

SAFETY EVALUATION REPORT

DOCKET: 70-1151

LICENSEE: Westinghouse Electric Company, LLC

SUBJECT: REQUEST FOR EXEMPTION FROM TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* 20.1703(c)(5)

BACKGROUND

By letter dated July 18, 2014, (Ref. 1), the Westinghouse Electric Company, LLC, (Westinghouse) submitted a request for an exemption from the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1703(c)(5); this regulation requires that a respiratory protection program include that a physician determine that an individual is medically fit to use respiratory protection equipment. Such a determination must be made prior to the initial fitting for a face sealing respirator, before the first field use of a non-face sealing respirator, and every 12 months thereafter—or periodically at a frequency determined by a physician. Westinghouse requested an exemption that would allow a nurse practitioner at the Columbia Fuel Fabrication Facility (CFFF) to determine an individual's fitness to use respiratory protection equipment. Westinghouse states that this would be consistent with the requirements of the South Carolina Nurse Practice Act, Title 40, and with the requirements of the Occupational Safety and Health Administration (OSHA).

Before sending requests for additional information (RAIs) to the licensee, the staff at the U.S. Nuclear Regulatory Commission (NRC) held a conference call on August 21, 2014, with Westinghouse to clarify the additional information that the licensee would need to submit (Ref. 2). The RAIs were sent to Westinghouse by letter dated August 22, 2014 (Ref. 3). Prior to Westinghouse sending a formal response to the RAIs, the NRC staff held an additional conference call with Westinghouse on September 23, 2014, to ensure that its responses would meet the NRC staff's expectations (Ref. 4). Westinghouse responded to the RAI by letter dated October 8, 2014 (Ref. 5).

REGULATORY REQUIREMENTS

Paragraph 70.17(a) of 10 CFR states that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Paragraph 20.1703(c)(5) of 10 CFR states the licensee shall implement and maintain a respiratory protection program that includes a determination by a physician that the individual user is medically fit to use respiratory protection equipment: (i) Before 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.

DISCUSSION

In Westinghouse procedure SYP-218, section 5.1, (Ref. 5) the licensee commits to the guidance in Regulatory Guide (RG) 8.15 (Ref. 6), which describes programs that meet the requirements of 10 CFR 20.1703 as well as concurrent requirements of OSHA in 29 CFR 1910.134. RG 8.15 provides that licensees whose respiratory protection programs fulfill the requirements in 10 CFR Part 20 Subpart H will also meet OSHA's basic program requirements in 29 CFR 1910.134 for respiratory protection; the intent is to relieve licensees of the burden of developing and maintaining two respiratory protection programs to comply with the two requirements. The OSHA requirements in 29 CFR 1910.134(e)(2)(i) allow a "physician or other licensed health care professional to perform medical evaluations." Paragraph 29 CFR 1910.134(e)(2)(i) specifies that the employer shall identify a physician or other licensed health care professional to perform medical evaluations using a medical questionnaire or initial medical examination or an initial medical examination that obtains the same information as the medical questionnaire.

In 1999, the NRC amended its regulations regarding the use of respiratory protection (Ref. 7). In the Statement of Considerations for the final rule amending these regulations, the NRC stated that, as described RG 8.15, a licensed health care professional can administer a medical examination, but the program must be designed by, and under the supervision of a physician. Elsewhere, however, the Statement of Considerations also stated that "the NRC staff believes that physicians need not administer each test personally, but that the physician may designate someone such as an office nurse to certify medical fitness as long as it is clear that the physician is ultimately responsible for the fitness determination. Likewise, the NRC staff believes that the physician should be involved in the supervision of the fitness program, the review of overall results, and individual cases that fall outside certain predetermined parameters, and supervision of personnel performing the tests."

The staff reviewed the exemption request and its supporting documents, including the South Carolina Nurse Practice Act (the Act), Title 40, which the licensee submitted as Enclosure 2 to its July 18, 2014, letter, and the licensee's responses to the RAIs. The Act allows a licensed nurse practitioner performing delegated medical acts to do so under the general supervision of a licensed physician who must be readily available for consultation. Specifically, the Act establishes that a qualified nurse may perform medical acts delegated by a physician and agreed to by both parties pursuant to an approved written protocol. Section 40-33-20 specifies that "delegated medical acts" means additional acts delegated by a physician and may include formulating a medical diagnosis and initiating therapies.

Westinghouse has a written protocol/agreement between the physician and nurse practitioner for delegated medical acts for which treatment may be initiated, continued, or modified. This document, which the licensee submitted as Enclosure 1 to its July 18, 2014, letter, specifies that a nurse practitioner may impose work restrictions and consult or refer to a physician any significant unexplained physical examination, historical finding, abnormal diagnostic finding, or whenever a patient requests. The protocol contains the requirements for various tasks that the nurse practitioner has to verify when performing one of these functions.

In a purchase order for medical services enclosed with the exemption request (Enclosure 3 to the licensee's July 18, 2014, letter (Ref. 1)), the description of services specifies that:

- A physician shall oversee establishing the elements necessary for an effective program that would determine whether an individual user is medically fit to use respiratory

equipment. These elements shall be documented, signed, and available to Westinghouse.

- A physician must oversee the respiratory medical evaluations and be available to the facility where the medical evaluations are performed and the staff implementing the medical evaluations.
- The nursing staff must be trained to perform the medical evaluations and have authority to restrict persons from using respiratory equipment with a physician verifying or removing any restrictions placed on personnel.

Section 6.1.1 of Westinghouse procedure SYP-218, "Respiratory Protection," states, in part, that a respirator user must be medically approved for respirator use by successfully performing a pulmonary function test. Section 6.2 of the procedure states, in part, that the medical department will develop guidelines for examining and perform medical examinations in accordance with the guidelines. This will include administering the OSHA Respirator Medical Evaluation Questionnaire to employees and subsequent evaluation.

ENVIRONMENTAL REVIEW

The NRC staff has determined that the exemption from the requirement of 10 CFR 20.1703(c)(5) belongs to a category of actions that the Commission has declared, per 10 CFR 51.22(c), to be a categorical exclusion. Specifically, 10 CFR 51.22(c)(25) states in pertinent part that granting an exemption is categorically excluded provided that: (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; and (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve ... (E) Education, training, experience, qualification, requalification or other employment suitability requirements.

The exemption to 10 CFR 20.1703(a) meets the criteria of section 51.22(c)(25) (i)-(v) and relates to the education, training, experience and qualifications and , employment suitability of the licensed health care professional to determine an individual's fitness to use respiratory protection.

Therefore, in accordance with 10 CFR 51.22(c)(22)(E), neither an environmental assessment nor an Environmental Impact Statement is necessary for this action.

CONCLUSION

Paragraph 70.17(a) of 10 CFR states that the NRC may grant the exemption from 10 CFR 20.1703(c)(5) if it determined that the exemption is authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest. Given the commitments in the licensee's exemption request and its enclosures, and the response to the RAIs, the NRC staff has determined that the medical evaluation of an employee to use respiratory protection for NRC-regulated activities may be delegated to a licensed nurse practitioner.

The NRC staff concluded that the exemption is authorized by law as 10 CFR 70.17(a) expressly allows for an exemption to the requirements of the regulation in 10 CFR 70.17(a), and the proposed exemption would not be contrary to any provision of the Atomic Energy Act of 1954, as amended. The exemption is consistent with the provisions in the South Carolina Nurse Practice Act, Title 40. Also, the exemption is consistent with the current OSHA standards in 29 CFR 1910.134(e)(2)(i). Therefore, the exemption is authorized by law.

The exemption allows the licensee to use a nurse practitioner to determine that an employee is able to use respiratory protection. The nurse practitioner has formal medical training and will operate under the oversight of a licensed physician who retains responsibility for the medical evaluations. The nurse practitioner is qualified to determine whether an employee is fit to properly use respiratory protection without undue risk to the individual's health. No degradation of safety at the CFFF results. Therefore, the exemption being issued by the NRC presents no undue risk to public health and safety.

The exemption will not involve or implicate the common defense or security. With the oversight respiratory protection, and hence, is able to perform their activities without undue risk. Therefore, granting the exemption will have no effect on the common defense and security.

By allowing a nurse practitioner at the CFFF to evaluate whether an employee can use respiratory protection, a physician would be less needed at the CFFF to perform routine activities and therefore have more time available to attend to more immediate and critical medical needs of the public. Moreover, as stated above, the intent of as explained in RG 8.15 is that the licensee's respiratory protection programs are in accordance with both NRC and OSHA regulations, to relieve licensees of the burden of developing and maintaining two respiratory protection programs to comply with both requirements. Although the NRC's requirements state that the licensee must maintain a program including the physician's determination that the user is fit to use the respiratory protection equipment, OSHA requirements and those of the State of South Carolina allow the licensee to have a nurse practitioner to make this determination. Issuing the exemption will ensure consistency with these requirements and fulfill the intent as stated in RG 8.15 with regard to this licensee. For these reasons, the exemption is in the interest of the public.

FINDINGS

The NRC staff finds that the approval of the exemption meets the requirement of 10 CFR 70.17(a), thus allowing the NRC to grant the exemption to 10 CFR 20.1703(c)(5).

PRINCIPAL CONTRIBUTORS

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Greg Chapman, Health Physicist
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REFERENCES

1. Letter from N. Parr, Westinghouse, "Westinghouse License SNM-1107 Exemption Request (Docket 70-1151)", July 18, 2014. ADAMS accession number ML14199A593.

2. Note from C. Ryder, U.S. NRC, "Summary of Conference Call: Exemption from Title 10 of the *Code of Federal Regulations* (10 CFR), Part 20.1703(c)(5) (Technical Assignment Control Number L33340)", August 21, 2014. ADAMS accession number ML14233A164.
3. Letter from C. Ryder, U.S. NRC, "Request For Additional Information: Request For An Exemption from Title 10 of the *Code of Federal Regulations* (10 CFR), Part 20.1703(C)(5) (Technical Assignment Control Number L33340)", August 22, 2014. ADAMS accession number ML14226A110.
4. Note from C. Ryder, U.S. NRC, "Exemption From 10 CFR 20.1703(c)(5): Clarifying Response to a Request of Additional Information", September 23, 2014. ADAMS accession number ML14266A124.
5. Letter from N. Parr, Westinghouse electric Company, "Westinghouse Nurse Practitioner Exemption Request Response (TAC L33340)", October 8, 2014. ADAMS accession number ML14282A033.
6. U.S. Nuclear Regulatory Commission, "Acceptable Programs For Respiratory Protection", Regulatory Guide 8.15, Revision 1, October 1999. ADAMS accession number ML003739512.
7. Federal Register, Vol. 64, No 194, page 54543. October 7, 1999.