) Number 12866, Regulatory Planning and Review, September 30, 1993, requires Federal agencies, to the extent permitted by law, to "avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations *or those of other Federal agencies.*" [emphasis supplied]. EO 12866 also requires each agency to "tailor its regulations to impose the least burden on society . . . consistent with obtaining the regulatory objectives tacking into account . . . the costs of cumulative regulations."
- o The National Technology Transfer and Advancement Act of 1995, P.L. 104-113, 110 Stat. 775, provides that, unless it is inconsistent with applicable law or otherwise impractical, "all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carryout policy objectives or activities determined by the agencies or departments."



- o Relationship with OSHA respiratory protection standard: NRC has expressed a desire to minimize dual regulation of its licensees. Recently OSHA promulgated a revision to its respiratory protection standard at title 29 CFR 1910.134 (63 FR 1152, January 8, 1998, and 63 FR 20098, April 23, 1998) . Many NRC licensees are obligated to adopt OSHA standards for their non-radiological respiratory protection programs. DOE facilities now comply with OSHA and ANSI Z88.2 in a single respiratory protection program.
- o Impact on external regulation of DOE: DOE is particularly sensitive to NRC regulations because of current extended regulation activities with NRC. DOE wants to resolve potential conflicts between the way DOE facilities may choose to comply with NRC recommendations and the way NRC expects DOE facilities to comply with its recommendations. DOE has a strong interest in ensuring that NRC regulations for respiratory protection are both protective of workers and consistent with current standards, including ANSI Z88.2 and OSHA, 29 CFR 1910.134.
- o Lack of up-to-date technical guidance for the proposed amendments: The proposed NRC standard provides little specificity within the text of the standard or in the proposed guidance on important technical aspects of the respiratory protection program. Rather, it depends on a yet to be revised guidance document (NUREG 0041). The regulated community may be uncertain as to what is expected by the NRC standard until final guidance is available.

Enclosed are the DOE's specific comments on NRC's proposed rule, "Respiratory Protection and Controls To Restrict Internal Exposures," which was published in the July 17, 1998, Federal Register and the Draft Regulatory Guide 8022.

Sincerely,



Joseph E. Fitzgerald, Jr.  
Deputy Assistant Secretary  
Worker Health and Safety

Enclosure

cc:w/enclosure  
Tom Towers, OSHA

Comments on the Nuclear Regulatory Commission (NRC)  
Respirator Proposed Amendment and Draft Guide (DG)-8022

Documents Reviewed:

1. Proposed rule, title 10 Code of Federal Regulations Part 20 (10 CFR 20), *Respiratory Protection and Controls to Restrict Internal Exposures*, 63 Federal Register 38511 - 38521, July 17, 1998.
2. NRC DG 8022, *Acceptable Programs for Respiratory Protection*, July 1998.

The comments below address specific provisions in the NRC proposed amendments and DG. Although the Department of Energy (DOE) recommends that the NRC standard be as consistent as possible with the Occupational Safety and Health Administration (OSHA) respiratory protection standard, DOE recognizes that NRC may not choose this alternative to its rulemaking. DOE is therefore submitting specific comments on the proposed amendment and the DG below. DOE has divided its comments between the proposed amendment to 10 CFR Part 20 and the DG-8022, to the extent practical. However, there is some overlap and DOE does not intend its comments to imply that specific provisions should appear in the amendments rather than in the DG. Also, many of our comments and recommendations may be more appropriately addressed in the revised guidance document (NUREG 0041), which has not been released for public comment. DOE is primarily concerned that the NRC respiratory protection recommendations are clearly stated with sufficient specificity to enable licensees to know what is required and for enforcement to be uniform. In addition, as noted below, DOE has specific concerns over some of the requirements.

DOE comments on proposed amendment to 10 CFR 20:

20.1003, Definitions

Fit check: Delete irritant smoke and isoamyl acetate as examples of a user fit check since these are not tests that the user should perform without assistance.

Fit factor: Use the OSHA definition, i.e., "Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn." The significance is in the use of the word "measure" versus "estimate." Qualitative fit tests do not "measure," but they do "estimate" the fit.

Fit test: Change the word "test" to "protocol" to more accurately describe a fit test. The protocol includes the test, but also includes preparation/calibration of the testing agents/device, exercises to be preformed, calculation of fit test result, etc.

20.1701

DOE agrees with the addition of decontamination as an example of an engineering control.

20.1702(c) Footnote:

DOE recommends that this footnote be included within the body of the standard in order to prevent its being overlooked. This is an important requirement and should not be relegated to a footnote.

20.1703

DOE supports the language change proposed in 20.1703 to state that any use of respirators to limit intakes of radioactive material triggers the recommendations of 20.1703, as a minimum.

20.1703(b)

NRC should publish general, performance-based criteria for its acceptance or rejection of applications for respirator approval.

As written, the proposed rule implies that NRC would consider applications for equipment, e.g., whole-body suits used for respiratory protection, that NIOSH had not tested or refused to certify. DOE discourages NRC from independently allowing the use of respiratory protection equipment that NIOSH has not considered eligible for testing or certification.

20.1703(c)(3):

"Functional check or testing for operability" should be defined.

20.1703(c)(4):

Greater specificity should be provided for each of the topics listed, either in the regulation or in the regulatory guide. Recommendations for the written respiratory protection program to address non-routine and emergency use of respirators should be added.

A requirement that the written procedures must be site-specific and must be updated whenever there are changes that affect employee exposure should be added. The program should be reviewed annually by the licensee and revised, as needed, to reflect actual conditions and practices.

#### 20.1703(c)(5)

The medical evaluation should require use of the OSHA respirator questionnaire, or an equivalent questionnaire. This would complement compliance with OSHA and increase program flexibility for the facility. Physicians will be using the OSHA questionnaire for their occupational patients. Workers will be familiar with the questionnaire as its use becomes required by OSHA.

One area of concern is medical records information collected for respirator wearers. The NRC licensee is responsible for ensuring that each respirator user at its facility meets the medical criteria established by its physician. DOE recommends that NRC include a provision (subject to State and Federal privacy laws) requiring the release or transfer of a worker's medical records upon written request by the subject worker. This requirement would provide at least four benefits. It would (1) potentially save workers the necessity of repeating medical tests in order to qualify for respirator work when they work at different sites; (2) allow the worker's employer's occupational physician to have this medical information; (3) save licensees the expense of providing medical evaluations for workers previously evaluated at other facilities; and, (4) guarantee the worker's right to information contained in the medical records held by the licensee.

OSHA regulates the retention and release of medical records at 29 CFR 1910.20 and DOE urges NRC to adopt these or similar recommendations. Consistent standards that would encourage the portability of medical records should be provided. Additionally, long-term medical record retention recommendations should be specified.

#### 20.1703(c)(6)

NRC has provided no scientific or technical justification for relaxing the fit test frequency from 12 to 36 months. DOE recommends that NRC publish or reference any scientific studies that support its recommendation to lengthen the fit test interval to up to three years. Absent such studies, DOE recommends retention of the 12 month fit test frequency.

#### 20.1703(e)

The fact that provisions for vision, communication, and low temperature are to be made at no cost to the employee should be clarified.

20.1703(f)

This requirement should address confined spaces that require entry permits, backup rescuers, emergency conditions, etc.

20.1703(h)

The wording should be revised to match OSHA at 1910.134(g)(1):

- (1) The employer shall not permit respirators with tight-fitting facepieces to be worn by employees who have:
- (A) Facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function; or
  - (B) Any condition that interferes with the face-to-facepiece seal or valve function....
    - ...(ii) If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user."

Appendix A

DOE supports the use of the American National Standards Institute (ANSI) recommended assigned protection factors (APF).

DOE does not agree with NRC's footnote (e) regarding single use respirators. There are fit test protocols available that meet the OSHA recommendations for fit testing and comments about the difficulty of performing effective positive or negative pressure user seal checks are not appropriate since several manufacturers provide devices for user seal checks.

Combination respirators: The National Institute for Occupational Safety and Health (NIOSH) does not certify combination respirator ensembles and the use of combinations, such as APRs within an air-supplied suit, may cause significant user stress. Combining respirator types voids the NIOSH certification for the individual components, since it is not an approved use for the respirator. Use of combinations must be restricted to NRC approvals based on the total system evaluation. The Table suggests that combinations do not require special approvals, DOE does not agree with this approach.

DOE supports the removal of the restrictions on the use of half face respirators for protection against plutonium that were previously listed in Footnote (g).

Footnote c: Which filter efficiency is necessary for APR's with an APF less than or equal to 100: 99 or 99.7 should be clarified or this footnote should be deleted altogether.

Footnote e: It is not difficult to perform a user seal check on disposable APR's. Many manufacturers provide a fit check mold that fits over the entire facepiece for this purpose. Any discussion of feasibility should be deleted since it is feasible in the current marketplace.

**Recommendations relating to DG-8022 (July 1998) that are not found in comments to the proposed amendment.**

General:

NRC should ensure that the selection, frequency, and quality assurance criteria are included in the regulatory guide.

Specify the minimum content, frequency, and documentation of training.

Add monthly inspection recommendations for emergency use respirators and add licensee inspection of all respirators periodically, for example, annually. Add recommendations for the removal from service for any respirator that is discovered to be defective until it is repaired. DOE supports and currently requires a user seal check prior to each use of a tight fitting respirator. The procedure for a user seal check should be referenced or specified. The OSHA protocol, found in Appendix B-1 to 29 CFR 1910.134, should be referenced or incorporated.

The following items should be added: no cost to employee, confidentiality, information provided to physician, information provided by physician to licensee and to the employee, provision of a powered air purifying respirator (PAPR) if employee has medical restrictions on the use of negative pressure respirators.

DOE recommends that NRC specify a minimum fit test protocol, for example, Appendix A of 29 CFR 1910.134. Regulated facilities will have to use these protocols for non-radiological respiratory protection, therefore, NRC should provide for consistency with these standards. Unless the protocols are required, fit testing practices may not provide the necessary protection for the respirator wearer. In Section II to Appendix A, OSHA details the performance recommendations for alternative fit test protocols. NRC should incorporate these criteria as well.

Add recommendations for quality assurance for breathing air if the licensee produces compressed breathing air. Such recommendations should include inspection and maintenance of air compressors, locations of air compressors, and unique couplings for breathing air lines. Add recommendations for certified breathing air or testing, if air is purchased.

Specific:

Page 5, section 2.1: It is recommended that the licensee should establish reasonable threshold values if an as low as reasonably achievable (ALARA) evaluation is performed to minimize the sum of internal and external dose. Additional guidance regarding the comparison to other industrial health and safety risks should be provided.

Page 7: It is recommended that a 15 percent inefficiency factor be used. Most of the published studies on work efficiency reduction while wearing a respirator are studies of subjects performing physically demanding tasks at close to maximal effort. Sub-maximal effort would not be expected to reduce work efficiency as greatly. Other studies have demonstrated that the use of respirators with less inspiratory resistance produces less work efficiency reduction. DOE recommends that work effort and respirator selection be evaluated before any inefficiency factors are applied.

Page 8: DOE recommends the following topics be included in the written procedures:

- o A qualified respirator administrator.
- o Providing respirators at no cost to employees.
- o Disinfection and cleaning.
- o Voluntary use of respirators.
- o Inspecting emergency use respirators monthly.

Page 11: DOE recommends quarterly or semi-annual inspections of emergency use respirators. ANSI and OSHA require monthly inspections of this equipment. DOE recommends that monthly inspections of all emergency use respirators be required.

Page 12 and 14: The discussion of half-mask respirators indicates that only 99 and 99.97 percent efficient filters are to be used in the workplace. DOE believes that the selection of a particulate filter efficiency should be made by a health physicist or industrial hygienist who is familiar with the

physical properties of the contaminants. The rule should reflect that respirator selection must be made by the qualified respirator administrator or designee, based on knowledge of site specific conditions.

Page 17: DG-8022 suggests that a qualitative fit test could show a fit factor of 500. OSHA has found that the concentration limits for the test agents effectively preclude the use of qualitative fit tests (QLFT) for fit factors greater than 100. If QLFTs to meet a fit factor estimate of 500 can meet the criteria published in 29 CFR 1910.134, appendix B, section II, then and only then, should consideration be given to raising the allowable fit factor estimate obtained by QLFT. DOE recommends that the DG should be re-written to limit the use of qualitative fit tests to determine fit factors at or below 100.

Page 18 : The conditions listed to trigger more frequent fit testing than the three-year maximum interval are conditions not always apparent to the licensee and could create discrimination issues for individual workers. One example is the weight change criterion. While this is a valid criterion, a supervisor should not be responsible for observing weight changes in employees. This is appropriately measured in the medical clinic, but the proposed standard does not require physicians to measure body weight each year. Unless the physician were made aware of the recommendations to perform a fit test whenever there was a weight change in excess of a specified threshold, weight changes would not be reported to the licensee. Annual fit testing would reduce the impact of the development of conditions that affect a good face to facepiece seal. Also, page 18 is not correctly representing the current OSHA respirator standard, 29 CFR 1910.134, that now makes 12-month fit testing intervals mandatory for all substances, but only requires one satisfactory fit test each time.

Page 22: DOE recommends that the NRC revise their position that one respirator manufacturer is adequate for respirator selection. In many cases, one respirator manufacturer may be sufficient, but where it is not, the licensee should be required to provide a respirator that fits, even if that means using a different manufacturer and maintaining an adequate inventory of parts for that different respirator. DOE believes that employees should be able to choose from an adequate selection so that every user can be assigned an appropriate respirator that provides an adequate fit and is comfortable to the wearer. The DG's observation that one percent of employees are not able to achieve an adequate fit factor with only one manufacturer leaves those individuals with no legal protection since employers are not obligated to provide an alternate manufacturer or a positive pressure respirator. DOE recommends that OSHA's standard 1910.134(d)(1)(iv), "The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user," be adopted.

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