

## Questions Regarding New Jersey Seeking Agreement State Status

Submitted: 5/16/2006

By: Mary J. Dorman, NJHPS President

Contact Information: [dormanm@wyeth.com](mailto:dormanm@wyeth.com) or 732-274-4478

1. In terms of the general steps involved, please describe the overall process the state's Radiation Protection Program would undergo to attain Agreement State status from the Nuclear Regulatory Commission (NRC). Include anticipated time frames, if possible.
  - The process of becoming an Agreement State begins with the "Letter of Intent" from the Governor, which notifies the NRC of the state's desire to become an NRC Agreement State. Governor Corzine signed the letter of intent on May 23, 2006. This letter of intent allows the state to start sending employees to NRC training on licensing procedures and inspection techniques. We will also need to adopt regulations that are compatible with NRC regulations. NRC regulations can be adopted by reference and fine tuned at a later date. Once our employees have been trained and have a radioactive materials program in place which includes similar licensing, inspection and response capabilities as the NRC, and new regulations adopted, the NRC will determine if the State's program is "adequate and compatible" with the NRC. Regulations must meet the NRC's compatibility criteria. The State's radioactive materials program must be adequately staffed and have resources to allow a "seamless" transfer for the licensees in New Jersey. Only when the State is prepared to take over the regulation of radioactive materials will the NRC sign the Agreement. The NRC's process for evaluating an Agreement State application can be found in State and Tribal Programs (STP) Procedure SA-700 (<http://www.hsrdo.org/nrc/procedures/sa700.pdf>). We believe it will take approximately three to five years from May 23, 2006 for NRC to agree to discontinue its authority over radioactive materials and transfer the program to New Jersey.
2. If New Jersey becomes an Agreement State, what specific types of NRC Licensees would be affected and approximately how many of these licensees are currently in New Jersey?
  - The NRC currently licenses approximately 500 facilities in New Jersey and the New Jersey Department of Environmental Protection (DEP) also licenses approximately 500 facilities. Most of the NRC licensees also hold state licenses, so that the total number of regulated entities as a result of the overlap will be approximately 700. Examples of licensees are hospitals, universities, research facilities, pharmaceutical companies, industrial facilities using radiography sources, gas chromatographs,

gauging devices, and lead paint analyzers.

- Materials licenses that will remain with the NRC include any federal facilities and licenses that authorize the exempt distribution of consumer products.
- There are also many users of generally licensed devices. For instance, it is estimated that there are over 50,000 tritium exit signs in New Jersey.

3. What do you deem to be the primary benefit(s) that will be realized by those licensees currently with the U.S. NRC?

- Based on the feedback we received, many members of the regulated community favor regulation by the state rather than the federal government. New Jersey already has a comprehensive radiation protection program encompassing x-ray, naturally occurring radioactive materials, clean-up of radioactively contaminated sites, monitoring around nuclear power plants, emergency response to radiological incidents, and non-ionizing radiation. There are also requirements for licensure of people, radiological technologists, nuclear medicine technologists, radon testers and mitigators, and qualified medical physicists. If New Jersey becomes an Agreement State, members of the regulated community could come to one program for all regulatory issues. The NRC will continue to regulate the nuclear power plants.
- Significant savings could be realized by the regulated community. New Jersey facilities that use radioactive materials pay 30 percent more in licensing costs to the NRC for their licenses than they would if New Jersey were an Agreement State.
- DEP staff respond to all incidents of stray radioactive materials in the environment, with an average of 80 incidents a year. The NRC does not have the capability to respond to these incidents. In fact, the NRC has often requested that DEP respond for them or assist them in some capacity. Many Agreement States have a closer relationship with licensees than the NRC and find that providing compliance assistance or other programs which initiate more frequent contact means that licensees are more conscious of their role in keeping closer control of their radioactive sources. That results in fewer incidents that require emergency response. This is consistent with DEP's "pollution prevention" philosophy.
- A number of radioactively contaminated sites in New Jersey contain material regulated by the NRC (such as thorium), as well as material regulated by the state (such as radium). Two agencies oversee the cleanup

and have different requirements for ensuring that the site poses no hazard to the public. One-stop clean-ups would enhance efficiency.

4. Do you anticipate any differences or changes that may be realized by current NJDEP licensees during the process as the Radiation Protection Program seeks agreement state status?
  - During the Agreement State process, the NJDEP will continue its licensing and inspection program, as well as its ability to respond to radiological emergencies uninterrupted. The DEP does not anticipate any significant impact on licensees during the process.
  - As a consequence of the DEP's efforts to improve business practices, the entire radiation protection regulatory program is being added to the computer system known as New Jersey Environmental Management System or NJEMS. This will result in greater efficiency with regard to processing registrations, licenses, inspection reports, and enforcement actions.
  
5. By what percentage do you expect the New Jersey Radiation Protection Program will expand in terms of staffing and scope, during the phases of seeking Agreement State status and thereafter, as the NRC licensees are incorporated in the New Jersey Radiation Protection Program?
  - During the approximate 3 years it takes for the Agreement State process to be completed, it is anticipated that 3-5 additional professionals that will assist in materials licensing and inspections. As part of the Agreement State application process, we will perform a staff needs analysis to refine the number of staff needed for the Agreement State program.
  
6. In your opinion, what are the most significant challenges and opportunities facing the New Jersey Radiation Protection Program during the process of preparing for Agreement State status? Please discuss how these will be met.

Challenges:

- DEP would be the responsible for all radioactive materials, including those that have been regulated by the NRC. New Jersey would be accountable for any past or existing regulatory problems. We anticipate that adequate staffing will be hired and trained to support existing staff in resolving these issues.

Opportunities:

- New Jersey would be able to further develop our homeland security strategy for the nuclear sector to include a larger universe of potential threats. Security of radioactive materials is a prime concern in New Jersey. The marine terminal operations at Port Newark/Elizabeth have

become an additional concern since 9/11. The Energy Policy Act of 2005 set a uniform standard for security of all radioactive materials, making the United States eligible to sign the International Atomic Energy Agency's Code of Conduct and thereby facilitating import and export of radioactive materials between the United States and other parties to the Code of Conduct. Agreement State status will enable New Jersey to share information more readily with U.S. Customs and other federal agencies to investigate and alleviate potential threats at our ports.

- Governor Corzine has stated his vision for New Jersey as “invest, prosper, and grow.” Agreement State offers several opportunities. First of all, New Jersey's strict regulatory climate has been singled out as a barrier to new investment. As an Agreement State, the radioactive materials regulations will be consistent with NRC, but the licensing fees will be 30% less. That is a benefit for business. Additionally, since the DEP already was the regulator for x-ray machines, accelerators, accelerator produced materials, radiologic technologists, nuclear medicine technologists, etc. adding the additional licenses for byproduct materials would make it a one-stop shop for all things radioactive in NJ. The regulatory infrastructure is already in place through the comprehensive computer system at DEP. Finally, through the Atlantic Compact, there is an agreement for long-term disposal of low-level radioactive waste, something that most other states will lack in a few years. Agreement State, properly implemented, can make New Jersey a magnet for industry that uses radioactive materials.

7. Please describe the training/preparation that will be made available for state inspectors so they will be skilled to address new radiation safety issues they may encounter with byproduct materials licensees.
  - The NRC offers essential training courses concerning radiation protection, inspection, licensing and emergency response available free of charge to radiation protection personnel in states that have written a “Letter of Intent” to become an Agreement State. The available training is quite comprehensive, and includes courses in inspection procedures, licensing practices, root cause/incident investigation, transportation of radioactive materials, nuclear medicine, industrial radiography, teletherapy and brachytherapy, irradiators, air sampling, MARSSIM, MARLAP, etc. The NJ staff asked to be admitted to these courses before the letter of intent was signed, but was told that it was only open to state staff who have a signed letter of intent. This was one of the driving forces to get the letter signed, so that staff can benefit from this training.
  - In addition, the DEP inspectors have real life experiences responding to actual emergencies and, as a result, have experience with a broad range of radioactive materials and health physics practices. They are currently

responsible for the licensing and inspection of state licensees and have also been the primary responders to radiological emergencies occurring in the state, whether the materials involved were state licensed or NRC licensed.

- DEP inspectors have accompanied NRC inspectors and will have the opportunity to continue accompanying and observing NRC inspectors during routine and reactive inspections of NJ licensees. As the Agreement State process progresses, DEP staff will work closely with NRC license reviewers in Region I to understand the NRC's licensing process.
  - New staff should come in to the program with the education and experience which will make it easy for them to achieve competency in radiation regulation. Starting salaries in NJ are higher than in many other Agreement States. The requirements for a radiation physicist 3, the lowest level title in the series which would be relevant to the radioactive materials section are:
    - Graduation from an accredited college or university with a Bachelor's degree in Engineering, Mathematics, or in one of the physical, biological, natural, or environmental sciences.
    - Two years of experience in the field of radiological health.
8. Fees received from New Jersey licensees for applications, inspections, registrations, etc., go to the New Jersey Treasury. Please describe how the Radiation Protection Program is funded?
- The Radiation Protection Program receives funding from several sources. There is an annual appropriation from the New Jersey Treasury General Fund as well as grants from the federal government. The Bureau of Nuclear Engineering is funded by the Nuclear Emergency Response Fund, through an assessment to the owners of nuclear power plants in New Jersey. Specific work that the radiation protection staff does to support site clean-ups, air permits, water or wastewater investigations is charged appropriately to those sources. There is a small agreement with the University of Medicine and Dentistry of New Jersey, School of Public Health, for work related to training of health officials and first responders. The NJ Health Physics Society is a participant in some of those activities. These activities are not funded through the general appropriation (and therefore not funded through fee revenue), so without the agreement with UMDNJ, our participation would not be possible.
9. Concerns regarding funding this endeavor also appear from individuals on a more personal, "citizen-perspective". During Governor Corzine's address to the state

regarding the budget, he made it clear there is a deficit in the budget and a need for tax increases is likely. What budgetary increases are anticipated for the process of seeking Agreement State status and thereafter if achieved, as compared to the current Radiation Protection Program budget? How might this impact the overall state budget?

- During the approximately 3 years it takes to become an Agreement State, we anticipate a budgetary increase will be necessary, or resources will have to be shifted from lower priority programs. This would cover the anticipated costs of additional personnel, training and travel. Because of the additional funding available through homeland security grants, additional vehicles and equipment have been obtained. Through the DEP-wide initiative to improve business practices, the data records system for licenses, inspections and enforcement have been developed, and the radioactive materials section will be an active user of that system by January 1, 2007.
- Once agreement state status is complete, the annual licensing fees received from the regulated community will cover the increased costs and not impact the state budget significantly. The fees would go to the General Treasury, and funding would be appropriated to the General Radiation account in an equal amount to cover the personnel and operating costs of the program. The difference would be that the fees for the radioactive materials licensees would be about 30% less than the NRC would charge.

10. Interestingly enough, the NJHPS is presently taking a retrospective look at the chapter's activities since its inception in 1971. A chapter meeting held during the mid-1970's discussed New Jersey seeking Agreement State status. Can you provide insight as to what actions have been taken in the past regarding this topic. Why has this surfaced again and what are your thoughts on why now might be the right time?

- Consideration for New Jersey to become an Agreement State has been on the table for at least 15 years. This was the result of interest by many members of the regulated community, as well as organizations such as the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). In September 1994, both the ACNP and the SNM petitioned the DEP at that time to "strongly dissuade" the NRC from adopting its proposed policies concerning Agreement States and those states considering the possibility of becoming Agreement States (59 Federal Register 37269; 59 Federal Register 40058). Both organizations felt that these policies were an attempt by the NRC to hold onto existing licensees and take back Agreement State licensees. It was felt that the NRC was attempting to

“take total oversight authority over licensees and eliminate the ability for states to operate as co-regulators with the NRC.” It was believed that the policies would “increase the number of licensees that the NRC regulates which will increase the user fees that the NRC is able to collect and threaten the continuation of accessible Nuclear Medicine services” in our state.

- Given the Governor’s interest in domestic security for chemical and radioactive facilities, clean-up of sites contaminated with large amounts of radioactive waste, and limiting costs to businesses operating in New Jersey, Agreement State status is a logical step.
- The NRC charges fees to its licensees to support not only the radioactive materials program, but the research program, regulatory development program, training program, etc. Although the NRC receives approximately 10% of its budget from the general treasury to offset program areas such as international programs and STP, NRC fees have increased substantially in recent years as more and more states are becoming agreement states, and fewer and fewer licensees are left. It will be economically advantageous for all licensees when New Jersey becomes an Agreement State.
- With the passage of the Energy Policy Act of 2005, NJ could lose our current regulatory authority for NARM radioactive materials.

11. If New Jersey does not seek Agreement State status, what is the Radiation Protection Program’s anticipated involvement when the NRC begins active regulatory responsibility of accelerator produced radionuclides?

- With the enactment of the Energy Policy Act of 2005 (EPAct), the State’s existing regulatory program for radioactive materials would be preempted and the NRC would take over regulation of the approximately 500 users of naturally occurring and accelerator produced radioactive material.
- Diffuse sources of naturally occurring radioactive material, Technically Enhanced Naturally Occurring Radioactive Material (TENORM), and certain activation products that result from accelerator use (e.g. targets, shielding, etc.) are not included in the EPAct and would need to be regulated by the state.
- The NRC would now be required to handle all DOT exemption requests/responses/investigations previously handled by the state.
- As liaison to the Domestic Security Preparedness Task Force for the nuclear sector, the DEP may find itself in a difficult position to adequately

fulfill its various outreach, compliance and monitoring responsibilities if our regulatory authority is preempted by NRC.

12. Please describe the process of generating and amending New Jersey Radiation Protection Program regulations. Specifically, when new NRC regulations are published, how will the state ensure timely incorporation of NRC updates? Can you speak about the process, rationale or guidelines New Jersey will employ as it adopts NRC regulations? What would drive more restrictive limits or regulations?

- When NRC undertakes rulemaking in the radioactive materials area, they not only promulgate a rule (with rule proposal, response to comment, and final rule published in the Federal Register), but they also publish how compatible they expect the Agreement State's rules to be. In areas of strict compatibility (Compatibility Categories A and B), the Agreement State's rules must be exactly the same as the NRC ( i.e. "essentially identical"). In areas where variability is warranted the NRC allows states more flexibility (Compatibility Categories C and Health and Safety or H&S). These categories allow the State to have more restrictive requirements as long as the State meets the "essential objective" of the regulation. An example of NRC regulation that has a compatibility category of C is the dose limit for the license termination rule (LTR). The NRC limit for the LTR is 25 mrem per year. DEP's equivalent to LTR is 15 mrem per year and has been determined to be compatible with the NRC regulation. Although all issues involved with rulemaking must be discussed with the Attorney General's office as well as the Office of Administrative Law, and the DEP's Office of Legal Affairs, it would seem logical that for rules involving strict compatibility, adoption by reference would be the easiest way for NJ to have rules in place quickly following NRC's adoption.
- To discuss the specifics regarding the process, rationale, or guidelines New Jersey plans on utilizing as it adopts NRC regulation at this stage of the game would be premature. However, as stated in the response to question #3, New Jersey already has a comprehensive radiation protection program. The same effort and process that was put into establishing such a program will continue to be utilized during the Agreement State process.
- The driving force for more restrictive limits or regulations is usually based on how best to protect the citizens and workers of New Jersey from unnecessary radiation exposures. Sometimes New Jersey's legislature steps in to define how standards may be set. In the case of New Jersey's clean-up standards, the Industrial Site Recovery Act had strict requirements for choosing a standard. New Jersey regulations have to adhere to New Jersey Legislative mandates. At the same time, the whole idea of becoming an "Agreement" state is to have regulations that

are largely the same and compatible with the NRC regulations. Adopting regulations by reference is one way to ensure that the regulations are consistent. (Jill: in light of the example I used above, does DEP plan to adopt the LTR by reference or continue to use its existing regulation?)

13. Will the NRC have oversight of the radioactive materials program in New Jersey?

- Although the NRC discontinues its authority when the Agreement is signed, it still maintains an oversight responsibility as long as the Agreement is in place. The NRC requires Agreement States to be remain “adequate and compatible” and reviews each agreement state program against a set of performance criteria that considers the State’s program in the areas of inspection, licensing and incident response, allegations, staffing and training and compatibility requirements (i.e., regulations). The same set of performance criteria used to review an Agreement State is also used to review an NRC regional program. These reviews take place approximately once every four years. Details of the NRC’s review program ” Integrated Materials Performance Evaluation Program” or IMPEP can be found at the STP website (<http://www.hsr.doe.gov/nrc/procedures/sa100.pdf>). If during an IMPEP review a State’s performance is found to be less than adequate and compatible, the NRC requires the State to take action to improve its performance. The NRC has not hesitated to place an Agreement State program under a closely monitored program to ensure that improvements are made. If a State does not improve its performance and the NRC determines that the State is not protecting the health and safety of its citizens, the NRC has the statutory authority to reassert its authority.