Part 20—Standards for Protection Against Radiation

[Nuclear Regulatory Commission amendments to its regulations regarding the use of respiratory protection and other controls to restrict intake of radioactive materials as Published in the Federal Register/Vol. 64, No. 194/Thursday, October 7, 1999.]

§ 20.1003 Definitions.

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Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.
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Assigned protection factor (APF) means the 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. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.
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Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.
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Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.
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Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).
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Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.
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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.
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Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.
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Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.
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Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.
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Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.
Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive material.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Subpart H—Respiratory Protection and Controls to Restrict Internal Exposure

§ 20.1701 Use of process or other engineering controls.

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.

§ 20.1702 Use of other controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means—

(1) Control of access;
(2) Limitation of exposure times;
(3) Use of respiratory protection equipment; or
(4) Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers’ industrial health and safety.

§ 20.1703 Use of individual respiratory protection equipment.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the NRC for authorized use of this equipment except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as necessary, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding—

   (i) Monitoring, including air sampling and bioassays;
   (ii) Supervision and training of respirator users;
   (iii) Fit testing;
   (iv) Respirator selection;
   (v) Breathing air quality;
   (vi) Inventory and control;
   (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
   (viii) Recordkeeping; and
   (ix) Limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before

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(i) The initial fitting of a face sealing respirator;
(ii) Before the first field use of non-face sealing respirators, and
(iii) Either every 12 months thereafter, or periodically at a
frequency determined by a physician.
(6) Fit testing, with fit factor 10 times the APF for negative pressure devices, and a fit factor 500 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 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(e) The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G–7.1, “Commodity Specification for Air,” 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include—

1. Oxygen content (v/v) of 19.5–23.5%;
2. Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
3. Carbon monoxide (CO) content of 10 ppm or less;
4. Carbon dioxide content of 1,000 ppm or less; and
5. Lack of noticeable odor.

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face—facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer’s face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.
§ 20.1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to the provisions of §§ 20.1702, 20.1703, and Appendix A to Part 20, in order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

§ 20.1705 Application for use of higher assigned protection factors.

The licensee shall obtain authorization from the Commission before using assigned protection factors in excess of those specified in Appendix A to Part 20. The Commission may authorize a licensee to use higher assigned protection factors on receipt of an application that—

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

APPENDIX A TO PART 20.—ASSIGNED PROTECTION FACTORS FOR RESPIRATORS

<table>
<thead>
<tr>
<th>Operating mode</th>
<th>Assigned Protection Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Air Purifying Respirators [Particulate only] :</td>
<td></td>
</tr>
<tr>
<td>Filtering facepiece disposable</td>
<td>Negative Pressure</td>
</tr>
<tr>
<td>Facepiece, half</td>
<td>Negative Pressure</td>
</tr>
<tr>
<td>Facepiece, full</td>
<td>Negative Pressure</td>
</tr>
<tr>
<td>Facepiece, half Powered air-purifying respirators</td>
<td>Powered air-purifying respirators</td>
</tr>
<tr>
<td>Facepiece, full Powered air-purifying respirators</td>
<td>Powered air-purifying respirators</td>
</tr>
<tr>
<td>Helmet/hood</td>
<td>Powered air-purifying respirators</td>
</tr>
<tr>
<td>Facepiece, loose-fitting Powered air-purifying respirators</td>
<td>Powered air-purifying respirators</td>
</tr>
</tbody>
</table>

II. Atmosphere supplying respirators
### [particulate, gases and vapors]:

<table>
<thead>
<tr>
<th>1. Air-line respirator:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Facepiece, half Demand</td>
<td>10</td>
</tr>
<tr>
<td>Facepiece, half Continuous Flow</td>
<td>50</td>
</tr>
<tr>
<td>Facepiece, half Pressure Demand</td>
<td>50</td>
</tr>
<tr>
<td>Facepiece, full Demand</td>
<td>100</td>
</tr>
<tr>
<td>Facepiece, full Continuous Flow</td>
<td>1000</td>
</tr>
<tr>
<td>Facepiece, full Pressure Demand</td>
<td>1000</td>
</tr>
<tr>
<td>Helmet/hood Continuous Flow</td>
<td>1000</td>
</tr>
<tr>
<td>Facepiece, loose-fitting Continuous Flow</td>
<td>25</td>
</tr>
<tr>
<td>Suit Continuous Flow</td>
<td>(g)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Self-contained breathing Apparatus (SCBA):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Facepiece, full Demand</td>
<td>h 100</td>
</tr>
<tr>
<td>Facepiece, full Pressure Demand</td>
<td>i 10,000</td>
</tr>
<tr>
<td>Facepiece, full Demand, Recirculating</td>
<td>h 100</td>
</tr>
<tr>
<td>Facepiece, full Positive Pressure Recirculating</td>
<td>i 10,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>III. Combination Respirators:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any combination of air-purifying and atmosphere-supplying respirators.</td>
<td>Assigned protection factor for type and mode of operation as listed above.</td>
</tr>
</tbody>
</table>

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**Notes:**

- **a** These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

- **b** Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 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.

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c The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radio-active gases and vapors (e.g., radioiodine).

d Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in § 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

e 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 95 percent efficient and all other requirements of this Part are met.

f The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

g No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., § 20.1703).

h The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

i This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.