



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 19, 2001

Docket No. 03007551

License No. 37-00448-19

A. Susan Bernini
Chief Operating Officer
Albert Einstein Healthcare Network
5501 Old York Road
Philadelphia, PA 19141

SUBJECT: INSPECTION 03007551/2001001

Dear Ms. Bernini:

On February 26 through March 1, 2001, Richard McKinley of this office conducted a safety inspection at the above address, 9880 Bustleton Avenue, and One Penn Boulevard, Philadelphia, Pennsylvania, and 8250 Old York Road, Elkins Park, Pennsylvania of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Kimberly Blair and others of your organization at the conclusion of the inspection. Your corrective actions and actions to prevent recurrence, documented in your letter to the NRC dated May 16, 2000, for previously identified violations (NRC Inspection No. 030-07551/2000-001) were also examined as part of this inspection. Your actions were sufficient to prevent recurrence and these violations are considered closed.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

Original signed by Mohamed M. Shanbaky

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

cc:
Karen Colucci, Radiation Safety Officer
Commonwealth of Pennsylvania

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	RMcKinley/rwm		MShanbaky/ms					
DATE	3/6/01		3/16/01					

OFFICIAL RECORD COPY

APPENDIX A MEDICAL BROAD-SCOPE INSPECTION RECORD (IP 87119)									
REGION I									
Insp. Record #	01-001	License #	37-00448-19	Docket #	030-07551				
Licensee Name	Albert Einstein Healthcare Network								
Street Address	5501 Old York Road								
City, State, Zip	Philadelphia, Pennsylvania 19141								
Location (Authorized Site) Being Inspected	Same as above. 8250 Old York Road, Elkins Park, PA 9880 Bustleton Avenue, Philadelphia, PA Germantown Community Health Services, One Penn Boulevard, Philadelphia, PA								
Licensee Contact Name	Karen Colucci—RSO				Phone #	(215)456-6264			
Priority	01	Program Code	02110	Description	Broadscope.				
Date of Last Inspection:		February 23-25 & March 9, 2000		Date of This Inspection		February 26-28 and March 1, 2001			
Type of Insp.	Announced		Routine	x	Initial				
	Unannounced	x	Special						
Next Insp. Date	02/02	Normal	x	Reduced		Extended			
Justification for change in normal inspection frequency:									
Summary of Findings and Actions									
No violations, Clear 591 or letter issued			x	Non-cited violations					
Violation(s), 591 issued			Violation(s), letter issued						
Follow up on previous violations:			The inspector reviewed preventive and corrective actions implemented by the licensee with respect to violations identified by Inspection No. 030-07551/2000-001 and found them satisfactory. (See also #2. below)						

Inspector - Printed Name	Richard W. McKinley		
- Signature	/RA/	Date	03/07/01
Approved - Printed Name	Mohamed M. Shanbaky		
- Signature	/RA/	Date	03/16/01

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY		
1.	AMENDMENTS AND PROGRAM CHANGES	
License amendments issued since last inspection; program changes (including major changes in facilities, activities, procedures, or personnel) noted in the license.		
AMENDMENT #	DATE	SUBJECT
None.		
2.	INSPECTION AND ENFORCEMENT HISTORY	
Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.		

A. 10 CFR 20.1301(a)(2) Failure to keep dose in unrestricted areas below 0.002 rem in any one hour.

The inspector reviewed records of inpatient therapies done since the last inspection, as well as revised forms for recording surveys. No more cases of dose rates in excess of 2 mrem/hr in unrestricted areas were observed. **CLOSED.**

B. 10 CFR 20.1101(c); 10 CFR 35.22(b) Failure to perform the annual review of the radiation protection program content and implementation for 1998.

The annual reviews of the radiation safety program for 1998 and 1999 have been done since the last inspection and were found satisfactory by the inspector. The 2000 review is scheduled for completion by the end of April, 2001. **CLOSED.**

C. 10 CFR 35.32(a) Failure to write all Written Directives with a specific dose or exposure time rather than a range of doses, and failure to write the foregoing prior to completion of the procedure.

Deficiencies in brachytherapy written directives were addressed by the licensee's letter of March 14, 2000, and accepted by NRC. The inspector verified that the new directives are being used. **CLOSED.**

3.

INCIDENT/EVENT HISTORY

List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

None.

PART II - INSPECTION DOCUMENTATION

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87119, Appendix B, "Medical Broad-Scope Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1.	ORGANIZATION AND SCOPE OF PROGRAM
	<p>Management organization; authorities and responsibilities; Radiation Safety Officer (RSO), Radiation Safety Committee (RSC) chairman and members; administrative controls, procedures, and management policies; authorized locations of use; type, quantity and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects.</p>
	<p>The radiation safety staff consists of the RSO and a radiation safety technologist. The licensee is trying to add a half-time person to the radiation safety staff. The technologist reports to the RSO and the RSO reports to the VP of Albert Einstein Health Network (AEHN). The current 2 radiation safety staff monitor nuclear medicine and brachytherapy at AEHN main campus, nuclear medicine at Germantown, Elkins Park, and Einstein One, and machines at all 4 locations.</p> <p>Nuclear medicine at the main campus involves 7 technologists who use 5 cameras to do 25-30 studies per day, including hearts, bones, thyroids, lungs, etc. Iodine-131 in activities greater than 30 millicuries is used only at the main campus. Elkins Park and Einstein One have 1 technologist and 1 camera each. Elkins Park does 2-3 studies per day, all imaging and uptakes. Einstein One does 4-6 studies per day, which can include hearts, bones, thyroids (including hyperthyroidisms), etc. At Germantown, 2 technologists use 2 cameras to do 6-10 studies per day, which can also include hyperthyroid cases. All technologists report to a Director of Imaging, who reports to the Chief of Radiology. No violations were noted at any location, but at the main campus 2 technologists resigned on February 28, 2001. The licensee expects difficulty replacing them. This should be checked by the next inspector. The RSC is reasonably active, and its chairman is the Director of Nuclear Medicine. There is no mobile service or distribution done, and no research studies at present. The licensee uses 35.500 material in the form of Gd-153 sources on the Vertex Plus cameras. Because no further use of the irradiator was planned, the irradiator was removed from the facility by J. L. Shepherd on February 14, 2001, and the irradiator source was transferred to J. L. Sheperd.</p> <p>Brachytherapy is all low dose rate without afterloaders, and is conducted only at the main campus. From 01/00 until the day of the inspection the licensee did 19 procedures, of which 14 were gynecological implants using Cs-137. The other 5 were done using Ir-192 ribbons. There are 2 physicists who do treatment planning, and 2 authorized users who do most prescribing. Within the next 6-12 months the licensee plans to begin doing prostate implants with I-125 seeds. The licensee also possesses 2 Sr-90 eye applicators in storage. They haven't been used for about 15 years.</p> <p>No violations were noted by the inspector.</p>

2.	MANAGEMENT OVERSIGHT
Management support to radiation safety; RSC, RSO; and program audits, including as low as is reasonably achievable (ALARA) reviews.	
A VP sits on the RSC, and management support to the program appears to be adequate. The RSC has met as required. Radiation safety, ALARA, and QMP audits are conducted by the RSO, except at Germantown where a consultant (Robinson) does them and reports to the RSO. The RSO appears to be short staffed, and there have been timeliness problems with some audits. Licensee management confirmed that they are seeking extra radiation safety staffing.	
3.	FACILITIES
Facilities as described; uses; control of access; engineering controls,(e.g., ventilation, hoods, filters, etc); irradiators and survey instrument calibrators; maintenance by authorized persons.	
Facilities at all 4 locations are as described in the license. Access to nuclear medicine areas is by combination lock. Radiation oncology areas use lock and key. A hood is used to store I-131 (capsules <30 mCi, liquid >30 mCi) and xenon. Areas where xenon is administered are kept under negative pressure. Survey instruments are sent to JRT Calibrations annually. Maintenance is done by individuals who have been inserviced at least annually.	
4.	EQUIPMENT AND INSTRUMENTATION
Dose calibrator; instrumentation for assaying alpha- and beta- radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.	
Each location has its own dose calibrator, and each has been calibrated as required. Generators are not used. One Sm-153 treatment has been done since the last inspection. It was assayed in a dose calibrator using established procedures. Each location has calibrated GM's available(see 3. above). The main campus also has ion chambers and NaI detectors available. Syringes with unit doses are used at all locations. Vials of bulk Tc-99m are also used at the main campus and at Germantown.	
Radiation oncology uses the nuclear medicine dose calibrator to assay Ir-192 seeds. The ion chamber and NaI detectors above are normally used in oncology.	
5.	MATERIAL RECEIPT, USE, CONTROL, AND TRANSFER
Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material.	

Materials and uses correspond to license authorizations, except that no research is being conducted at present and the irradiator has been transferred to J. L. Shepherd. Radiopharmaceuticals are being used for 35,100,200,300 cases. No improper uses were observed by the inspector. Licensed materials were observed to always be locked up when not in use. All radiopharmaceuticals are delivered by courier from the pharmacy. The courier has a key at all locations for deliveries made before operating hours. Some locations return syringes and unused doses to the pharmacy. The main campus does not return syringes. Radiation oncology orders Ir-192 to be delivered to nuclear medicine, where it is assayed by a physicist and taken to radiation oncology. Seeds are returned to the vendor after use. No transfers are done other than vendor returns.

6.	THERAPIES
	Safety precautions; postings; contamination control; stay times; surveys; release criteria of patients and rooms.
	<p>Only 1 I-131 therapy in excess of 30 millicuries has been done in the last 14 months. A records review and interview of personnel showed that all surveys were done, including unrestricted areas, the patient room, decontamination, and bioassays. The patient was released when the dose rate at 1 meter fell below 5mR/hr. Nurses who were interviewed showed good understanding of safety precautions, postings, stay times, and when to admit new patients.</p> <p>The 19 brachytherapies done since 1/00 were put into the same rooms as was the I-131 patient. Restricted areas, the room, and the patient were surveyed before and after treatment. Nurses also showed good understanding of these procedures. The inspector observed no case in which dose rates in any unrestricted areas exceeded 2 mR in any one hour. Four portable shields are available.</p>
7.	QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS
	QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records.
	The inspector reviewed the records of all I-131 and brachytherapy treatments. The new forms described in the licensee letter of March 14, 2000 are in use. Audits are done quarterly by the RSO, except at Germantown, where they are done by the consultant. All written directives conformed to the new format. Neither the inspector nor the licensee auditor noted any deficiencies or events.
8.	AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
	Radiation and contamination surveys; air sampling; leak tests; inventories; handling of radioactive materials; protective clothing; dosimetry; records; and public doses.

All radiation and contamination surveys have been done as required. Xenon trap checks have been done monthly, an adequate interval for the number of xenon lung studies done. No xenon loading problems were noted by the inspector. Leak tests and inventories have been done as required. Personnel were observed using acceptable techniques for handling radioactive materials, and protective clothing is used. Public doses are determined by posting Luxel badges at strategic locations. The inspector reviewed records of all of the preceding, and observed that public doses were below regulatory limits.

9.	TRAINING AND INSTRUCTIONS TO WORKERS
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Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users; retraining and periodic training programs; training of ancillary personnel such as housekeeping, security, and maintenance; adequacy of training and instruction.

The inspector observed nuclear medicine technologists at work and interviewed several, finding their knowledge of routine activities adequate. This area should be revisited at the next inspection because of staff turnover. Nurses who were interviewed showed good understanding of emergency procedures. Several ancillary services receive radiation safety training, including security, housekeeping, maintenance, cardiology technologists, etc. This training is done annually and the inspector reviewed records of such training. The records were complete and detailed. Training appeared to be adequate for the areas covered.

10.	RADIATION PROTECTION
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Radiation protection program with ALARA provisions (worker and general public external and internal exposure control; effluent control); external and internal dosimetry program; exposure evaluations; dose records and reports; and patient release.

The radiation protection program appears to be adequate to keep public and occupational exposures ALARA. External dosimetry is provided by Landauer. Maximum annual whole body and extremity exposures have been 484 mR and 3110 mR, respectively. The corresponding exposures in radiation oncology have been 186 mR and 870 mR. Thyroid bioassays were done on those individuals involved with the one inpatient I-131 treatment. In that case, the inspector also observed that instructions had been given to the patient to minimize exposure to the public and family from the patient. Records of all of the above are kept by the RSO.

11.	RADIOACTIVE WASTE MANAGEMENT
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Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents, and compactors; and records.

Nuclear medicine waste which is not sent back to the pharmacy is decayed in storage. Diagnostic waste is placed into Pb-lined 30 gal drums, then later transferred to unlined drums, all in the hot lab area. The I-131 waste is placed in the basement waste storage room of the Korman Research Building. On the third floor of the same building are 2 other waste rooms. Room H on the third floor contains 5-55 gal drums partially full with research waste. These drums contain P-32, I-125, and H-3 waste. All of this waste is more than 3 years old, and no nonhuman research is going on at present. Nevertheless, the license indicated that, for economic reasons, these drums will be disposed of in the future after they become full. This should be checked again at the next inspection. Room G on the same floor contains Sr-90 sources in a shielded safe. Hoods and compactors have never been used. An incinerator was used in the past, but is no longer. The inspector examined waste disposal records and found them adequate.

12.

DECOMMISSIONING

Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements.

No decommissioning has been done since the last inspection, nor is any being planned for the near future.

13.

TRANSPORTATION

Quantities and types of licensed material shipped; packaging design requirements; HAZMAT communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

The only transporting done by the licensee since the last inspection has been the return to the pharmacy of nuclear medicine material, the return to the vendor of miscellaneous sealed sources, and the removal of the irradiator. In the first two instances the material was packaged in the original container, surveyed, and supplied with labels and shipping papers provided by the vendor. NM material is shipped as LQ. The irradiator was removed by J. L. Shepherd of California. HAZMAT training is part of annual radiation safety training. Records and reports are available from the RSO.

14.

NOTIFICATIONS AND REPORTS

Theft; loss; incidents; overexposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals.

There have been no thefts, losses, incidents, overexposures, or changes in RSO. Changes in authorized users have been reviewed by the RSC and documented. Radiation reports are compiled by Landauer and are made available to individuals. Pregnant workers have been monitored, including the RSO.

15.	POSTING AND LABELING		
Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material.			
The inspector observed that all area postings and container labeling were appropriate. Regulatory documents are available from the RSO, and some of them are also posted.			
16.	INDEPENDENT AND CONFIRMATORY MEASUREMENTS		
Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date.			
<p>At main campus: 0.02 mR/hr in hallway outside NM, 0.04-0.07 mR/hr in hot lab, 0.02-0.06 mR/hr in camera rooms, 0.07 mR/hr in center of oncology source room, 0.2 mR/hr beside source safe, 0.07 mR/hr in center of I-131 waste room, 0.02 mR/hr in center of research waste room(H), 0.06 mR/hr in source room (G).</p> <p>At Einstein One: 0.01-0.02 mR/hr in hot lab and camera room.</p> <p>At Elkins Park: 0.03 mR/hr in hot lab, 0.01 mR/hr in camera room.</p> <p>At Germantown: 0.04-0.2 mR/hr in camera room 2004, 0.02 mR/hr in camera room 2005, 0.1 mR/hr in hot lab.</p> <p>All measurements were made with a Ludlum 14 C, NRC # 9658, calibrated 7/13/00. Results were comparable to licensee measurements.</p>			
17.	VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES		
State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.			
None.			
18.	PERSONNEL CONTACTED		
Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone). Use # to indicate individual present at entrance meeting. Use * to indicate individual present at exit meeting.			
Name		Title	Phone No.
			In Person or By phone

*Huyen Tran, M.D.	Director, Nuclear Medicine		Main campus
*Karen Colucci	RSO		Main campus
*Mike Blowitski	R.S technologist		Main campus
JoAnn Molloy	Medical secretary		“
Carol Butsch	NM technologist		“
Brenda Tilchman	Lead technologist		“
Glenda Leggett	NM technologist		“
Faaek Guirgues	NM technologist		“
*Alan Baker	Medical physicist		“
Patrick Glennon	Medical Physicist		“
Chris Anilado, RN	8 TH floor nurse		“
Ellen Zane, RN	8 th floor nurse		“
Denise Friel, RN	8 th floor nurse		“
Marybeth Rocco	NM technologist		“
Elaine Sharpless	NM technologist		“
LaToya Springs	Cardiology technologist		“
*Robert Quanstrom, RN	Cardiology nurse		“
Andrea Morris	NM technologist		Einstein One
Salak Fultze	NM technologist		Elkins Park
*Barbara Lachima	Manager of Imaging Services		All campuses
Robert Dubin	NM technologist		Germantown
Keisha Gray-Brown	NM technologist		Germantown
*Sandy Lee	Cancer Service Line Administrator		Main campus
*Kimberly Blair	Vice President		All campuses
*Russ Waltman	Radiology Administrator		Main campus

19.	PERFORMANCE EVALUATION FACTORS (PEFs)						
	A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight	Y		N		x
	B.	RSO too busy with other assignments	Y		N		x
	C.	Insufficient staffing	Y	x	N		
	D.	Radiation Safety Committee fails to meet or functions inadequately	N/A		Y	N	x
	E.	Inadequate consulting services or inadequate audits conducted	N/A		Y	N	x

REMARKS: (Consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program.)	
Licensee oversight of the program is adequate, but somewhat strained by lack of manpower. A half-time person is being recruited, but has not been found yet. The next inspector should inquire about this.	
20.	SPECIAL CONDITIONS OR ISSUES
Special license conditions; year-2000 effects of computer software.	
None.	
PART III - POST- INSPECTION ACTIVITIES	
1.	REGIONAL FOLLOWUP ON PEFs
See 19. Above.	
2.	DEBRIEF WITH REGIONAL STAFF
Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.	
Reported to supervisor.	
3.	YEAR-2000 ISSUES
Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.	
None.	

TO ADVANCE TO NEXT SECTION USE **PAGE DOWN** KEY

APPENDIX A - ATTACHMENT A DECOMMISSIONING TIMELINESS INSPECTION									
Licensee:		Albert Einstein Healthcare Network				Date of Inspection:		2/26-28/01 and 3/1/01.	
1.		COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE							
NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.									
A.		License to conduct a <i>principal activity</i> <u>has</u> expired or been revoked:				Y		N	x
B.		Licensee <u>has</u> made a decision to permanently cease <i>principal activities</i> , at the entire site, or at any separate buildings, or at any outdoor areas, including inactive burial grounds.				Y		N	x
C.		A 24-month duration has passed in which no <i>principal activities</i> have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds.				Y		N	x
D.		If "Yes" to either A or B or C above:							
		(1) Identify Site/Bldg./Area:							
		(2) Date of occurrence of A, B, or C:							
2.		NOTIFICATION REQUIREMENTS							
A.		Licensee has provided written notification to the U.S. Nuclear Regulatory Commission (NRC) within 60 days of the occurrence of 1.A., 1.B., or 1.C., above.				Y		N	
		If "Yes," date of notification:							
B.		If the licensee is requesting to delay initiation of the decommissioning process, the licensee <u>has</u> provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C. above.				N/A		Y	N
		If "Yes," date of notification:							
Basis for Findings:									
3.		DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS							
A.		Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g); 10 CFR 40.42(g); 10 CFR 70.38(g); or 10 CFR Part 72?				Y		N	

	If "No" to 3.A., answer the following items B. - F.					
B.	The decommissioning work scope is covered by current license conditions.	Y		N		
C.	Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay.	Y		N		
D.	If licensee has initiated decommissioning, give date the decommissioning was initiated:					
E.	If decommissioning has been completed, it was completed within 24 months of notification to NRC.	N/A	Y	N		
F.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification to NRC.	N/A	Y	N		
Basis for Findings:						
	If "Yes" to 3.A., answer the following items G. - J.					
G.	The decommissioning plan has been submitted to NRC within 12 months of notification.	Y		N		
	If "Yes," date of submittal:					
	If NRC approved, date of NRC approval:					
H.	Has the licensee submitted an alternative schedule request?	Y		N		
	If "Yes," date of submittal:					
I.	If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan.	N/A	Y	N		
J.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.	N/A	Y	N		
Basis for Findings:						
Violations identified, if any:						

END

