



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

**REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415**

March 1, 2000

Richard Cucolo
Director
New York Department of Labor
Division of Safety and Health
NYS Office Campus, Building 12, Room 522
Albany, NY 12240

Dear Mr. Cucolo:

A periodic meeting with New York Department of Labor was held on November 23, 1999. The purpose of the meeting was to review and discuss the status of the Department's Agreement State program. The NRC was represented by Kathleen Schneider from the NRC's Office of State Programs and me. Specific topics and issues of importance discussed at the meeting included the NRC's responses to the Department's questions raised in Clayton Bradt's August 18, 1999 letter and the Department's response to the recommendations from the 1998 IMPEP revised final report.

I have completed and enclosed a general meeting summary, including any specific actions taken as a result of the meeting.

If you feel that our conclusions do not accurately summarize the meeting discussions, or have any additional remarks about the meeting in general, please contact me at (610) 337-5042, or e-mail at adw@nrc.gov to discuss your concerns.

Thank you for your cooperation.

Sincerely,

Duncan White
Regional State Agreements Officer
Division of Nuclear Materials Safety

Enclosure: As stated

cc:
Clayton Bradt, NY Labor, Radiological Health Unit
John Spath, NYSERDA
R. Bores, RI
K. Schneider, OSP

R. Cucolo
New York Department of Labor

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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
NEW YORK DEPARTMENT OF LABOR

DATE OF MEETING: November 23, 1999

ATTENDEES:	<u>NRC</u>	<u>STATE</u>
	Duncan White	Peter Chiefari
	Kathleen Schneider	Clayton Bradt
	Paul Lohaus (by telephone)	
	Fred Combs (by telephone)	
	Hampton Newsome (by telephone)	

DISCUSSION

The proposed status for each of the recommendations and suggestions in Section 5.0 of the 1998 New York revised final IMPEP report is summarized below (number corresponding to those in the draft final IMPEP report). The recommendations and suggestions from Section 5.0 of the revised final IMPEP report can be found in Attachment 1.

1. Since the last IMPEP review, the Department has been inspecting all new licensees within six months of receipt of licensed material. It is recommended that this item be closed at the next IMPEP review.
2. The Department maintains tracking forms for each license reviewer and inspector that includes the training requirements. It is recommended that this item be verified at the next IMPEP review.
3. The Department stated that they are aware of the requirements in OSP Procedure SA-300 for notifying the NRC of reportable events. NRC staff emphasized that incidents should be reported to NRC on a monthly basis in accordance with OSP Procedure SA-300 in order to meet a satisfactory finding for the indicator, Response to Incidents and Allegations. The importance of providing information to close out the events was also stressed. It is recommended that this item be verified at the next IMPEP review.
4. The rule making package, which included a number of NRC amendments, identified during the last IMPEP review was adopted by the Department on April 15, 1999. A copy of these changes to Part 38 of Title 12 of the rules and regulations for the State of New York was provided to NRC staff at the meeting for compatibility review. The Regional State Agreements Officer (RSAO) reviewed these amendments to the Department's regulations and had no comments regarding their compatibility. A letter transmitting this review will be provided to the Department.

The Department stated that they continue to disagree with the 1998 IMPEP findings for the sealed source and device (SS&D) evaluation program indicator (recommendations 5 through 8). NRC staff indicated the report stands as issued. NRC staff noted, however, that NRC and OAS have responded to the issues on areas needing change identified from the NYDL and other State SS&D reviews. An NRC/OAS working group was established and has made recommendations to revise the evaluation criteria for the SS&D indicator to be more performance based (Mr. Bradt was a member of this working group). An OAS team also

reviewed the NRC's SS&D program. It is expected these two initiatives will result in modification of the IMPEP SS&D review criteria.

NRC staff reviewed the Department's actions taken in response to the 1998 IMPEP findings and had no further questions regarding the Department's approach to SS&D reviews. The Department is currently reviewing two amendments to existing sheets using the protocol discussed in the 1998 report and subsequent correspondence.

5. The Department utilizes a number of NRC guidance documents and has customized appropriate checklists to for use with the type of devices (static eliminators, small beta gauges and tritium signs) registered by the Department. It is recommended that this item be verified at the next IMPEP review.
6. The Department policy for conducting SS&D reviews includes a review of the action by two qualified reviewers. It is recommended that this item be verified at the next IMPEP review.
7. The Department's two SS&D reviewers are qualified consistent with Department policy, NRC Management Directive 5.6, and the scope of devices anticipated to registered by the Department. It is recommended that this item be verified at the next IMPEP review.
8. The Department indicated that if an SS&D application was received for review outside the current scope of devices and experience of the current SS&D reviewers, they would request engineering assistance from outside the RHU or the Department. It is recommended that this item be verified at the next IMPEP review.

With regards to the suggestions in the 1998 report, the Department hired an individual from the Department of Health (Charles Burns) with licensing and inspection experience in October 1998. The audit of the financial assurance files was completed during the course of ongoing license renewal and amendments. The Department indicated that they have updated and maintained their allegation tracking system for each allegation.

After discussing the status of the review comments and the Department and NRC's last round of correspondence, it was agreed by both the Department and the NRC attendees that this periodic meeting report would document and serve as the response to the December 30, 1998 IMPEP review and that no additional response would be required from the Department.

A portion of the meeting included a telephone conference call with Hampton Newsome (Office of General Counsel), Paul Lohaus (OSP) and Fred Combs (OSP) to discuss the items raised in the Department's August 18, 1999 letter. The sixth item was discussed separately later in the meeting. In addition to discussing the first five items in the letter, the conference call included a discussion of the Department's questions in an April 12, 1999 letter regarding pre-decisional documents. Copies of the April 12 and August 18, 1999 letters are found in Attachment 2. The discussions are summarized below and will serve as a record of closure for both letters:

1. Item 1, August 18 Letter. The basis for NRC legislative authority to conduct reviews of Agreement State programs is in Section 274 j. of the Atomic Energy Act (AEA) which was added when Congress amended the AEA to incorporate mill tailing language as part of the Uranium Mill Tailings Radiation Control Act (UMTRCA). The Department indicated that the addition of oversight language appears to only apply to mill tailing issues, not an entire state program. This interpretation was previously raised by the Department in the April 13, 1999 letter from Rita Aldrich commenting on OSP procedure SA-102. NRC indicated that it has been the intent of Congress that NRC has the authority to review state programs. The NRC staff agreed to review the background information on UMTRCA to determine Congress' intent. NRC staff did not identify any information that would change NRC's interpretation of Section 274 j. Background documents reviewed by the NRC were provided to the Department. A list of all documents provided to the Department can be found in Attachment 3.
2. Item 2, August 18 Letter. The legislative authority for NRC to conduct pre-market approval of devices and sources containing radioactive material stems from Sections 81 and 161b of the AEA. Section 81 gives the NRC authority for domestic distribution over byproduct material. Section 161b gives NRC authority to establish rules and regulations.
3. Item 3, August 18 Letter. The legislative authority which permits the return of the State's SS&D portion of its Agreement to the NRC is found in Section 274.j. of the AEA which permits the termination of part or all of an Agreement. The NRC initially reviewed this issue in 1980 in relation to low level radioactive waste (LLRW) and partial or limited Agreements. In addition, this issue was also specifically addressed by the Commission more recently in SECY-95-136 and SRM-95-136 for the SS&D program regarding return of a State's SS&D program to the NRC. The Commission also addressed limits to the proposed Oklahoma Agreement in SECY-99-123 and SRM-99-123.
4. Item 4, August 18 Letter. The NRC exposure to liability resulting from approvals of SS&D is limited by the Federal Torts Claim Act. The NRC is not aware of any action taken with regard to NRC's liability for approving SS&D. The degree of an Agreement State's exposure to liability would be determined by individual State law. There was also a discussion of the term "approval." The NRC and Agreement States do not "approve" SS&Ds, but rather determine that the sources and devices are acceptable for licensing under the conditions of use and the limitations set out in the registration certificates. The certifications are then used by NRC and other Agreement States as part of the basis for licensing use of the sources and devices. Consequently, liability may be limited for the NRC and the Agreement States.
5. Item 5, August 18 Letter. With regard to the investigation of alleged misconduct by a member of an IMPEP team member, the NRC talked to the individual who originally raised the concern regarding the NRC's actions and the individual was satisfied with the outcome. The investigation determined that no misconduct occurred.

6. April 12 Letter. Regarding the Department's concerns regarding pre decisional documents, the NRC staff indicated in accordance with agency procedures, such documents would be provided on a need-to-know basis. Staff also noted agency procedures provide that if at any point during an investigation an immediate health and safety concern is identified, the Agreement State would be immediately notified. The Department expressed concern regarding NRC conducting investigations involving Department licensees in the State of New York without prior notification. The Department proposed that the NRC notify the Department's Inspector General (IG) office when an investigation involving a Department licensee is being conducted. There would be no need to provide details. Subsequent to the meeting, the RSAO discussed the Department's concern and proposed solution with the Region I Director for the Office of Investigations (OI) field office. The OI Director agreed with this approach. The NRC requested that the Department provide an appropriate contact in the IG office.

Since the IMPEP in February 1998, the program lost Robert Kelley and Rita Aldrich to retirement. Mr. Kelley was replaced in October 1998 by Charles Burns who transferred from the State Department of Health. Mr. Burns performs licensing and conducts inspections for the Department's Albany office. The retirement of Ms. Aldrich has left the program director position vacant. Her retirement has particularly impacted the licensing program, where she had contributed to reducing the backlog in applications from hundreds of actions to 90. Consequently, the backlog has increased from 90 to 140 actions since her departure in August 1999. At the time of the meeting, Mr. Chiefari, Assistant Director for the Division of Safety and Health, was acting supervisor for the Radiological Health Unit (RHU). Subsequent to the meeting in January 2000, Mr. Chiefari left employment with the Department. Richard Cucolo, the Director of the Division, is currently acting supervisor of the RHU. The Department has requested an examination for the Principal Radiophysicist position (i.e., civil service title for the program director position) and expects that the exam will be given in 2000.

The Department indicated that a working group will be formed with the Department of Health to discuss a merger of the RHU into the State Department of Health. The relocation of the RHU would require a legislative change. NRC staff raised the issue of the transfer of the regulatory oversight for nuclear pharmacies from RHU to Health that was discussed during the New York State Health periodic meeting held in October 1999. The Department indicated that this is on hold pending completion of the working group report on the RHU transfer. There have been no other program changes. The Department indicated that there were no changes to the budget or funding sources that would impact the Department's Agreement State program.

NRC staff discussed recent changes in NRC management, (the new Chairman and changes in the EDO's office); the status of NRC rule making initiatives including medical, release of solid material and general licensing; the OAS review of NRC's sealed source and device evaluation program; and the status of NRC's response to the Congressional inquiry regarding Tennessee's amendment of the Manufacturing Sciences Corporation's license that approved the release for unrestricted use of several thousand tons of nickel.

Mr. Chiefari indicated that the Department will be initiating strategic planning in the near future and inquired what the NRC had done in this area. NRC staff indicated that NRC developed a strategic plan and is currently going through the process again. After the meeting, the NRC staff provided RHU with the electronic address for the NRC's strategic plan.

NRC staff and RHU discussed their concerns regarding Megarad (Item No. 6 in the Department's August 18, 1999 letter). The NRC staff indicated that the company currently has a Radiation Safety Officer (RSO) that meets the requirements in 10 CFR 34.42(a) and was the RSO at another NRC licensee. In response to a concern raised by RHU regarding the duties of the RSO versus company management, NRC staff indicated that the RSO has the specific authority under 10 CFR 34.42(c) to ensure that operations are conducted safely. The most recent NRC inspection of Megarad determined that the licensee was in compliance with NRC requirements.

NRC staff discussed the concept of reducing the time that the IMPEP team would spend at each New York agency responsible for the Agreement to determine if the State is adequate and compatible. The Department favored this approach. The NRC staff also indicated that any inspection accompaniments could be conducted well in advance of the on-site review.

The next periodic meeting will be scheduled for early 2001. The next IMPEP review is scheduled for fiscal year 2002.

ATTACHMENT 1

NEW YORK DEPARTMENT OF LABOR RECOMMENDATIONS AND SUGGESTIONS FROM 1998 IMPEP REPORT

RECOMMENDATIONS:

1. The review team recommends that NYDL perform initial inspections of licensees within six months of the licensees' receipt of licensed material, or commencement of licensed activities. (Section 3.1.2)
2. The review team recommends that NYDL document its training program to include overall policy and minimum training requirements for both the licensing and compliance staff. (Section 3.3.2)
3. The review team recommends that NYDL notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.2)
4. The review team recommends that NYDL management take appropriate action to move the rule package through the rule promulgation process. (Section 4.1.2.2)
5. The review team recommends NYDL establish and use additional procedures for conducting SS&D reviews based on the guidelines presented in the SS&D Workshop and tailored to NYDL's specific policies, requirements, and regulations. (Section 4.2.1)
6. The review team recommends that NYDL establish a clear policy for what constitutes a concurrence review in accordance with guidelines in Management Directive 5.6. (Section 4.2.1)
7. The review team recommends that the NYDL develop a formal qualification program for granting signature authority which would ensure that reviewers both meet the qualifications listed in Management Directive 5.6 and are able to apply these qualifications appropriately during an SS&D evaluation. (Section 4.2.2)
8. The review team recommends that NYDL explore one of the following options to meet the qualifications for an SS&D program for New York:
 - a. Prior to performing another review, provide additional structured training for the SS&D reviewers in the area of engineering principles and materials and their application. This training must provide the reviewers with sufficient knowledge and understanding in the areas listed in Management Directive 5.6 to perform adequate SS&D safety reviews commensurate with the types, complexity, and radiation hazards anticipated for an SS&D safety review.
 - b. If NYDL determines that maintaining SS&D evaluation authority with a staff that has sufficient qualifications and training to conduct adequate reviews is not viable, return the SS&D program to NRC. (Section 4.2.2)

SUGGESTIONS:

1. The review team suggests that the NYDL management consider whether additional staffing is warranted when considering the impacts of the licensing and inspection workloads, the regulation development needs, and the SS&D program improvement needs. (Section 3.3.2)
2. The review team suggests that NYDL continue to audit their financial assurance files to ensure that they contain all required information and are current with NYDL requirements. (Section 3.4.2)
3. The review team suggests that attention be given to the NYDL's tracking system for allegations to ensure that the system accurately indicates when the response to each allegation has been completed and the matter is considered closed out. (Section 3.5.2)
4. The review team suggests that NYDL consider the comments identified in Appendix F, and take action as NYDL deems appropriate. (Section 4.2.1)

ATTACHMENT 2

NEW YORK DEPARTMENT OF LABOR
CORRESPONDENCE

1. Letter dated April 12, 1999 from Rita Aldrich, DOL to Stephen Salomon, OSP
2. Letter dated August 18, 1999 from Clayton Bradt, DOL to Duncan White, Region I



STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 169
State Office Building Campus
Albany, NY 12240

April 12, 1999

Mr. Stephen N. Salomon
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Salomon:

We request clarification on SP-99-019, "Predecisional Documents."

This document states in part that "sensitive" predecisional documents pertaining to allegations and investigations will only be provided to Agreement States on a "need-to-know" basis and only to "Agreement States that we determine can protect the information from public disclosure." In the procedure attached to SP-99-019, "need-to-know" is said to mean that the Agreement State receiving the information "is directly involved with the issue or licensee." Exactly what does this mean?

Is NRC implying that it will withhold information from a state concerning events within that state, or regarding a facility licensed to use AEA materials by that state, if NRC judges that the state cannot "protect" such information from public disclosure?

Depending on your response, we may have extensive further comments.

Sincerely,

A handwritten signature in cursive script that reads "Rita Aldrich".

Rita Aldrich
Principal Radiophysicist

RA:jmp
cc: Agreement States



STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 169
State Office Building Campus
Albany, NY 12240

August 18, 1999
Duncan White
State Agreements Officer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. White:

We have reviewed your proposed agenda for our September 21 meeting and have the following additions:

1. The legislative authority under which NRC conducts reviews of state programs. (Please be prepared to cite relevant sections of the Atomic Energy Act and New York's Agreement.)
2. The legislative authority under which NRC conducts pre-market approvals of devices/sources containing radioactive material. (Please be prepared to cite relevant sections of the Atomic Energy Act.)
3. The legislative authority under which a State can elect to return the SS&D portion of its agreement to the NRC. (Please be prepared to cite relevant sections of the Atomic Energy Act.)
4. The State's and NRC's exposure to liability resulting from approvals of devices/sources containing radioactive material.
5. The status of NRC's investigation of alleged misconduct by a member of the IMPEP team reviewing the Department of Labor's SS&D program.
6. NRC's investigation into allegations of misconduct against the president of MegaRad, Inc.

Recognizing that some of the above topics involve technical legal issues, we believe that it would be useful to have a representative from your Office of General Counsel, who can speak authoritatively on these matters, attend the meeting. If you have any questions, please contact this me at (518) 457-1202.

Sincerely,

Clayton J. Bradt, CHP
Associate Radiophysicist

cc: Peter Chiefari
John Spath
Kathleen Schnieder

ATTACHMENT 3

The following documents were provided (location on NRC web page or hard copy) to the Department after the periodic meeting on November 23, 1999 in response to the issues discussed:

1. **SECY-95-136 and SRM-95-136: Options to Improve and Standardize the Evaluation and Approval of Sealed Source and Devices Manufactured in Agreement States**
2. **SECY-99-123 and SRM-99-123: Proposed Oklahoma Agreement**
3. **NRC's current Strategic Plan and Organizational Charts and Functions**
4. **SECY-80-472: Revised Criteria for States (to update NRC policy to allow States to enter into Agreements for low-level waste and incorporate UMTRCA provisions)**
5. **Senate Report No. 99-199: Low-Level Radioactive Waste Policy Act Amendments of 1985**
6. **House of Representatives Report No. 95-1480 Part 2: Uranium Mill Tailings Radiation Control Act of 1978**
7. **SECY-95-112 and SRM-95-112 and 115: Final Policy Statement on Adequacy and Compatibility of Agreement State Programs**
8. **SECY-91-039: Evaluation of Agreement State Compatibility Issues**
9. **Chapter X "The States and Atomic Regulation" from *Controlling the Atom: The Beginning of Nuclear Regulation***
10. **Legislative History on P.L. 86-373: Amending the Atomic Energy Act of 1954, as Amended with Respect to Cooperation with States; New Section 274 Added, Volumes I and II**