



# THE SAFETY EQUIPMENT ASSOCIATION

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(63FR38511)

OFFICE OF  
FULL  
ADJUDICATION

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DOCKETED  
USMRC

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

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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.

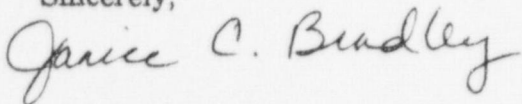
Additionally, ISEA believes that a half face piece disposable respirators without seal enhancing elastomeric components and are not equipped with two or more adjustable suspension straps should not be categorically discounted and effectively given an APF of 1. These respirators are half masks and provide 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 do 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