Sollenberger, Dennis

FSMB

From: Torre Taylor
Sent: Wednesday, February 18, 2009 10:57 AM
To: Bruce Watson; Donna Janda; Gary Purdy; J Bruce Carrico; Joan Olmstead; Sandra Gabriel; Monica Orendi
Cc: Dennis Sollenberger; Torre Taylor
Subject: Staff assessment for the NJ agreement application
Attachments: staff assessment assignments feb 2009.doc; Enclosure 4 NJ Staff Assessment dennis revision jan 2009.docm

Importance: High

Correction to date to complete assessment -

Sorry - I lost a week there. The due date is really 2/27 and we'll try for a team meeting on 2/25 or 26 pending schedules.

Hello,

I've attached a draft staff assessment and team assignments per my earlier email.

The draft staff assessment is the one from the Virginia agreement that is currently being worked on by Monica. Certain text is highlighted that needs to be revised based on NJ's application. We may not have gotten all text highlighted that needs to be changed - be sure and check the language carefully. For the section on Personnel - so much will change, we didn't bother highlighting it.

Most of the questions are a short paragraph, but there is a reference section as to where the information is found. I still don't have an ADAMs ML number yet - so if you can be specific as to which volume and section of the application your reference is in, I can add the ML in later.

Dennis suggested that for your assignments, if there are outstanding issues from your review, list them in bullets after the paragraph - we will resolve those as we proceed with the staff assessment.

Monica did the regulation review portion for the NJ application - so I've included her on this email as well.

We ask that you complete your sections by February 20, 2009. Dennis and I are trying to schedule a team meeting on 2/18 or 19 (depending on how the teams' schedule looks) to discuss the assessment and address any questions.

Let me know if you have problems opening the document - there is a funny extension but I've been able to open it by right click and open.

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G/33

Sections and Questions in Staff Assessment for NJ Agreement Application

Name	Section	Question	Comments
Torre and Dennis	Objectives	Q.1	
	Personnel	Q. 20	
	Staff Conclusion		
Bruce Carrico	Prior Evaluation of Uses of Radioactive Materials	Q.14	Coordinate response with Sandra
Joan	Inspection	Q.17, 18	
	Administration	Q. 23-27	
Sandra	Prior Evaluation of Uses of Radioactive Materials	Q.14	Coordinate response with Bruce
Donna	Inspection	Q.16	
	Enforcement	AQ.19	
Bruce Watson	No assignment		
Gary	No assignment		
Monica	Radiation Protection	Qs. 2-12	
	Prior Evaluation of Uses of Radioactive Materials	Qs. 13, 15	
	Personnel	Q. 21, 22	
	Administration	Q. 28	

DRAFT ASSESSMENT

of the proposed

NEW JERSEY PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS

as described in the

REQUEST FOR AN AGREEMENT

This Assessment examines the proposed State of New Jersey (State or New Jersey) Program with respect to the ability of the program to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954 (Act), as amended.[1] This Assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")[2] using the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700 "Processing an Agreement". Each criterion, and the staff assessment related thereto, is addressed separately below.

OBJECTIVES

1. Protection. **A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.**

The proposed Agreement State Program for the State, regulating radioactive materials, would be located in the Division of Radiological Health (DRH), in the Office of Epidemiology, which is an organizational unit in the Virginia Department of Health, Office of Public Health (VDH). The VDH is designated by law to be the Commonwealth's radiation control agency. The authorities to issue, amend, suspend or revoke licenses; place conditions and to issue orders; or assess administrative fines is vested by Statute in the VDH.

Although by law, certain authority for regulating radioactive material is delegated to the Virginia Board of Health, the Commissioner for Public Health is vested with all the authority of the Board when it is not in session. The Commissioner for Public Health is the head of the VDH and can then delegate these responsibilities to the appropriate Division. The Commissioner has delegated these responsibilities to the DRH.

The NRC staff verified that the Commonwealth's Radiation Protection Program design for distributing regulatory responsibilities to the program staff is similar to designs used successfully in other Agreement States, and that all necessary program elements have been addressed.

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[1]According to paragraph (a) of Section 274, the radioactive materials subject to the Act are byproduct, source and special nuclear materials.

[2]NRC Statement of Policy published in the Federal Register, January 23, 1981 (46 FR 7540-7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register, July 21, 1983 (48 FR 33376).

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority and Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes: 32.1-2, 32.1-16, 32.1-19, 32.1-20, 32.1-228, 32.1-228.1, 32.1-229, 32.1-229.3. Commonwealth Regulations 12 VAC 5-481.

RADIATION PROTECTION STANDARDS

2. Standards. **The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass.**

In conjunction with the rulemaking authority vested in the Virginia Board of Health by Virginia Statute 32.1-229 of the Code of Virginia, VDH has the requisite authority to promulgate rules for protection against radiation.

The NRC staff verified that the VDH adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Commonwealth Regulations Title 12 Section 5-481, Radiation Protection Regulations. Therefore, VDH has adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority and Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes: 32.1-2, 32.1-16, 32.1-19, 32.1-20, 32.1-228, 32.1-228.1, 32.1-229, 32.1-229.3. Commonwealth Regulations 12 VAC 5-481.

3. Uniformity of Radiation Standards. **It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR Part 20 of the NRC regulations based on officially approved radiation protection guides.**

The Commonwealth, by statute, must promulgate and enforce rules for the regulation of byproduct, source, and special nuclear material that are in accordance with Section 274 of the Act, as amended. The NRC staff verified that the Commonwealth adopted regulations compatible with 10 CFR Part 20.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related

correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Virginia Statutes: 32.1-2, 32.1-16, 32.1-19, 32.1-20, 32.1-228, 32.1-228.1, 32.1-229, 32.1-229.3. Commonwealth Regulations 12 VAC 5-481.

4. Total Occupational Radiation Exposure. **The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.**

The NRC staff review verified that the Commonwealth has adopted regulations compatible with the NRC regulations in 10 CFR Part 20, including Subpart C, the occupational dose limits and Subpart D, the dose limits to individual members of the public. Commonwealth licensees are required to consider the radiation doses to individuals from all sources of radiation, except background radiation and radiation from medical procedures. Like NRC licensees, Commonwealth licensees are required to consider the radiation dose whether the sources are licensed or unlicensed.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

5. Surveys, Monitoring. **Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.**

NRC requires surveys and monitoring pursuant to Subpart F of 10 CFR Part 20. The NRC staff review verified that the Commonwealth has adopted regulations compatible with 10 CFR Part 20 Subpart F. Therefore, Commonwealth licensees are required to conduct surveys and personnel monitoring to the same standards required of NRC licensees.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

6. Labels, Signs, Symbols. **It is desirable to achieve uniformity in labels, signs and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.**

The NRC staff review verified that the Commonwealth has adopted regulations compatible with the NRC regulations in Subpart J of 10 CFR Part 20. Therefore, the radiation labels, signs and symbols, and the posting and labeling requirements in the

Commonwealth regulations are compatible with those contained in the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

7. Instruction. **Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19, Section 19.16 and to be represented during inspections as specified in Section 19.14 of 10 CFR 19.**

   The NRC staff review verified that the Commonwealth has adopted regulations compatible with the NRC regulations 10 CFR Part 19.

   The staff concludes that this criterion is satisfied.

   References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

8. Storage. **Licensed radioactive material in storage shall be secured against unauthorized removal.**

   The NRC staff review verified that the Commonwealth has adopted regulations compatible with the NRC regulations in Subpart I of 10 CFR Part 20.

   The staff concludes that this criterion is satisfied.

   References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

9. Radioactive Waste Disposal. **(a) Waste disposal by material users. The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR Part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority. Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR 20. The waste disposal standards shall include a waste classification scheme and provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR Part 61.**

   The NRC staff review confirmed that the Commonwealth has adopted regulations that are compatible with the NRC regulations in Subpart K of 10 CFR Part 20 - Waste

Disposal. These regulations deal with general requirements for waste disposal including waste classification, transfer, and waste manifests and are applicable to all licensees.

The staff therefore concludes that Criterion 9(a) is satisfied.

(b) Land Disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons, which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR Part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97-425).

The NRC staff review confirmed that the Commonwealth is not seeking authority to regulate the land disposal of low-level radioactive waste. Therefore, Criterion 9(b) does not apply to the Commonwealth.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

10. Regulations Governing Shipment of Radioactive Materials. **The State shall, to the extent of its jurisdiction, promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U. S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR Part 71.**

The NRC staff verified that the Commonwealth has adopted regulations compatible with the NRC regulations in 10 CFR Part 71. The Commonwealth's regulations specifically exempt areas of exclusive NRC jurisdiction.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

11. Records and Reports. **The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e)**

at request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The NRC staff review verified that the Commonwealth has adopted regulations compatible with the NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 61 70, 71, and 150. The records and reports referenced in Criterion 11 are regulatory requirements in these parts. The Commonwealth has adopted the necessary record and reporting requirements.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

12. Additional Requirements and Exemptions. **Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.**

The NRC staff has verified that the Commonwealth has adopted a regulation which is compatible with 10 CFR 30.34, Terms and conditions of licenses, in 12 VAC 5-481-500. The Commonwealth regulations provide the radiation control agency authority to impose, by order or license condition, additional health and safety requirements beyond the requirements specified in law and the rules. The agency also has legal authority to grant reasonable and necessary exceptions to the regulatory requirements, either by order or by license condition.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

PRIOR EVALUATION OF USES OF RADIOACTIVE MATERIALS

13. Prior Evaluation of Hazards and Uses, Exceptions. **In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards, and the capability of the user or possessor prior to his receipt of materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the processor and user. These categories fall into two groups: those materials and uses which may be**

completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating specific use.

The Commonwealth has adopted regulations containing regulatory requirements for applying for and issuing licenses, which are compatible with NRC's regulations.

The NRC staff review confirmed that the Commonwealth's regulations provide that only NRC may issue a license authorizing the distribution of agreement materials that will subsequently be exempt from regulatory control.

Since Criterion 13 was adopted, the Commission has determined that the regulatory authority to conduct safety evaluations of sealed sources and devices may be retained by the NRC, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement the authority. The Commonwealth has decided not to seek authority for evaluation of sealed sources and devices.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

14. Evaluation Criteria. **In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be consistent with NRC licensing regulatory guides for various categories of licensed activities.**

The NRC staff review determined that the Commonwealth has established a series of checklists, regulatory guides, licensing procedure guides and a set of applicable forms. The Commonwealth has developed a series of regulatory guides for use by license applicants. The NRC staff determined that the licensing procedure guides cover the handling of license applications from the point of submittal through issuance of the completed license. The Commonwealth licensing procedures are similar to NRC's procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314).

15. Human Use. **The use of radioactive materials and radiation on or in humans shall**

not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

The NRC staff verified that the Commonwealth has adopted compatible regulations to the NRC regulations in 10 CFR Part 35. Therefore the Commonwealth's regulations include training and experience requirements for use of radioactive material which are equivalent to the NRC requirements.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

INSPECTION

16. Purpose, Frequency. **The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance.**

The NRC staff confirmed that the Commonwealth has statutory authority to conduct inspections of licensees. The Commonwealth has adopted regulations compatible with equivalent parts of the NRC regulations containing provisions relating to inspections and tests.

The Commonwealth has adopted a schedule for inspection of licensees at least as frequent as the schedule used by NRC. The Program staff has developed internal procedures and accompanying forms for the inspection areas which cover scheduling, preparation, performance basis, tracking and documentation of inspection results. The inspection procedures are similar to NRC procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

17. Inspections Compulsory. **Licensees shall be under obligation by law to provide access to inspectors.**

The NRC staff review confirmed that Commonwealth law provides authority for radiation control Program inspectors to enter public or private property at all reasonable times for the purpose of investigating conditions related to radiation use.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

18. Notification of Results of Inspection. **Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.**

The NRC staff review determined that the Commonwealth has adopted procedures to convey a copy of the formal inspection report to the licensees, both when violations are found, and when no violations are found. The procedures identify the staff responsible and specify the time limit for preparing the inspection report, the process for management review and approval, and provide instructions for distribution of the report to the licensee and to the Commonwealth's official files.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314).

ENFORCEMENT

19. Enforcement. **Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties.**

The NRC staff review confirmed that the Commonwealth is authorized by law to enforce the Commonwealth's regulations using a variety of sanctions, including the imposition of administrative fines, the issuance of orders to suspend, modify or revoke licenses, and any other action deemed appropriate by the Program. The Program may assess civil penalties in accordance with Commonwealth Law and Department regulations.

The Program has adopted policies and procedures to implement the enforcement authority. The Commonwealth enforcement procedures are similar to the NRC procedures with regard to the use of severity levels for violations.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

PERSONNEL

20. Qualifications of Regulatory and Inspection Personnel. **The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspections of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments (their selection, use and calibration), laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants of other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.**

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life science, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training - radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which are out of the ordinary. These people should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in the field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, the trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree

or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories, proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

Based on the review of the organizational charts and position descriptions for the VDH, the VDH training and qualification plan, and the curricula vitae for the current staff members, the NRC staff concludes that the VDH has a staffing plan that provides a sufficient number of adequately trained and qualified technical staff.

a. Assessment of the Agreement Materials Staffing

There are 386 NRC specific licenses in the Commonwealth. The Commonwealth currently conducts a licensing and inspection program for naturally occurring or accelerator-produced radioactive material (NARM) users. There are approximately 216 NARM licenses in the Commonwealth. Approximately 180 of the NARM licenses are dually licensed by the Commonwealth and the NRC. It is estimated that there will be approximately 420 total Commonwealth licenses.

The staff of the Radioactive Materials Program (RMP) will be responsible for implementing the Agreement State Materials Program. The Commonwealth staffing plan allocates nine staff to the materials program. This includes six Radiation Safety Specialists for licensing and inspection, one Supervisor, and two Program Support Staff. Currently there are four licensing and inspection staff and the RMP supervisor in place. Additionally, one full-time equivalent (FTE) program support staff is available in the business unit. Radiation Safety Specialists will be utilized in all aspects of the materials program. They will perform inspections, conduct licensing reviews, and participate in enforcement activities. The Radiation Safety Specialists will devote one hundred percent of their time to the agreement state program. One hundred percent of the RMP supervisor's time will also be devoted to the Agreement State program. That time will be divided among various duties, including management review of licensing and inspection actions, personnel responsibilities, rules development, inspector accompaniments, general supervision, and other management duties.

Based on the RMP staffing allocation of nine technical, supervisory and administrative FTE for the agreement state program, and subtracting the two Radiation Safety Specialists and one Program Assistant that will be requested for hire in FY 2009, the technical, supervisory, and administrative staffing level devoted to the agreement state program is 6 FTE. The Review Team's evaluation of the State's staffing analysis concludes that adequate staffing exists for the RMP without the two additional Radiation Safety Specialists and one additional Program Assistant.

The two additional Radiation Safety Specialist FTE and one Program Assistant FTE that will be added to the RMP at a later date will provide extra strength and flexibility to the RMP.

The Commonwealth's estimate of approximately 420 licensees has resulted in an RMP estimate that the current RMP staff of six FTE is adequate for transition to becoming an Agreement State. This projection is based on data from the NRC Region I Office. This level of staffing should allow for keeping the inspection program and licensing program current. Based on the workload analysis, NRC staff concludes that the four Radiation Safety Specialists and RMP Supervisor along with the Program Support Staff provides an adequate level of staffing to handle anticipated licensing, inspection, allegations, and incident response workload satisfactorily.

The staff concludes that the proposed RMP has an adequate number of staff to transition to and meet the anticipated needs of the Agreement State Program.

The staff concludes that criterion 20(a) is satisfied.

b. Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the RMP's staff that would be involved in the Agreement State Materials Program and the procedures for training and qualifying new staff members. Under the proposed Agreement, the RMP Supervisor would direct the Agreement State Materials Program and would be primarily responsible for the Program's administration and will provide the immediate day-to-day supervision of the Agreement State Materials Program. This individual holds a bachelors degree in Business. He has over 14 years experience in health physics and supervision. He has 8 years Agreement State materials program experience, including experience in an Agreement State materials program from another state, and 6 years of radiological experience in the U.S. Navy.

Based on the NRC staff review, all of the non-supervisory technical staff members have at least a bachelor's degree in a physical or life science. One staff member has a bachelor's degree in environmental studies, one staff member has a bachelor's degree in chemistry, one staff member has a bachelor's degree in environmental health, and the remaining staff member has a master's degree in physics.

The RMP's technical staff has significant health physics and radiation science experience. This includes work in health physics at state regulatory agencies, the military and private industry. RMP technical staff has completed or are scheduled to complete the NRC recommended core courses, or have received waivers from the RMP supervisor in accordance with RMP training procedures, based on their prior training and experience.

RMP technical staff has accompanied NRC staff on inspections of NRC licensees in the Commonwealth. Additionally, the RMP staff has been inspecting and processing licensing actions for NARM users in the Commonwealth; performing approximately 80 inspections and processing approximately 150 licensing actions annually. Several of the technical staff have licensing and/or inspection experience from prior employment in other Agreement State materials programs.

NRC staff believes that the RMP technical staff identified by the Commonwealth to participate in the Agreement State Materials Program are trained in accordance with the RMP plans, have sufficient knowledge and experience in radiation protection, the use of radioactive materials, the standards for the evaluation of applications for licensing, and

techniques of inspecting licensed users of radioactive materials.

The NRC staff concludes that the proposed RMP has a sufficient number of adequately trained staff to transition to the Agreement State Materials Program and to meet program needs.

The staff concludes that criterion 20(b) is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Program Organization and Staff Descriptions, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314).

21. Conditions Applicable to Special Nuclear Material, Source Material and Tritium. **Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms, (1) transfers of special nuclear material, source material and tritium, and (2) periodic inventory data.**

The NRC staff review did not note any aspects of the RMP that could potentially interfere with duties imposed on a holder of materials by the NRC. In addition, the Commonwealth's regulations specifically exempt areas of exclusive NRC or other Federal jurisdiction from Commonwealth regulation. The staff is therefore satisfied that the RMP will not interfere with duties imposed on the holder of materials by the NRC.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

22. Special Nuclear Material Defined. **Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:**

175 (grams contained U-235)/350 + 50 (grams U-233)/200 + 50 (grams PU)/200 = 1

The NRC staff determined that the Commonwealth's definition of special nuclear material in quantities not sufficient to form a critical mass in 12 VAC 5-481-10, is compatible with that of the Commission's.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Regulations 12 VAC 5-481.

ADMINISTRATION

23. Fair and Impartial Administration. **State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:**

    a. **Formulation of rules of general applicability;**
    b. **Approving or denying applications for licenses or authorization to process and use radioactive materials; and**
    c. **Taking disciplinary actions against licensees.**

The NRC staff review confirmed that the VDH is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. These general statutory provisions also apply to the protection of personnel radiation exposure records from public disclosure, maintaining the confidentiality of allegers, and administrative and judicial requirements for requesting and holding hearings on enforcement matters.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes: 2.2-4000 – 2.2-4031, 32.1-227 – 32.1-238, 32.1-2 – 32.1-20, 32.1-27.

24. State Agency Designation. **The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.**

The NRC staff determined that the VDH is designated by VA Statute 32.1-228.1 to be the lead agency for the carrying out the terms of the proposed Agreement, which will assure against duplicate regulations or licensing by Commonwealth and local authorities. In addition, to the extent that this criterion deals with duplicate regulation between a State and the NRC (see FSME Procedure SA-700 Handbook, Evaluation Criteria 4.1.1.2., paragraph b, and 4.2.2.2), the staff determined that the RMP, which specifically excludes from Commonwealth regulation any areas in which the jurisdiction of the NRC or another Federal agency is exclusive, gives sufficient assurance against duplicate regulation between the Commonwealth and the NRC in the regulation of agreement material.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes: 2.2-4000 – 2.2-4031, 32.1-227 – 32.1-238, 32.1-2 – 32.1-20, 32.1-27.

25. Existing NRC Licenses and Pending Applications. **In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or the processing of license applications by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State Law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.**

The NRC staff review confirmed that Commonwealth Statute 32.1-229.3(B) contains a provision that provides for recognition of existing NRC and Agreement State licenses. Commonwealth regulation 12 VAC 5-481-550 recognizes NRC licenses while 12 VAC 5-481-590 provides a process for recognition of other Agreement State licenses.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, Section on Statutory Authority, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes: 2.2-4000 – 2.2-4031, 32.1-227 – 32.1-238, 32.1-2 – 32.1-20, 32.1-27. Commonwealth regulations 12 VAC 5-481.

26. Relations with Federal Government and Other States. **There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.**

The NRC staff review verified that the proposed Agreement commits the Commonwealth to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation and to assure that the RMP will continue to be compatible with the NRC's program for the regulation of agreement materials.

In a revised Policy Statement on Adequacy and Compatibility of Agreement State Programs (published September 3, 1997 at 62 FR 46517), the Commission determined that providing reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. The Commonwealth has adopted procedures to provide such reports to NRC.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes 32.1-229. Commonwealth regulations 12 VAC 5-481.

27. **Coverage, Amendments, Reciprocity. An amendment providing for discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State may relate to any one or more of the following categories of materials within the State, as contemplated by Public Law 86-373 and Public Law 95-604:**

    a. **Byproduct material as defined in Section 11e(1) of the Act,**
    b. **Byproduct material as defined in Section 11e(2) of the Act,**
    c. **Source material,**
    d. **Special nuclear material in quantities not sufficient to form a critical mass,**
    e. **Low-level wastes in permanent disposal facilities, as defined by statute or Commission rules or regulations containing one or more of the materials stated in a, c, and d above but not including byproduct material as defined in Section 11e(2) of the Act;**

    but must relate to the whole of such category or categories and not to a part of any category. If less than the five categories are included in any discontinuance of jurisdiction, discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State of the others may be accomplished subsequently by an amendment or by a later Agreement.

    Arrangements should be made for the reciprocal recognition of State licenses and NRC licenses in connection with out-of-jurisdiction operations by a State or NRC licensee.

    The NRC staff review verified that the proposed Agreement provides for the Commission to relinquish, and the Commonwealth to assume, regulatory authority over the types of material defined in categories a, c, and d above.

    Since this criterion was adopted, the Commission has determined that the Agreement States may assume the authority to evaluate the safety of sealed sources and devices to be distributed in interstate commerce as a separate portion of the Agreement, or to allow NRC to retain that authority. The Commonwealth has chosen not to assume that authority.

    The proposed Agreement stipulates the desirability or reciprocal recognition of NRC and other Agreement State licenses, and commits the Commission and the Commonwealth to cooperate to accord such reciprocity. The Commonwealth's regulations provide for the reciprocal recognition of licenses from other jurisdictions.

    The staff concludes that this criterion is satisfied.

    References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Commonwealth Statutes 32.1-227, 32.1-238.

Commonwealth Regulations 12 VAC 5-481.

28. **NRC and Department of Energy Contractors. The State should provide exemptions for NRC and DOE contractors which are substantially equivalent to the following exemptions:**

    a. **Prime contractors performing work for the DOE at U.S. Government-owned or controlled site;**

    b. **Prime contractors performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;**

    c. **Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and**

    d. **Any other prime contractor or subcontractor of DOE or NRC when the State and the NRC jointly determine (i) that, under the terms of the contract or subcontract, there is adequate assurance that the work there under can be accomplished without undue risk to the public health and safety; and (ii) that the exemption of such contractor or subcontractor is authorized by law.**

The NRC staff review verified that the Commonwealth has adopted compatible regulations to NRC regulations in 10 CFR Parts 30, 40 and 70 including §30.12, §40.11, and §70.11 wherein the specified exemptions are contained. The NRC staff concludes that the Commonwealth regulations do provide for exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with the criterion.

The staff concludes that this criterion is satisfied.

References: Letter dated June 12, 2008, from Governor Kaine to Chairman Klein, request for an Agreement, and additional related correspondence between the NRC and the State (ADAMS: ML081720184, ML081760524, ML081760523, ML081760623, ML081760624 and ML082470314). Virginia regulations 12 VAC 5-481.

STAFF CONCLUSION

The NRC staff has reviewed the proposed Agreement, the certification by the Commonwealth in the application for an Agreement in letter dated June 12, 2008, from Governor Kaine to Chairman Klein, and the supporting information provided by the staff of the VDH.

Section 274d. of the Act provides that the Commission shall enter into an Agreement under Section 274b. with any State if:

(a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and

(b) The Commission finds that the State program is in accordance with the requirements of

Section 274o. and in all other respects compatible with the NRC's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

The staff concludes that:

On the basis of this Assessment, the Commonwealth of Virginia meets the requirements of the Act. The RMP, as defined by its statutes, regulations, personnel, licensing, inspection, and administrative procedures, is compatible with the program of the NRC and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.