

SAFETY EVALUATION REPORT

DOCKET: 70-27

LICENSEE: Babcock & Wilcox Nuclear Operations Group, Inc.
Lynchburg, Virginia

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

BACKGROUND

By cover letter dated September 17, 2010, Babcock & Wilcox Nuclear Operations Group, Inc. (B&W NOG), submitted a request for an exemption from certain requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1703(c)(5) [Agencywide Documents Access and Management System (ADAMS) Accession Number ML102650524]. In particular, 10 CFR 20.1703(c)(5) requires that the licensee's respiratory protection program include a determination by a physician that anyone using respiratory protection equipment is medically fit to do so. Such a determination must be made prior to initial fitting for a face sealing respirator, before the first field use of a non-face sealing respirator, and every 12 months thereafter—or at a period determined by a physician. B&W NOG requested an exemption that would allow nurse practitioners to determine an individual's fitness to use respiratory protection equipment.

DISCUSSION

The staff reviewed the exemption request and its supporting documents, including those submitted in response to a Request for Additional Information [ADAMS Accession Number ML12067A058].

In the Statement of Considerations published in the *Federal Register* when the applicable portions of Part 20 were revised (64 FR 54548), the U.S. Nuclear Regulatory Commission (NRC) repeated that its position remained consistent with Regulatory Guide 8.15:

“...The established NRC position, as described further is Reg. Guide 8.15, continues to be that a license health care professional can administer a medical exam, but the program must be designed by, and under the supervision of a physician....”

In Section 4.3.1.1.2 of the existing License Application [ADAMS Accession Number ML063190489], the licensee commits to the guidance in Regulatory Guide 8.15 (NRC, 1999), which describes programs that meet the requirements of 10 CFR 20.1703, as well as concurrent requirements of the Occupational Safety and Health Administration (OSHA) listed in 29 CFR 1910.134, “Respiratory Protection,” and they are compatible. The staff noted that the OSHA requirement in 29 CFR 1910.134(e)(2)(i) allows a “...physician or other licensed health care professional to perform medical evaluations....”

Elsewhere in the Statement of Considerations, the NRC emphasized that a licensed health care professional may administer a medical exam:

“...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 licensee has a single program for protection against respiratory hazards from both industrial and radioactive materials. It is executed in conformance with the site Radiation Protection Manual under Procedure RP-05, *Respiratory Protection*. General Requirement 20 of Section 6.0 of RP-05, page 4 of 11, states that a respirator wearer must have a current medical physical as specified by a licensed medical doctor. This requirement does not contradict the request that the physical be performed by another medical practitioner. Attachment 3 to RP-05 lists the typical tests and procedures in an individual’s physical examination, including consultation with a physician, followed up with an evaluation and a written lab report. The attachment lists additional tests that may be recommended by the examining physician.

In response to a Request for Additional Information dated June 5, 2012 [ADAMS Accession Number ML12198A305], B&W NOG provided the following clarifications:

1. B&W NOG confirmed that the medical qualification program is designed by and under the supervision of a physician.
2. In Enclosure 2 of the response to the Request for Additional Information [ADAMS Accession Number ML12198A306], B&W provided the Licensed Nurse Practitioner Agreement, which documented the supervisory role of the physician.

Compliance with Virginia Code

There is a written protocol/agreement between the physician and nurse practitioner in the B&W NOG medical clinic for all functions, including physicals performed by the nurse practitioner. The protocol contains the requirements for various tasks that the nurse practitioner has to verify when performing one of these functions.

The staff reviewed the exemption request and its supporting documents, including 18VAC 90-30-10. Paragraph 18VAC 90-30-120.A states that a licensed nurse practitioner is authorized to engage in practices constituting the practice of medicine in collaboration with and under the medical direction of a licensed physician.

In paragraph 18VAC 90-30-120.E, “collaboration” is defined as participation in the development of a written protocol, including provision for periodic review and revision; development of guidelines for availability and ongoing communications, which provide for and define consultation among collaborating parties and the patient; and periodic joint evaluation of services provided (e.g., chart review, and review of patient outcomes).

In paragraph 18VAC90-30-120.E, “medical direction and supervision” is defined as participation in the development of a written protocol including provision for periodic review and revision; development of guidelines for availability and ongoing communications that provide for and define consultation among collaborating parties and the patient.

In 18VAC90-30-10, “protocol” is defined as a written statement, jointly developed by the collaborating physician(s) and the nurse practitioner(s) that directs and describes the procedures to be followed and the delegated medical acts appropriate to the specialty practice

area to be performed by the licensed nurse practitioner(s) in the care and management of patients.

Based on the above, the NRC staff determined that, under Commonwealth of Virginia law, a licensed nurse practitioner, providing a medical examination, including a determination and written certification that there are no medical contradictions disclosed by the medical examination, would do so in accordance with a written protocol.

The licensee also commits to the guidance in Regulatory Guide 8.15 (NRC, 1999) which describes programs which meet the requirements of 10 CFR 20.1703 as well as concurrent requirements of the Occupational Safety and Health Administration (OSHA) listed in 29 CFR 1910.134, "Respiratory Protection," and they are compatible.

Compliance with other Federal Requirements

Requirements for the Occupational Safety and Health Administration (OSHA) under the Department of Labor for respiratory protection for general industry are listed in 29 CFR 1910.134.

Requirements for a respiratory protection program are listed in 29 CFR 1910.134(c), which requires a written program. The licensee has a single program for protection against respiratory hazards from both industrial and radioactive materials. It is executed in conformance with the site Radiation Protection Manual under Procedure RP-05, *Respiratory Protection*.

Requirements for selection of a respirator are listed in 29 CFR 1910.134(d). The licensee's general requirements are specified in the Radiation Protection Manual RP-05 in Section 6 "Procedure."

The requirements in 29 CFR 1910.134(e)(2)(i) specify that the employer shall identify a physician or other licensed health care professional (PLHCP) 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. General Requirement 20 of Section 6.0 of RP-05, page 4 of 11, states that a respirator wearer must have a current medical physical as specified by a licensed medical doctor. Attachment 3 to the Radiation Protection Manual RP-05 lists the typical tests and procedures in an individual's physical examination (the questionnaire), including consultation with a physician, followed up with an evaluation and a written lab report. The attachment lists additional tests that may be required by the examining physician.

ENVIRONMENTAL REVIEW

The staff determined that the request is administrative in nature and does not result in a change in the types or significant increase in the amounts of any offsite effluents, no significant increase in individual or cumulative occupational radiation exposure and construction impact, nor significant increase in the potential for or consequences from radiological accidents.

Therefore, in accordance with 10 CFR 51.22(c)(11), neither an Environmental Assessment nor an Environmental Impact Statement is warranted for this action.

CONCLUSION

The staff concludes that the activities to be authorized by the issuance of this exemption is in compliance with law, and will not constitute an undue risk to the health and safety of the public, workers, or the environment.

The staff recommends that a new Safety License Condition S-13 be issued to reflect the use of nurse practitioners for medical examinations required by the respiratory protection program as follows:

S-14 Notwithstanding the requirements of 10 CFR 20.1703(c)(5), the licensee may use nurse practitioners to conduct the required medical examinations.

PRINCIPAL CONTRIBUTOR

Merritt N. Baker