



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

May 24, 2016

Paul J. Bembia, Director
West Valley Site Management Program
New York State Energy Research
and Development Authority
9030-B Route 219
West Valley, NY 14171-9500

**SUBJECT: REGULATORY AUDIT PLAN FOR REVIEW OF OFFSITE
CHARACTERIZATION AND PUBLIC DOSE COMPLIANCE DEMONSTRATION
PROCESSES FOR THE WESTERN NEW YORK NUCLEAR SERVICE
CENTER IN FOLLOW UP TO AERIAL GAMMA RADIATION SURVEY
CONDUCTED IN 2014 (CSF-1, Docket No. 050-00201, CAC L53127)**

Dear Mr. Bembia:

The U.S. Nuclear Regulatory (NRC) staff understands that the New York State Energy Research and Development Authority (NYSERDA) is expected to submit an offsite characterization and dose assessment evaluation for NRC review after June 2016, and that the evaluation will include an assessment of the risk associated with potential offsite residual radioactivity identified in NYSERDA's and the U.S. Department of Energy's final aerial radiation survey report, "An Aerial Radiological Survey of the Western New York Nuclear Service Center," October 4, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15309A187). Once submitted, the NRC staff will review the submittal to make a determination on whether the measured levels of offsite radioactivity above background pose a human health and safety concern.

As requested by NYSERDA, the NRC staff plans to conduct an audit of NYSERDA documentation supporting the evaluation prior to NYSERDA's submittal of the offsite characterization and dose assessment evaluation. The audit will be performed at NYSERDA's Ashford Office complex near the West Valley Site in New York. The audit will be held on June 9, 2016. The purpose of the audit is to prepare for the submittal of the NYSERDA's characterization and dose assessment evaluation to enable a more efficient and timely review. Objectives of the audit include evaluation of the following:

- Appropriate application of data collection and analysis methods;
- Technically sound measurement methods or calculation approaches to estimate the dose to members of the public (10 CFR 20.1402 dose limit 0.25 mSv/yr (25 mrem/yr) Total Effective Dose Equivalent (TEDE) will be used as a benchmark to assess the risk-significance of the potential offsite residual radioactivity that clearly identify assumptions, rationale for selection and elimination of pathways, and rationale for any modeling parameters; and

- Transparent and traceable documentation that includes sufficient characterization and dose assessment information to allow NRC staff to independently evaluate NYSERDA's dose assessment once submitted.

Enclosed is a copy of the plan the NRC staff will follow on the audit. The audit will assess whether the information is sufficient for the NRC staff to evaluate NYSERDA's assessment of public health and safety upon receiving NYSERDA's characterization and dose assessment evaluation submittal. An audit report will be issued by the NRC by September 30, 2016. Information in the audit report may be used in the NRC staff's safety evaluation report on NYSERDA's characterization and public dose assessment.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact Ms. Amy Snyder, Senior Project Manager. She can be reached at (301) 415-6822 or Amy.Snyder@nrc.gov.

Sincerely,

/RA/

Michael A. Norato, Ph.D., Chief
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 050-00201
License No. CSF-1

Enclosure:
Comments on Plan

cc w/enclosure:
B. Bower, DOE-WV
P. Giardina, EPA
T. Rice, NYSDEC
D. Samson, NYSDOH

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ADAMS Accession No.:

ML16133A270

OFFICE	DUWP	DUWP	DUWP	OGC (NLO)	DUWP
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DATE	5/12/16	5/12/16	5/13/16	5/23/16	5/24/16

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**REGULATORY AUDIT PLAN FOR REVIEW OF OFFSITE CHARACTERIZATION AND
PUBLIC DOSE COMPLIANCE DEMONSTRATION PROCESSES FOR THE WESTERN NEW
YORK NUCLEAR SERVICE CENTER IN FOLLOW UP TO AERIAL GAMMA RADIATION
SURVEY CONDUCTED IN 2014**

LICENSEE: New York State Energy Research and Development Authority
(NYSERDA)

LICENSEE CONTACT: Paul Bembia, et al.

DATE: June 9, 2016

LOCATION: NYSERDA
Ashford Office Complex
9030-B Route 219
West Valley, NY 14171-9500

REVIEWERS: Cynthia Barr, Senior Systems Performance Analyst
Robert Nelson, Health Physicist

PROJECT MANAGER: Amy Snyder, Senior Project Manager

A. Background

Aerial Radiation Survey Report

An aerial radiation survey performed by the U.S. Department of Energy (DOE) and the New York State Research and Development Authority (NYSERDA) in September 2014 identified areas near the Cattaraugus Creek flood plain between Lake Erie and the West Valley licensed reprocessing plant boundaries that may have radioactivity above background (REF 6, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15309A187).

The previous five aerial surveys conducted between 1968 and 1984 also showed low levels of off-site radioactivity potentially above background along the Cattaraugus Creek stream system vicinity. However, the 2014 survey results indicate the possibility of new areas of low levels of offsite radioactivity potentially above background, not observed before. Notably, two areas on the Seneca Nation Cattaraugus Reservation not previously surveyed and another offsite location near the West Valley licensed reprocessing plant boundaries along the trajectory of the Cs-Prong release. The Cs-Prong is believed to be a result of the documented 1968 unplanned airborne release from the West Valley licensed reprocessing plant.

The NRC reviewed the draft aerial radiation survey reports (ADAMS Accession No. ML15169A414) and provided comments (ADAMS Accession No. ML15169A414). The NRC performed independent scoping calculations using data from the draft 2014 aerial survey report; past reports and studies; and assumptions based on professional judgment, to estimate the

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potential dose associated with the off-site levels of radioactivity measured on the Seneca Nation Cattaraugus Reservation and concluded that the levels of radioactivity would likely not pose an immediate human health and safety concern, but that additional information was necessary to definitively assess the risk posed by the potential radioactivity.

Although the aerial radiation survey data provides useful information on the potential for residual radioactivity in the environment, the data is of insufficient resolution and quality to be relied on to assess potential risk to members of the public. The NRC concluded that the source of the potential offsite radioactivity identified by the 2014 aerial radiation survey could only be postulated given that more detailed characterization of the areas of potential concern was not available at the time the draft aerial radiation survey report was shared with the NRC. The NRC concluded that definitive answers regarding the extent and type of offsite radioactivity, in the absence of other data or information that is relevant and less uncertain, required collecting and analyzing environmental samples. Additional information regarding the source and the extent and type of radioactivity require collecting and analyzing environmental samples (ADAMS Accession No. ML15169A414).

NYSERDA is the current licensee, and therefore, responsible to assess the potential risk associated with residual radioactivity and, if the assessment reveals a health and safety concern, to take actions to reduce the levels of radioactivity, as necessary. The NRC would then review NYSERDA's assessment to make a determination on whether the measured levels of radioactivity above background pose a threat to public health and safety.

NYSERDA informed the NRC that it would conduct interviews to determine current land use, sampling and analysis, and perform a dose assessment and would submit its results to the NRC (REF 3, ADAMS Accession No. ML15309A199).

Sampling and Analysis and Dose Assessment Plan

The NRC also reviewed drafts of NYSERDA's sampling and analysis and dose assessment plan, dated August 31, 2015 (REF 13, ADAMS Accession No. ML15273A277) and September 2, 2015 (REF 11, ADAMS Accession No. ML15273A270, respectively. The NRC provided comments on these drafts (REF 5, ADAMS Accession No. ML15281A416 and REF 10, ADAMS Accession No. ML15257A168). The objective of these NRC's reviews was to provide comments regarding whether the NRC believed that NYSERDA's proposed strategy appeared to be reasonable for (1) the characterization of the off-site areas of potential concern for use in risk assessment analyses, and (2) assessment of risk associated with the offsite residual radioactivity. NYSERDA provided its final plan (REF 8, ADAMS Accession No. ML15279A498), dated October 1, 2015 to the NRC with a response matrix (REF 9, ADAMS Accession No. ML15279A504), addressing comments that it received from the NRC and other regulatory agencies.

NYSERDA has completed the sampling and analysis and requested that NRC, among other regulatory agencies, review the draft characterization and dose assessment evaluation submittal (REF 18, ADAMS Accession No. ML16088A159). NRC declined to review a non-public draft document, but agreed to perform an audit of NYSERDA's processes before the results were made publicly available upon submittal to the NRC.

Regulatory Criteria for Evaluation of the Submittal

The NRC has jurisdiction for offsite radiological releases from the licensed facility not associated with West Valley Demonstration Project Act activities (REF 17, ADAMS Accession No. ML020580080). As a starting point for evaluating NYSERDA future characterization and dose assessment evaluation submittal, the NRC has informed NYSERDA that, the NRC will use the unrestricted release limit of 0.25 mSv/yr (25 mrem/yr) TEDE found in 10 CFR 20.1402 as a benchmark to determine whether mitigating actions might need to be taken in the future to reduce risk to levels that are protective of human health.

B. Regulatory Audit Bases

A regulatory audit is usually conducted with the intent to gain understanding, to verify information, and to identify information that will need to be submitted to support the basis of a licensing or regulatory decision. Performing a regulatory audit of licensee information is expected to assist the staff in efficiently conducting its review or gain insights on the licensee's processes or procedures.

Specifically, NYSERDA's future submittal will be supported by documentation, such as the site characterization plan, quality assurance project plan, data quality objectives, and other aspects of data evaluation (such as intermediate calculations) that are not required by regulation to be submitted. However, the information that the staff relies upon to make its safety determination must be submitted. During the audit of NYSERDA's processes, if the NRC staff identifies information that it needs, the NRC staff will communicate this to NYSERDA.

This regulatory audit is a planned, license-related activity that includes the examination and evaluation of primarily non-docketed information. No decisions or conclusions about verification of public health and safety will be made at the audit nor will any documentation provided by the licensee or its contactors at the audit be removed or docketed.

C. Regulatory Audit Objectives

Objectives of the audit include evaluation of the following:

- Appropriate application of data collection and analysis methods;
- Technically sound measurement methods or calculation approaches to estimate the dose to members of the public (10 CFR 20.1402 dose limit 0.25 mSv/yr (25 mrem/yr) Total Effective Dose Equivalent (TEDE) will be used as a benchmark to assess the risk-significance of the potential offsite residual radioactivity that clearly identify assumptions, rationale for selection and elimination of pathways, and rationale for any modeling parameters; and
- Transparent and traceable documentation that includes sufficient characterization and dose assessment information to allow NRC staff to independently evaluate NYSERDA's dose assessment once submitted.

D. Information and Other Material Necessary for Audit

The types of information that the staff may audit include, but are not limited to, the following: (1) process information, (2) procedures, (3) calculations, (4) design information, and (5) computer code information. The audit team will view the plans, procedures, existing data, and available calculations.

The NRC staff requests the following be made available at the NYSERDA facility to complete the audit:

- Plans and procedures used for the offsite sampling and dose assessment modeling (e.g. sampling and analysis plan, quality assurance project plan, land use survey plan or land use survey interview questions, procedures in Section 13 of NYSERDA's October 2015 sampling and analysis plan (REF 8, ADAMS Accession No. ML15279A498), and any other procedures included thereafter
- Instrumentation calibration records and minimum detectable concentration (MDC) calculations
- Characterization results (tabular and graphical): available raw data, the processed data (tabular form), and any data reports
- Figures showing areas of concern and locations used for establishing background levels
- A draft of the field characterization report(s)
- Results of land use surveys/interviews and support for the selected exposure scenario(s)
- A draft of the current dose modeling report that NYSERDA plans to submit to the NRC including a listing of input parameters and basis for selection.
- Calculations used to develop the source inventory (e.g., calculation of concentrations to be used in dose modeling)
- Modeling files (e.g., input and output files)
- Data Quality Objectives
- Comparison of previous sampling results from the mid-1990 characterization campaign from selected locations in the survey box in or near the Cs-prong area (as discussed in comment No. 5, REF 9, ADAMS Accession No. ML15279A504) and the basis of the Cs-Prong dose assessment
- NYSERDA's "comparison report" or schedule when it will be available that will include "identifying the source or likely source of any contamination that might be identified," (as noted in comment 1, REF 3, ADAMS Accession No. ML15309A199).
- Other documents, which the licensee deems as necessary to support the NRC staff's audit, outlined under audit activities

The NRC Project Manager will coordinate with NYSERDA in advance of audit activities to verify specific documents will be available and identify any changes to the audit schedule and requested documents. Documents will be handled appropriately throughout the audit. While the NRC staff will take notes, the NRC staff will not docket hard copies or electronic files of any material that it reviewed as part of the audit.

E. Special Requests

The NRC staff requests that NYSERDA provide:

- Subject matter experts available to discuss the data collection, data reduction, and analysis for the land use survey effort, sampling and analysis effort and the dose modeling effort
- Internet access and printing capability
- A conference room set up for the use of three NRC staff with conference call capability

F. Logistics:

The audit will take place at the NYSERDA facility in West Valley, NY. The audit will start on the morning of June 9, 2016 (Thursday) and conclude at the close of business June 9, 2016 (Thursday).

The NRC's tentative schedule for the audit is as follows:

- Thursday, June 9, 2016 (8:00 am – 4:00 pm)¹
 - 8:00 a.m. Entrance meeting (NRC staff – purpose of audit; NYSERDA staff – brief overview of sampling, processes, etc.)
 - 8:30 a.m. – Sampling and Analysis
 - Modifications from October 2016 final plan (REF 8, ADAMS Accession No. ML15279A498) and how changes were documented
 - Instrumentation
 - Instrument use, detection capability, and end use
 - MDCs
 - Survey Instrument Calibration
 - Quality Assurance Project Plan
 - Field
 - Laboratory
 - Background
 - QC samples
 - Data Quality Objectives
 - Characterization and Data Collection/Results – Summary Data
 - Discuss criteria for determining areas of interest to be investigated
 - Clarification of survey spacing and basis
 - Clarification of variability of concentrations with depth and depth discrete sampling
 - Survey results
 - Surface and subsurface sampling results
 - Criteria for and the number of samples submitted for expanded analysis

¹ The NRC staff estimates that they may be available on June 8th beginning 3 pm. The NRC staff may want to start reviewing documentation on June 8th, if NYSERDA can accommodate such a request. The NRC PM will coordinate with NYSERDA regarding this possibility.

- Background sampling locations and results
 - Quality control samples
- Data Interpretation
 - Uncertainties in data and parameters should be described.
 - Data reduction techniques and resolution
 - Explain how the data was used to characterize the extent (lateral and vertical) of the radionuclides of interest (in this case the potential contaminants of concern) including any interpolation techniques for walkover surveys and soil sampling for applicable survey boxes or if appropriate, how the radiological conditions cannot be distinguished from background in the location that that assessment applies to applicable specific survey boxes.
- 10:00 a.m. – Dose Modeling
 - Clarify how data from different sources is integrated for use in the dose assessment
 - Development of exposure scenarios based on current or reasonably foreseeable land use and basis
 - Input Parameters
 - Key modeling assumptions
 - Parameter selection and basis
 - Source – development of radionuclide inventories, with justification for any radionuclide surrogates (e.g., Am, Pu, or Sr), if applicable.
 - Identification of key uncertainties.
 - Results
 - Significant pathways
 - Most limiting radionuclide(s)
 - Comparison of draft results against the 0.25 mSv/yr (25 mrem/yr) TEDE dose limit found in 10 CFR 20.1402 for unrestricted use
 - Comparison of draft result against other standards and information as indicated by NYSERDA in its final sampling and analysis plan (page 3-4, REF 7, ADAMS Accession No. ML15279A498)
- 12:00 noon – working lunch (order-in)
- 1:00 p.m. - Continuation of morning topics with NYSERDA, et al. and/or NRC Audit team meeting/Calculation Time (NRC staff only)
- 2:00 p.m.- NRC Audit Team Internal Meeting/Calculation Time (NRC staff only)
- 3:00 p.m. – Audit Exit with NYSERDA- Teleconference to include NRC HQ and RI (non-public)- Note- NRC will not be reaching any conclusions during this audit- will communicate what NRC will need to be submitted later on for NRC to reach conclusions regarding health and safety impacts.
- 4:00 p.m.- Complete Audit

G. Deliverables

After completion of the audit, the audit team will issue an audit summary no later than September 30, 2016, that will be declared and entered as an official agency record in the NRC's ADAMS records management system. The audit summary will be publicly available. The audit outcome may be used to identify any additional information to be submitted for making regulatory decisions.

H. References

1. NYSERDA, E-mail from P. Bembia re: Update on the NYSERDA Soil Sampling Project and Schedule for Completion, March 23, 2016, ADAMS Accession No. ML16088A159
2. NYSERDA, Email from P. Bembia, NYSERDA, Revised West Valley Aerial Gamma Radiation Survey Report, November 02, 2015, ADAMS Accession No. ML15309A174
3. NYSERDA, Responses to Comments on Draft Aerial Radiation Survey, dated October 27, 2015, ADAMS Accession No. ML15309A199
4. NYSERDA, E-mail from P. Bembia re: Update on the West Valley Aerial Radiation Survey and Soil Sampling Work, October 21, 2015, ADAMS Accession No. ML15390A295
5. NRC, Response to Request Regarding the Document Titled, "Field Sampling and Dose Assessment Plan for the Western New York Nuclear Service Center in Follow-Up to Aerial Gamma Radiation Survey Conducted in 2014, October 13, 2015, ADAMS Accession No. ML15281A416
6. U.S. Department of Energy and NYSERDA, Final Aerial Radiation Survey Report, "An Aerial Radiological Survey of the Western New York Nuclear Service Center, October 4, 2015, ADAMS Accession No. ML15309A187
7. NYSERDA, E-mail from A. Mellon, Revised Field Sampling and Dose Assessment Plan, October 1, 2015, ADAMS Accession No. ML15279A476
8. NYSERDA, Field Sampling and Dose Assessment Plan for the Western New York Nuclear Service Center in Follow-Up to Aerial Gamma Radiation Survey Conducted in 2014, dated October 1, 2015, ADAMS Accession No. ML15279A498
9. NYSERDA, Attached File to E-mail, Comments on the Draft Field Sampling and Dose Assessment Plan for the Western New York Nuclear Service Center in Follow-Up to Aerial Gamma Radiation Survey Conducted in 2014, October 1, 2015, ADAMS Accession No. ML15279A504
10. NRC, Response to Request Regarding the Document Titled, "Field Sampling and Dose Assessment Plan for the Western New York Nuclear Service Center in Follow-Up to Aerial Gamma Radiation Survey Conducted in 2014, September 15, 2015, ADAMS Accession No. ML15257A168

11. NYSERDA, Email from A. Mellon, "Draft Field Sampling and Dose Assessment Plan for Review," September 2, 2015, ADAMS Accession No. ML15273A270
12. NYSERDA, Email from P. Bembia, "Availability of the Field Sampling and Dose Assessment Plan for West Valley Aerial Radiation Survey Follow-Up Work," August 24, 2015, ADAMS Accession No. ML15273A288
13. NYSERDA, Draft Field Sampling and Dose Assessment Plan for the Western New York Nuclear Service Center in Follow-Up to the Aerial Gamma Radiation Survey Conducted in 2014, dated August 31, 2015, ADAMS Accession No. ML15273A277
14. NRC, Response to Request to Review and Comment on the Draft Report Titled, "An Aerial Radiological Survey of the Western New York Nuclear Service Center", June 30, 2015, ADAMS Accession No. ML15169A414
15. NYSERDA, Email from P. Bembia, "Agency Review of the Draft Report on the West Valley Aerial Gamma Radiation Survey", May 15, 2015, ADAMS Accession No. ML15273A327
16. NYSERDA and US DOE, Attachment to P. Bembia, May 15, 2015 email, Draft An Aerial Radiological Survey of the Western New York Nuclear Service Center, "For Customer Review Only", ADAMS Accession No. ML15273A331
17. NRC, letter from Martin J. Virgilio, Director Office of NMSS to Erin M. Crotty, Commissioner, State of New York Department of Environmental Conservation, March 7, 2002, ADAMS Accession No. ML020580080
18. NYSERDA, E-mail from P. Bembia to A. Snyder (NRC) re: Update on the NYSERDA Soil Sampling Project and Schedule for Completion, dated March 23, 2016, ADAMS Accession No. ML16088A159