

**Meeting with Nuclear Industry to Discuss Potential 10 CFR Part 20 Licensing Needs
Due to the COVID-19 Public Health Emergency**

April 15, 2020

Discussion Topics

Under the NRC's regulations in 10 CFR 20.2301, "Applications for exemptions," "The Commission may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property." Under this section, individual licensees may request exemptions from medical evaluation frequency and fit-testing frequency requirements that are specified in 10 CFR 20.1703(c)(5)(iii) and 10 CFR 20.1703(c)(6) to ensure that respiratory protection program requirements do not result in licensees taking actions that may be contrary to the Center for Disease Control and Prevention (CDC) COVID-19 guidance¹. The NRC is considering the use of an expedited review process for these requests, under certain circumstances that would be specified in an NRC letter to the nuclear industry.

Similar to the process that the NRC is using for certain exemption requests from 10 CFR Part 26 and Part 55 related to the COVID-19 public health emergency, the NRC would provide criteria for licensees' exemption requests that would allow the NRC to provide a determination on the request within an accelerated timeframe.

The NRC has not finalized the criteria for this expedited review process, but currently anticipates that licensees would be asked to include information like that listed below in their exemption requests.

Medical Evaluations: To receive expedited review of their exemption requests from 10 CFR 20.1703(c)(5)(iii), licensees may be requested to provide information like the following:

- A statement that the licensee cannot meet the medical evaluation requirements of 10 CFR 20.1703(c)(5)(iii) without workers taking actions that may be contrary to CDC guidance;
- A statement that the licensee will temporarily apply a licensee-specific process to ensure worker safety to manage personnel with overdue medical evaluations;
- An estimate of the number of impacted personnel and the organizational positions, using generic position descriptions, that will be included in the licensee-specific process;
- An estimate of the date and time when the licensee will no longer be able to comply with the regulatory requirements in 10 CFR 20.1703(c)(5)(iii);
- A statement that, except for physical medical examinations at medical facilities, the licensee has completed, or will complete within the required frequency (plus a 90-day grace period), all applicable respiratory protection program medical evaluation requirements (e.g., medical history questionnaire);
- A statement that a licensed physician has reviewed the medical history questionnaire prior to the expiration of the current medical evaluation (plus a 90-day grace period) and determines that an extension of the wearer's physical medical evaluation due date is acceptable such that the wearer remains qualified to use assigned respiratory protection equipment during the extension; and

¹ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

- A statement that impacted employees have been informed of the general risks of wearing respiratory protection (e.g., information similar to that found in Appendix D of 1910.134), the rationale for medical evaluations², and the contents of any approved exemption.

In considering requests for exemption from this section of the regulations, the NRC may impose additional requirements to provide continued reasonable assurance of public health and safety. For example, the NRC may limit the exemption:

- To personnel having known, stable medical histories as determined by a licensed physician;
- To not apply in the following situations;
 - When an employee reports signs or symptoms that could impact his or her ability to use a respirator (unless cleared by a licensed physician);
 - When a physician or other licensed health care professional (PLHCP), supervisor, or respirator program administrator informs the employer that an employee needs to be reevaluated;
 - When information from the respiratory protection program, including observations made during fit-testing and program evaluation, indicates a need for employee reevaluation; or
 - When a change occurs in workplace conditions (e.g., physical work effort, protective clothing, temperature) that may result in a substantial increase in the physiological burden placed on an employee.
- Further, in any approval letter, the NRC would provide a date and time when the exemption would expire.

Fit-Testing Requirements: To receive expedited review of their exemption request from 10 CFR 20.1703(c)(6), licensees may be requested to provide information like the following:

- A statement that the licensee cannot meet the meet the fit-testing requirements of 10 CFR 20.1703(c)(6) without workers taking actions that may be contrary to CDC guidance;
- A statement that the licensee will temporarily apply a licensee-specific process to ensure worker safety to manage personnel with overdue respiratory protection fit-tests;
- An estimate of the number of impacted personnel and the organizational positions, using generic position descriptions, that will be included in the licensee-specific process;
- An estimate of the date and time when the licensee will no longer be able to comply with 10 CFR 20.1703(c)(6);
- A statement that employees covered by the exemption would receive refresher training on donning their assigned respirator and are informed of the rationale for respiratory fit-testing³ and the contents of any approved exemption.

² ANSI Z88.6-2006 provides an acceptable rationale for medical evaluations. "The effects of physical work effort, protective clothing, temperature, humidity, and the physiologic burden placed on a worker using a respirator must be considered during the medical evaluation for respirator use. The PLHCPs shall provide reasonable assurance that a worker can endure these stressors without adverse medical consequences and recommend any limitations on respirator use related to the medical condition of the employee of the work place conditions in which the respirator will be used."

³ ANSI Z88.10-2001 provides an acceptable rationale for respirator fit-testing. "The purpose of respirator fit-testing is to verify that the selected make, model, and size of a tight-fitting facepiece adequately accommodates an individual's unique facial characteristics. This is accomplished so there is reasonable assurance that the wearer has learned to don the facepiece properly and can achieve the anticipated protection during use."

In considering requests for exemption from this section of the regulations, the NRC may impose additional requirements to provide continued reasonable assurance of public health and safety. For example, the NRC may limit the exemption:

- To personnel having experience with the respirators to which they will be assigned (i.e., those who have undergone at least one prior fit-test evaluation with the same make, model, and size of the assigned respirator facepiece);
- To not apply if any of the following has occurred since an individual was fit-tested with their assigned respirator:
 - A weight change of 10% or more;
 - Significant facial injury or scarring in the area of the tight-fitting respirator facepiece seal;
 - Significant dental changes (e.g., multiple extractions without prosthesis or acquisition of new dentures);
 - Reconstructive or cosmetic surgery in the area of the tight-fitting; respirator facepiece seal; or
 - Any other condition that might change the fit of the tight-fitting respirator.
- Further, in any approval letter, the NRC would provide a date and time when the exemption would expire.