

July 21, 2010

Mr. Leslie Foldesi, Director  
Division of Radiological Health  
Department of Health  
James Madison Bldg.  
109 Governor Street, Room 730  
Richmond, VA 23219

Dear Mr. Foldesi:

As you are aware, the U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) for the evaluation of Agreement State Programs. Per our previous discussion, I will be the team leader for the IMPEP review of the Virginia program scheduled for November 1-5, 2010. The review team will include Ken Lambert from the NRC Region III Office, Steve James from the State of Ohio, and me.

Enclosed is the document, "Integrated Materials Performance Evaluation Program Questionnaire." The questionnaire was previously furnished to you electronically. I ask that you send your responses via e-mail to me at [james.lynch@nrc.gov](mailto:james.lynch@nrc.gov) by October 15, 2010. I am sending the document in advance of the IMPEP review in order to provide time for you to allocate the staff resources necessary to complete the document by the due date.

Also included with the questionnaire is the document "Materials Requested to Be Available for the On-Site Portion of an IMPEP Review." We encourage States to have the items listed prepared prior to the IMPEP team's arrival.

I request that you set up an appointment with the appropriate State Senior Management Official to discuss the results of the IMPEP review of the Virginia Agreement State Program on the morning of November 5th.

If you have any questions, please call me at (630) 829-9661.

Sincerely,

/RA/

James L. Lynch  
State Agreements Officer

Enclosure:  
As stated

cc w/encl: Michael Welling, Assistant Director

Mr. Leslie Foldesi, Director  
Division of Radiological Health  
Department of Health  
James Madison Bldg.  
109 Governor Street, Room 730  
Richmond, VA 23219

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cc w/encl: Michael Welling, Assistant Director  
Steve James, State of Ohio

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

**VIRGINIA**

**Reporting Period: March 31, 2009 to Present**

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

**A. GENERAL**

1. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

**B. COMMON PERFORMANCE INDICATORS**

**I. Technical Staffing and Training**

2. Please provide the following organization charts, including names and positions:
  - (a) A chart showing positions from Governor down to Radiation Control Program Director;
  - (b) A chart showing positions of current radiation control program including management; and
  - (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.
3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

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<sup>1</sup> Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

- |    | <u>Name</u>   | <u>Position</u> | <u>Area of Effort</u> | <u>FTE%</u> |
|----|---|-----------------|-----------------------|-------------|
| 4. | Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, as appropriate.                       |                 |                       |             |
| 5. | Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements. |                 |                       |             |
| 6. | Identify any changes to your qualification and training procedure that occurred during the review period.   |                 |                       |             |
| 7. | Please identify the technical staff that left your program during the review period.  |                 |                       |             |
| 8. | List any vacant positions in your program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.  |                 |                       |             |
| 9. | For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.     |                 |                       |             |

## II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: licensee name, license number, your inspection interval, and rationale for the difference.
11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800; the number of initial inspections; and the number of increased controls inspections that were completed during the review period.
12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, increased controls, and initial inspections that were conducted overdue per the applicable guidance. Priority 1, 2, and 3 licensees and initial inspections must be conducted at least as frequently as the inspection intervals established in IMC 2800. Increased controls inspections should be conducted at the intervals established in the Staff Requirements Memorandum for COMSECY-05-0028.

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority (IMC 2800)

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- (4) Last inspection date or license issuance date, if initial inspection
- (5) Date Due
- (6) Date Performed
- (7) Amount of Time Overdue
- (8) Date inspection findings issued

- 13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees, increased controls, and initial inspections that are currently overdue, per the applicable guidance. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection.
- 14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and the number of candidate licensee reciprocity inspections that were completed each year during the review period.

### III. Technical Quality of Inspections

- 15. What, if any, changes were made to your written inspection procedures during the reporting period?
- 16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<u>Inspector</u>	<u>Supervisor</u>	<u>License Category</u>	<u>Date</u>
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- 17. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

### IV. Technical Quality of Licensing Actions

- 18. How many specific radioactive material licenses does the Program regulate at this time?
- 19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.
- 20. Identify any licensees or groups of licensees that were issued increased controls during the review period. Those licensees that were initially identified during the initial implementation of increased controls need not be listed.
- 21. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.
- 22. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

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23. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

V. Technical Quality of Incident and Allegation Activities

24. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
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25. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.
26. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

C. **NON-COMMON PERFORMANCE INDICATORS**

I. Compatibility Requirements

27. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.
28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.
29. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations, please describe their use.
30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

II. Sealed Source and Device (SS&D) Evaluation Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of devices issued during the review period. The table heading should be:

<u>SS&amp;D Registry Number</u>	<u>Manufacturer, Distributor or Custom User</u>	<u>Product Type or Use</u>	<u>Date Issued</u>	<u>Type of Action</u>
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32. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9  
Technical Quality of Licensing Actions - Questions 18-23  
Technical Quality of Incident and Allegation Activities - Questions 24-26

III. Low-Level Radioactive Waste Disposal Program

33. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9  
Status of Materials Inspection Program - Questions 10-14  
Technical Quality of Inspections - Questions 15-17  
Technical Quality of Licensing Actions - Questions 18-23  
Technical Quality of Incident and Allegation Activities - Questions 24-26

IV. Uranium Recovery Program

34. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9  
Status of Materials Inspection Program - Questions 10-14  
Technical Quality of Inspections - Questions 15-17  
Technical Quality of Licensing Actions - Questions 18-23  
Technical Quality of Incident and Allegation Activities - Questions 24-26

MATERIALS REQUESTED TO BE AVAILABLE FOR  
THE ON-SITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- ☐ List of open license cases, with date of original request, and dates of followup actions.
- ☐ List of licenses terminated during review period.
- ☐ Copy of current log or other document used to track licensing actions.
- ☐ List of all licensing actions completed during the review period (sorted by license reviewer, if possible).
- ☐ Copy of current log or other document used to track inspections.

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- List of all inspections completed during the review period (sorted by inspector, if possible).
- List of inspection frequencies by license type.
- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

- All State regulations
- Statutes affecting the regulatory authority of the State program
- Standard license conditions
- Technical procedures for licensing, model licenses, review guides
- SS&D review procedures, guides, and standards
- Instrument calibration records
- Inspection procedures and guides
- Inspection report forms
- Documented training plan, if applicable
- Records of results of supervisory accompaniments of inspectors
- Emergency plan and communications list
- Procedures for investigating allegations
- Procedures for investigating incidents
- Enforcement procedures, including  
procedures for escalated enforcement,  
severity levels, civil penalties (as  
applicable)
- Job descriptions



**STATE REGULATION STATUS**

State: Virginia

[2 amendment(s) reviewed is identified by a  
at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 10-6

Date: March 2, 2010

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183;	01/01/1994	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

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1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 <b>(Superceded by 1997-5)</b>	06/30/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 <b>(Superceded by 2002-2 and 2005-2)</b>	10/20/1998	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 <b>(Superceded by 2004-1)</b>	04/01/1999	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 <b>(Superceded by 2004-1)</b>	02/10/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 <b>(Superceded by 2002-2)</b>	07/10/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	Final ML100280901	No Comments 03/02/2010 ML100350973	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	

2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	Final ML100280901	Comments 03/02/2010 ML100350973	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Final ML081760528 ML082960329	No Comments 11/10/2008 ML082970632	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			