UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD - SUITE 102
KING OF PRUSSIA, PA 19406-1415

December 13, 2022

EA-22-048

John Rossi,
Vice President of System
and Fairfield Region Operations
Hartford Healthcare
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY $8,000 – ST. VINCENT'S MEDICAL CENTER, NRC INSPECTION REPORT NO. 03001245/2022001

Dear John Rossi:

This letter refers to a routine inspection of St. Vincent's Medical Center (St. Vincent's) conducted by the U.S. Nuclear Regulatory Commission (NRC) on March 2 and 3, 2022, with continued in-office review through July 12, 2022. The purpose of the inspection was to examine activities performed under your NRC license and to review the circumstances involving the improper disposal of a sealed source on October 22, 2021. Based on the results of the inspection, the NRC identified twelve apparent violations (AVs) of NRC requirements. The NRC discussed the AVs with you during a telephonic exit meeting on July 12, 2022. The AVs were described in the NRC inspection report sent to you with a letter dated August 8, 2022 (ML22222A008).[1]

In the August 8, 2022, letter transmitting the inspection report, we informed you that the AVs were being considered for escalated enforcement action, including a civil penalty. In the letter, we requested that you attend a pre-decisional enforcement conference (PEC) to discuss the AVs. On September 15, 2022, a PEC was conducted in the NRC's Region I office with members of your staff to discuss the AVs, their significance, their root causes, and your corrective actions. Subsequent to the PEC, you submitted a letter dated September 26, 2022 (ML22311A539), in which you provided further detail on some of the actions discussed during the conference. A summary of the PEC and the corrective actions described by St. Vincent's at the conference and in the letter dated September 26, 2022, is included as Enclosure 1 to this letter.

Based on the information developed during the inspection and the information that you provided during the conference and in your September 26, 2022, letter, the NRC has determined that

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

violations of NRC requirements occurred and is proceeding with enforcement action. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice; Enclosure 2), and the circumstances surrounding them are described in detail in the subject inspection report.

Three of the violations are related to the failure to maintain control over a sealed cesium-137 source when, on October 22, 2021, a St. Vincent's contract employee, without knowledge that the source was being stored in a biohazard waste container, disposed of it along with other waste and failed to conduct a radiological survey of the waste shipment. The violations related to this event include the failures to: (1) dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2001(a); (2) monitor the surface of by-product material prior to disposal as decay-in-storage waste, as required by 10 CFR 35.92(a)(1); and (3) conduct a semi-annual physical inventory of sealed sources in your possession, as required by 10 CFR 35.67(g).

The NRC considers the improper disposal of NRC-regulated material a significant regulatory and security concern because of the potential for misuse of the material and exposure to members of the public. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III (SL III) problem. The NRC Enforcement Policy can be found on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $8,000 is considered for a SL III problem by a licensee of St. Vincent's type (see Tables 8A.e and 8B of the Enforcement Policy). Because St. Vincent's has not been the subject of escalated enforcement actions within the last two years or the period between the last two inspections, the NRC staff considered whether credit was warranted for corrective action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC staff determined that corrective action credit was not warranted for St. Vincent's actions taken to address the violations because immediate corrective action to restore safety and compliance once the violation took place was not taken. The NRC staff considered that on October 27, 2021, a representative of the biohazardous waste facility to which the source was inadvertently shipped informed St. Vincent's that the waste shipment had higher than normal radiation levels (indicating it likely contained a radioactive source). For the next two weeks, St. Vincent's staff evaluated whether the source in question was their source and, on November 19, 2021, contracted Landauer Services, who, on December 2, 2021, retrieved the source and returned it to the St. Vincent's facility. St. Vincent's explained that the source likely remained within its lead storage container because the container's seal was unbroken upon its retrieval. However, the NRC staff considered that from October 27, 2021, to December 2, 2021, the source remained at an unlicensed facility that was not authorized for its possession and that, during that time, St. Vincent's did not assure the proper security and control of its licensed material.

Therefore, to emphasize the importance of performing radiological surveys on waste shipments to ensure the security and control of licensed material, and considering the circumstances of this case, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,000. In addition, issuance of this Notice constitutes escalated enforcement action that may subject St. Vincent's to increased inspection effort.

You may choose to pay the proposed civil penalty by submitting your payment, with the invoice enclosed to this letter (Enclosure 3), to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

In addition, you may pay the proposed civil penalty in accordance with NUREG/BR-0254 (Enclosure 4). When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the "enforcement action identifier" when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

Nine additional violations related to St. Vincent's failure to maintain an effective radiation safety program, and failure to implement an adequate radiation exposure monitoring program, are also documented in the enclosed Notice as SL IV violations consistent with the NRC Enforcement Policy. These violations, for which no civil penalty is imposed, are cited in the enclosed Notice because they were identified by the NRC inspector.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notice, or you may request alternative dispute resolution (ADR) mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch at 610-337-5078 **within 10 days** of the date of this letter. You may also contact both ICR and Ms. DeFrancisco for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil penalty, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already addressed on the docket in Inspection Report No. 03001245/2022001 and your letter dated September 26, 2022.

Additionally, in accordance with NRC Inspection Manual Chapter 2800, “Materials Inspection Program,” Section 07.03, the NRC will conduct a follow-up inspection to evaluate the adequacy of St. Vincent’s corrective actions. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC’s Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/.

If you have any questions concerning this matter, please contact Anne DeFrancisco of my staff at 610-337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

David C. Lew Digitally signed by David C. Lew
Date: 2022.12.13 07:58:22 -05'00'

David C. Lew
Regional Administrator

Enclosures:
1. Summary of September 15, 2022, Pre-Decisional Enforcement Conference and Description of Corrective Actions
2. Notice of Violation and Proposed Imposition of Civil Penalty
3. Civil Penalty Invoice
4. NUREG/BR-0254, “Payment Methods”

Docket No. 03001245
License No. 06-00843-03

cc w/encls:
Greg Hisel, CHP, Radiation Safety Officer
State Connecticut

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY $8,000 – ST. VINCENT'S MEDICAL CENTER, NRC INSPECTION REPORT NO. 03001245/2022001 DATED DECEMBER 13, 2022

DISTRIBUTION w/encl:

ADAMS
SECY RIDSSECYMAILCENTER
OEMAIL
OEWEB
D Dorman, EDO RIDSEDOMAILCENTER
C Haney, DEDM
M Lombard, OE RIDSOEMAILCENTER
T Martinez-Navedo, OE
J Peralta, OE
N Hasan, OE
C Rivera-Diaz, OE
J Lubinski, NMSS RIDSNMSSOD RESOURCE
R Lewis, NMSS
K Williams, NMSS
M Burgess, NMSS
Enforcement Coordinators
RII, RIII, RIV (M Kowal; D Betancourt-Roldan; J Groom)
L Baer, OGC RIDSOGCMAILCENTER
T Steinfeldt, OGC
H Harrington, OPA RIDSOPAMAILCENTER
R Feitel, OIG RIDSOIGMAILCENTER
D D'Abate, OCFO RIDSOCFOMAILCENTER
D Lew, RA R1ORAMAIL RESOURCE
R Lorson, DRA R1ORAMAIL RESOURCE
B Welling, DRSS, RI R1DRSSMAILRESOURCE
T Bloomer, DRSS, RI
A DeFrancisco, DRSS, RI
R Elliott, DRSS, RI
H Ahmed, DRSS, RI
D Screnci, PAO-RI / N Sheehan, PAO-RI
F Gaskins, SAO-RI/ L Hanson, SAO-RI
B Klukan, ORA, RI
S Lewman, ORA, RIII
R McKinley, ORA, RI

DOCUMENT NAME: https://usnrc.sharepoint.com/teams/Region-I-MLA/Inspection Reports/Inspection Documentation - Draft/St Vincents NOV-III-CP EA-22-048.docx ML22286A061

X SUNSI Review/ MMM		X Non-Sensitive ☐ Sensitive			X Publicly Available ☐ Non-Publicly Available	
OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	RIII/ORA	NMSS
	M McLaughlin	A DeFrancisco	B Klukan	R McKinley	S Lewman	M Burgess
DATE	10/27 /22	11/09/22	11/10/22	11/10/22	11/14/22	12/01/22
OFFICE	OE	OGC			RI/DRSS	RA
NAME	J Peralta	T Steinfeldt NLO			B Welling	D Lew
DATE	12/01/22	12/01/22			12/09/22	12/13/22

OFFICIAL RECORD COPY

ENCLOSURE 1

SUMMARY OF SEPTEMBER 15, 2022, PRE-DECISIONAL ENFORCEMENT CONFERENCE AND DESCRIPTION OF CORRECTIVE ACTIONS

Licensee: St. Vincent's Medical Center

License No. 06-00843-03

Docket No. 03001245

EA No. 22-048

On September 15, 2022, representatives of St. Vincent's Medical Center (St. Vincent's) met with NRC personnel in the Region I office located in King of Prussia, Pennsylvania, to discuss the apparent violations identified in NRC Inspection Report Number 03001245/2022001. The conference was held at the request of NRC Region I.

The licensee presented a summary of the causes for the apparent violations and corrective actions. Regarding the improperly disposed source, they described the timeline of the event and St. Vincent's response. Specifically, they stated that the source was inadvertently included in a biohazard waste shipment on October 22, 2021. This occurred when a temporary employee, without knowledge that the source was being stored in a biohazard waste container, disposed of it along with other waste and failed to conduct a radiological survey of the waste shipment. A waste facility representative contacted St. Vincent's on October 27, 2021, and informed them that the waste shipment had higher than normal radiation levels (indicating it likely contained a radioactive source). For the next two weeks, St. Vincent's staff evaluated if the source was truly theirs. On November 19, 2021, after confirming the source was theirs, St. Vincent's contracted with Landauer Services who, on December 2, 2021, retrieved the source and returned it to the St. Vincent's facility. On June 2, 2022, St. Vincent's disposed of the source and other unused sources. The St. Vincent's representatives did not provide additional detail about how the source was stored/controlled at the waste facility, other than to state that they believe it was never removed from within the shielded pig because the pig was still taped shut when they retrieved it.

The licensee's representatives described the corrective actions St. Vincent's has implemented to prevent reoccurrence:

- All Nuclear Medicine Technologists (NMT) were administered a read and sign training related to radioactive waste management and attended DOT HAZMAT shipping courses.
- All NMTs will receive "competency-based" training upon hire and annually thereafter.
- All additional unused sources have been removed from the facility and the Radiation Safety Officer (RSO) (or a designee) will perform quarterly audits and source inventory going forward.

The licensee's representatives also described the actions taken in response to the other AVs, which include:

- Appointing a Y-90 representative to the Radiation Safety Committee (RSC) and having the RSO ensure that RSC membership is updated, as needed.

- Completing the 2021 annual radiation protection program audit.
- Performing monthly and quarterly dosimetry reviews, including review of ALARA I and II exposures, dynamic exposures, and unreturned dosimetry.
- Implementing a more robust process for monitoring radiation exposure of employees on hire who are also working at other facilities where they may be monitored for radiation exposure.
- Updating the written directives for Y-90 procedures and measuring dose and performing TEDE calculations for patient release.
- Updating the leak test work standard and performing quarterly leak testing.
- Developing a new written directive work standard to capture the target organ on the directive.

On September 26, 2022, St. Vincent's submitted a follow-up letter to the NRC that outlined some corrective actions that were not fully expressed in their PEC presentation. In the letter, St. Vincent's described that they standardized their nuclear medicine, waste management, and source storage procedures and policies and placed binders with these documents in each Hot Lab. They also described training to be performed with all new employees on the use of these procedures. Additionally, they stated that communication enhancements will be performed, to include daily safety reminders in the Hot Labs, increased discussions among the radiation safety staff, and improvements to the Radiation Safety Committee charter and standing agenda. Finally, they discussed improvements to the dosimetry program, including enhanced instruction to workers and development of an exposure records request form to be issued annually to their workers' other employers.

The PEC attendance list and the licensee's and NRC's PEC presentations are attached to this summary.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this summary and its enclosures will be made available to the public.

Attachments:
1. Attendance List
2. Licensee Presentation
3. NRC Presentation

Attachment 1
St. Vincent's Medical Center
Pre-Decisional Enforcement Conference

Attendance List

NRC

Region I:
Tamara Bloomer, Deputy Director, Division of Radiological Safety and Security (DRSS)
Shelbie Lewman, Regional Counsel, Region III
Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch (MLAB), DRSS
Robin Elliott, Senior Health Physicist, MLAB, DRSS
Hiba Ahmed, Health Physicist, MLAB, DRSS
Cherie Crisden, Enforcement Specialist, Office of The Regional Administrator

Office of Enforcement:
Carmen Rivera-Diaz, Senior Enforcement Specialist

Office of Nuclear Materials Safety & Safeguards:
Michele Burgess, Senior Enforcement Specialist

Office of the General Counsel:
Thomas Steinfeldt, Attorney

St. Vincent's Medical Center

John Rossi, Vice President
Mohammed Aljallad, Corporate Radiation Safety Officer (RSO), Hartford Healthcare
Greg Hisel, RSO, St. Vincent's Medical Center
Jacqueline Hoell, General Counselor
Curtis McCloggan, Radiology Director
Kelli Hannan, Radiology Manager

ST. Vincent's Medical Center NRC Pre-decisional Enforcement Conference

September 15, 2022

Hartford HealthCare

Agenda

Opening Remarks & Attendee Introductions	T. Bloomer, NRC, Deputy Division Director, DRSS
St. Vincent's Opening Remarks	St. Vincent's Representatives
Overview of Enforcement Process	C. Crisden, NRC, Enforcement Specialist
Summary of Apparent Violations	R. Elliott- NRC, Senior Health Physicist
St. Vincent's Presentation	St. Vincent's Representatives
NRC Caucus	NRC Staff
Closing Enforcement Remarks	C. Crisden, NRC, Enforcement Specialist
Closing PEC Remarks	T. Bloomer NRC, Deputy Division Director, DRSS
Public Comments	

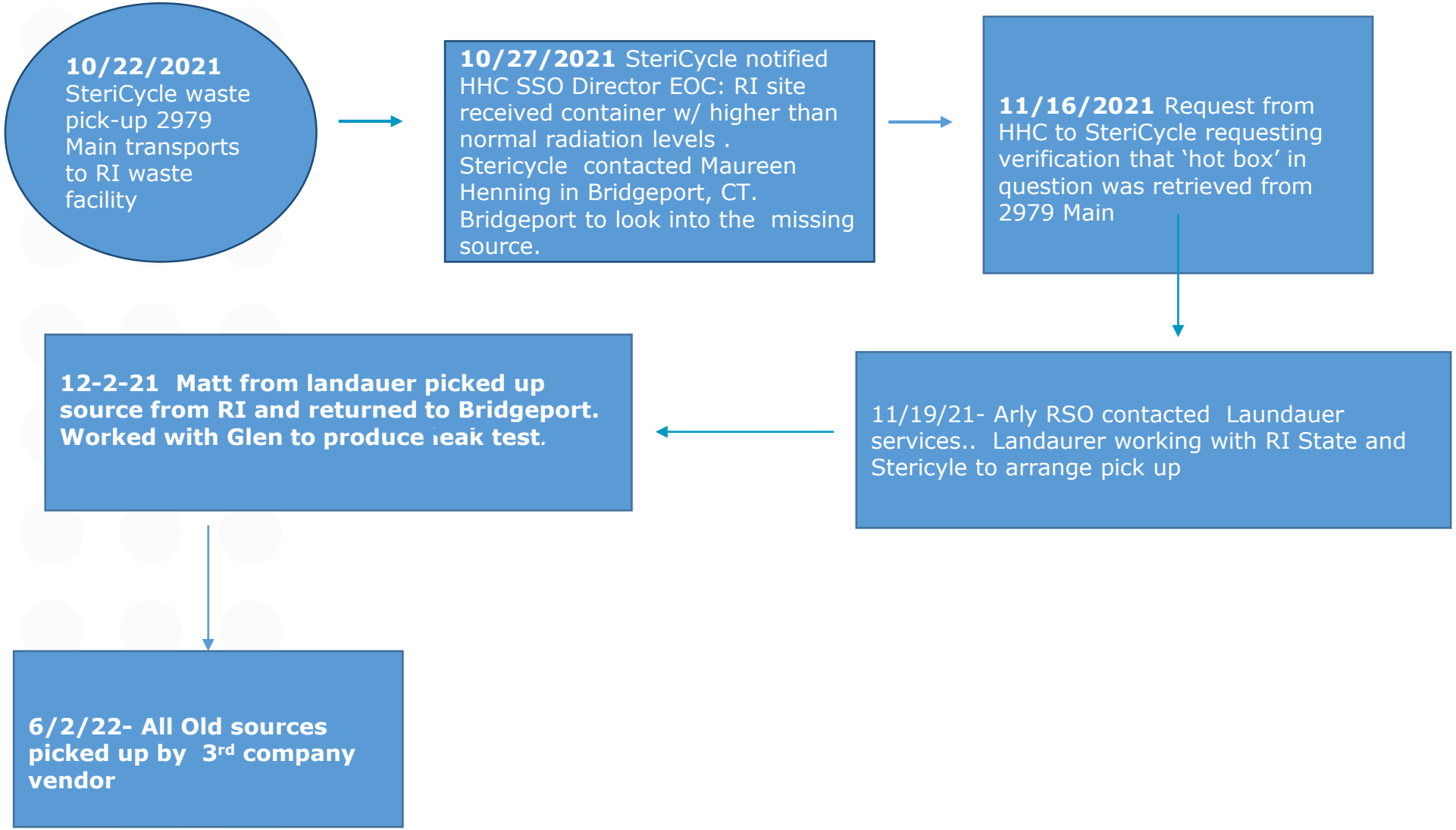
Opening Remarks

Good Afternoon. I want to begin by thanking the NRC for their time, professionalism and willingness to collaborate in connection with an inspection conducted in March 2022 at St. Vincent's Medical Center. At St. Vincent's, we take ownership of our actions every day. We hope to convey to the NRC that we have taken this matter very seriously, took swift action and made improvements where necessary based on the NRC findings. Today we will review with you the apparent violations, our understanding of how they occurred, additional documentation to consider and a comprehensive list of corrections the Hospital took in response to the NRC findings. It is my hope that our presentation today will provide a clear understanding of St. Vincent's Medical Center commitment to maintain a safe, compliant and effective Radiation Safety Program.

Hartford HealthCare, Fairfield Region and St. Vincent's Medical Center Team:

- Dr. Mohammad Aljallad, PH.D DABR, DABSNM, MRSE-HHC System RSO Director, HHC Radiation Protection Program
- Curtis Mccloggan , Fairfield Region Radiology Director
- John Rossi, VP of System and Fairfield Region Operations
- Gregory Hisel- Fairfield Region RSO
- Kelli Hannan, Fairfield Region Radiology Manager

Timeline Reconstruction Process Overview



Hartford HealthCare

Sealed Source Control

Apparent Violation(s) 10 CFR 20.2001(a) 10 CFR 35.92(a) 10 CFR 35.67(g)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiency (e.g. policy/procedure, in-service program, repairs, etc.	A review of the policy for decay in storage completed by radiation safety committee 4 22-22. No changes were recommended All nuclear medicine technologists have reviewed Stericycle and Radioactive Waste Management Training and signed attestations Nuclear medicine (NM) technologists to complete competency based training on initial hire and annually. NM personal will take the courses DOT HAZMAT shipping requirement provided by Landauer and another from Hartford Healthcare All additional Legacy sources removed (all sources that were in storage and not in use where sent to storage, only sources in use remain onsite)	April 22, 2022 September 5th 2022 All completed by 8/30/22 thru 8/2023 6/2/22
The corrective steps that have been taken and the results achieved	RSO or designee will conduct quarterly audits and source inventories of each nuclear, legacy sources and cardiac medicine labs (records audit)	3rd quarter completed Sept.
Identify the staff member, by title who has been designated the responsibility for monitoring the individual plan of correction submitted for each deficiency.	Radiation Safety Officer	

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) 10 CF R 35.24(f)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiency (e.g. policy, procedure, in-service program repairs. Etc.)	Dr. Terrence Hughes has been appointed as the Y-90 AU representative for the Radiation Safety Committee	April 19th 2022
Identify the staff member by title. Who has been designated the responsibility for monitoring the individual plan of correction submitted each violation	RSO will make sure the RSC membership is updated as necessary. The Committee Chair will be responsible for committee attendance	Implemented and ongoing Attendance reflected in the RSC meeting.

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) 10 CFR 20.1101.(c)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiency (e.g. policy, procedure, in-service program repairs. Etc.)	2021 radiation safety program completed 6 -16 2022	June 2022 Done as a standard; yearly review done in March.
Identify the staff member by title, who has been designated the responsibility for monitoring the individual plan of correction submitted each deficiency.	The Imaging Director is held accountable to the operational schedule and the Regional RSO conducts the program evaluation and reports to radiation safety committee The system HHC RSO will be available for ad hoc auditing	

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) 10 CFR 20.1101 10 CFR 20.1301 10 CFR 20.1201 (a) 10 CFR 20.1201(f)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiencies (e.g. policy, procedure, in-service program repairs. Etc.)	A monthly/quarterly Dosimetry review is performed by HHC RSO and SVMC RSC including ALARA 1 and 2, dynamic exposures, and unreturned badge compliance A previous exposure request and a second position process have been implemented to monitor radiation exposure of employees on hire and if employees are working in other facilities	Implemented and ongoing Obtained dose history on Physicians for 2021/22 est. and calculated to their records. And will be reviewed as a standard item for review.
Identify the staff member by title. Who has been designated the responsibility for monitoring the individual plan of correction submitted each deficiency	The system HHC RSO and designee(s)	Annually requesting all staff whom works a second position to sign a release for 2nd radiation badge release.

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) 10 CFR 35.75 (a)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiencies (e.g. policy, procedure, in-service program repairs. Etc.)	• Provide updated Written Directives for Y90 • Patient radiation exposure is measured and documented for each patient before release. • TEDE calculations for patient release by RSO/Physicist • Y90 case from 5/21 with the new and old form	Implemented 4/22 and ongoing. All forms have been updated by the RSC and have been put in as part of the annual program review conducted by the RSC. Y90 Case from 2021 has been updated to the new form.
Identify the staff member by title. Who has been designated the responsibility for monitoring the individual plan of correction submitted each deficiency.	The system HHC RSO and designee(s)	Ongoing

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) 10 CFR 35.67(b)(2)	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiencies (e.g. policy, procedure, in-service program repairs. Etc.)	Wipe Test Policy, Wipe Test Log, and GE service report standard work reviewed. And most accessible area for leak tests included in work standard. This is done quarterly. Leak tests performed by Lead NM tech and RSO during quarterly audits	QTR 3 CY September 3rd 2022 has been completed by the RSO or designee.
Identify the staff member by title. Who has been designated the responsibility for monitoring the individual plan of correction submitted each deficiency	Imaging Director with ad hoc monitoring by RSO and submitted to RSC for oversight	Ongoing

Implementation of a Radiation Safety Program for adequate radiation exposure monitoring

Apparent Violation(s) Condition 14 of NRC	Action Plan	Date Completed
Measures to prevent the recurrence of the identified deficiency (e.g. policy, procedure, in-service program repairs. Etc.)	New standard work developed "Written Directive" to capture the target organ dose. The target organ is now captured in this document	April 2022 Bring a sample of the target
Identify the staff member by title who has been designated the responsibility for monitoring the individual plan of correction submitted for each deficiency	Authorizing User (AU) working in collaboration with the RSO and/or designee	Ongoing


Hartford
HealthCare

PRE-DECISIONAL ENFORCEMENT CONFERENCE

September 15, 2022

1:00-3:00

LOGISTICS

- Open, Hybrid Meeting that will be transcribed
  - Recording feature of TEAMS
  - Transcript will be non-public
- Please turn on camera when speaking
  - State name and affiliation prior to speaking
  - When not speaking, turn off camera and mute microphone

AGENDA

Opening Remarks & Attendee Introductions	T. Bloomer
St. Vincent's Opening Remarks	St. Vincent's Representatives
Overview of Enforcement Process	C. Crisden
Summary of Apparent Violations	R. Elliott
St. Vincent's Presentation	St. Vincent's Representatives
NRC Caucus	NRC Staff
Closing PEC Remarks	T. Bloomer
Public Comments	

NRC OPENING REMARKS

- Today's Pre-Decisional Enforcement Conference (PEC) with St. Vincent's Medical Center is being conducted at the NRC's request to discuss a number of apparent violations (AVs) of NRC requirements.
  - 3 AVs are related to an event involving the improper disposal of a sealed cesium-137 source.
  - 9 AVs are related to failure to maintain an effective radiation safety program and radiation exposure monitoring program.

- Please Note:
  - The NRC has not made a final enforcement decision on this matter.
  - This PEC is your opportunity to provide us information you want the NRC to consider in making a final decision.

- Introductions

ST. VINCENT'S OPENING REMARKS

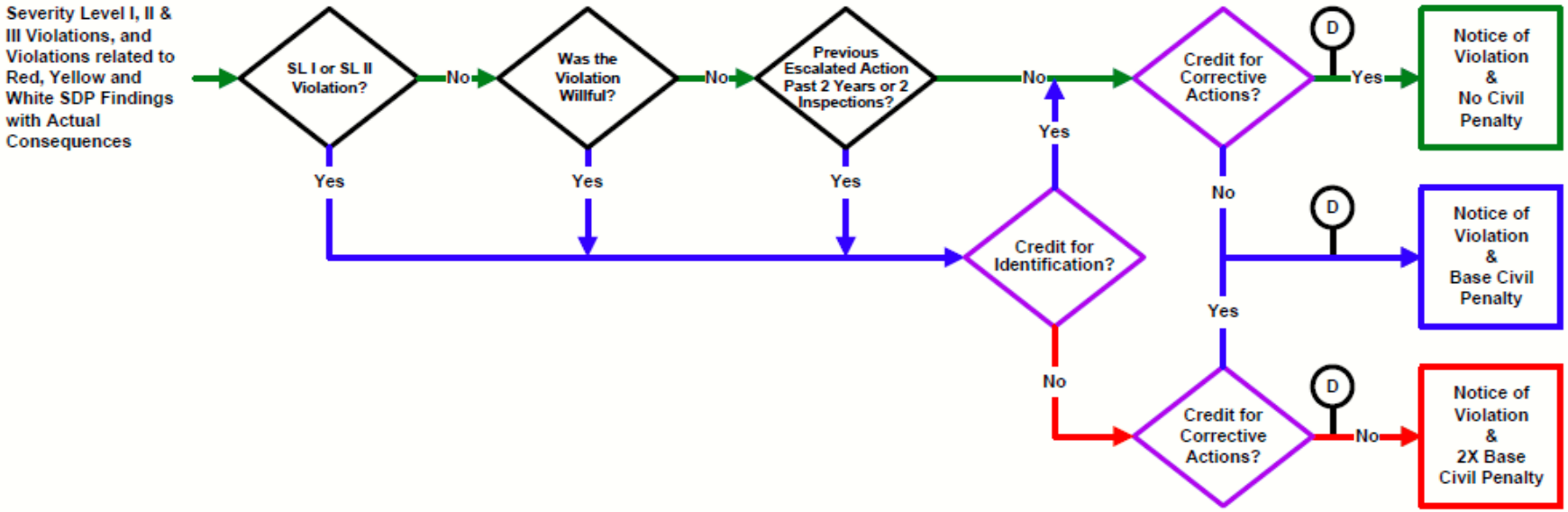
ESCALATED ENFORCEMENT PROCESS

- NRC Enforcement Policy available at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html

- The significance of violations is assessed using Severity Levels.
  - SL I is the most significant and SL IV is the least.
  - SL I, SL II, and SL III violations are considered for escalated enforcement action.

- Factors used in determining Severity Level:
  - Actual Consequences
  - Potential Consequences
  - Impact to the Regulatory Process
  - Willfulness

ESCALATED ENFORCEMENT PROCESS



ESCALATED ENFORCEMENT PROCESS

- Special Considerations for Loss of Regulated Material.
  - These are violations involving the loss, abandonment, improper transfer, or improper disposal of material.
  - The NRC considers such violations to be of significant regulatory and security concern because of the potential for unauthorized use and overexposure to members of the public from its misuse.
  - Consequently, such violations typically receive escalated enforcement action, including a civil penalty outside of the normal civil penalty assessment process.
    - When the material is recovered, the NRC staff may consider the licensee's actions taken to retrieve it and the risk to the public while it was outside the licensee's control.

ENFORCEMENT PROCESS – ROLE OF PEC

- Following this PEC, the NRC will issue the final enforcement outcome.
- A PEC is not a forum for negotiating the enforcement action. It is an opportunity for you to present additional information you want the NRC to consider.
- The NRC staff's final position will not be communicated today. Rather, the NRC staff at this conference will consider the information you present, in conjunction with the information from the inspection, to reach a final decision.

SUMMARY OF APPARENT VIOLATIONS

- March 2 and 3, 2022, a special, routine NRC Inspection was initiated to follow up on the improper disposal event and conduct a routine inspection of licensed activities.

- Improper Disposal Event:
  - Sealed source had been stored in a lead-lined radioactive waste container.
  - October 22, 2021, a "per-diem" Nuclear Medicine Technologist who was unaware of the presence of the source, inadvertently disposed of it with biohazardous waste they had placed in the container that day.
  - October 27, 2021, the biohazardous waste facility identified the source and contacted St. Vincent's.
  - St. Vincent's recovered the source on December 2, 2021.

SUMMARY OF APPARENT VIOLATIONS

- The NRC inspectors identified 3 Apparent Violations related to this event:
  - Failure to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits as required by 10 CFR 20.2001(a).
  - Failure to monitor the surface of by-product material prior to disposal as decay-in-storage waste, as required by 10 CFR 35.92(a)(1); and
  - Failure to conduct a semi-annual physical inventory of sealed sources in your possession, as required by 10 CFR 35.67(g).

SUMMARY OF APPARENT VIOLATIONS

- Routine Inspection of St. Vincent's Performance identified that the Radiation Protection program was not providing adequate oversight of the uses of licensed material.

- 9 Apparent Violations identified:
  - Failure to include an authorized user on the Radiation Safety Committee for each type of use of byproduct material permitted by the license, as required by 10 CFR 35.24(f);
  - Failure to review periodically (at least annually) the radiation protection program content and implementation, as required by 10 CFR 20.1101(c);
  - Failure to implement procedures for the safe use of unsealed byproduct material, for which the licensee's procedure to ensure radiation exposure is as low as reasonably achievable (ALARA) required a formal annual review of the radiation safety program including ALARA considerations, pursuant to NRC License Condition 14;

SUMMARY OF APPARENT VIOLATIONS

- 9 Apparent Violations (Continued):
  - Failure to reduce the dose that an individual may be allowed to receive in the current year by the amount received while employed by any other person, as required by 10 CFR 20.1201(f);
  - Failure to implement procedures for the safe use of unsealed byproduct material, for which the licensee's ALARA procedure states the Radiation Safety Committee will consider exposures exceeding ALARA Level I in comparison with exposures of others performing similar tasks and record the review in the Radiation Safety Committee minutes and will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding ALARA Level II and, if warranted, take action, pursuant to NRC License Condition 14;
  - Failure to control the occupational dose to individual adults to the annual dose limits, as required by 10 CFR 20.1201(a);

SUMMARY OF APPARENT VIOLATIONS

- 9 Apparent Violations (Continued):
  - Failure to control release of a Yttrium-90 (Y-90) microsphere patient without determining that members of the public would not be exposed in excess of 5 mSv total effective dose equivalent (TEDE), as required by 10 CFR 35.75(a);
  - Failure to test sealed sources for leakage at intervals not to exceed 6 months, as required by 10 CFR 35.67(b)(2); and
  - Failure to conduct your program in accordance with the letter dated February 20, 2014, which requires you to include the treatment site on the written directive, pursuant to NRC License Condition 14.

ST. VINCENT'S MEDICAL CENTER PRESENTATION

QUESTIONS & ANSWERS

BREAK / NRC CAUCUS

QUESTIONS & ANSWERS

CLOSING REMARKS

ENCLOSURE 2

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Vincent's Medical Center
Bridgeport, Connecticut

Docket No.: 03001245
License No.: 06-00843-03
EA-22-048

During an NRC inspection conducted between March 2, 2022, and July 12, 2022, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 20.2001(a) requires, in part, that a licensee shall dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits in 10 CFR Part 20.

Contrary to the above, from October 22, 2021, through December 2, 2021, the licensee failed to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits of 10 CFR Part 20. Specifically, on October 22, 2021, the licensee inadvertently transferred a sealed source containing 114 µCi of cesium-137 to an unauthorized recipient. The licensee retrieved the source on December 2, 2021.

B. 10 CFR 35.92(a)(1) requires, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level.

Contrary to the above, on or about October 22, 2021, the licensee held byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity but did not monitor the byproduct material at the surface before disposal. Specifically, the licensee disposed of medical waste generated during the use of licensed material with a physical half-life of less than 120 days and did not survey the waste prior to disposal.

C. 10 CFR 35.67(g) requires, in part, that licensees in possession of sealed sources or brachytherapy sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a semi-annual physical inventory of all sealed sources in its possession. Specifically, the licensee moved three sealed sources from their Hamden, Connecticut office in September 2019 to their Heart and Vascular Center in Bridgeport, Connecticut but did not include the sources on the

inventory until February 2022, and, therefore, did not conduct a semi-annual physical inventory of all sealed sources in its possession from September 2019 to February 2022.

This is a Severity Level III Problem (NRC Enforcement Policy Section 6.3).
Civil Penalty - $8,000

II. Violations Not Assessed a Civil Penalty

D. 10 CFR 35.24(f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.

Contrary to the above, the licensee was authorized for two or more different types of uses under Subparts E, and F of 10 CFR Part 35 and their RSC did not include an authorized user of each type of use permitted by the license. Specifically, the license authorized 10 CFR 35.1000 Y-90 microsphere use and no authorized user representing this use was part of the RSC membership. Additionally, the license authorized 10 CFR 35.300 uses, and the authorized user for 10 CFR 35.300 use was not present at any of the RSC meetings held from January 18, 2021, to March 2, 2022.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

E. 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, for more than one year prior to March 2, 2022, the licensee did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, the licensee did not conduct an annual review of the radiation protection program from the last inspection, performed on April 13, 2021, and for an undetermined period of time prior to that.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

F. License Condition 14 of License No. 06-00843-03 requires, in part, that the licensee conduct their program in accordance with the statements, representations, and procedures contained in the application dated September 30, 2013. The application dated September 30, 2013, requires the licensee to, in part, develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

The licensee's ALARA program 35.20 dated February 4, 1981, states: "Management Commitment: We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc. and consultations with the radiation protection staff or outside consultants."

Contrary to the above, the licensee did not perform a formal annual review of the radiation safety program including ALARA considerations, nor did the licensee review the operating procedures and past exposure records, inspections, etc. Specifically, quarterly audits were performed of the Nuclear Medicine and Radiation Oncology departments; however, no formal annual review was performed for 2020 and for an undetermined period of time prior to 2020.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

G. 10 CFR 20.1201(f) requires, in part, the licensee to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, between April 13, 2021, and March 2, 2022, and for an undetermined period of time prior to that date, the licensee did not reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the licensee had per diem employees and physicians (contract employees) that worked at other facilities where radiation exposure was received and did not have a program to capture their exposure record from other employers to reduce their allowable exposure at St. Vincent's.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

H. License Condition 14 of License No. 06-00843-03 requires, in part, that the licensee conduct their program in accordance with the statements, representations, and procedures contained in the application dated September 30, 2013. The application dated September 30, 2013, requires the licensee to, in part, develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

The licensee's ALARA program 35.20 dated February 4, 1981, in the section on the Establishment of Investigational Levels to Monitor Individual Occupational External Radiation Exposures, states the following:

- With respect to ALARA Level I investigations, "the Radiation Safety committee (RSC) will consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes;"
- With regard to ALARA Level II investigations: "The Radiation Safety Officer (RSO) will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action;" and
- Regarding the investigations, "the minutes, containing details of the investigation, will be made available for NRC inspectors for review at the time of the next inspection."

Contrary to the above, the licensee's RSC did not consider exposures exceeding ALARA Level I in comparison with exposures of others performing similar tasks as an index of ALARA program quality and record the review in the Committee minutes, and the RSO did not investigate in a timely manner the cause(s) of all personnel exposures equaling

or exceeding Investigational Level II and, if warranted, take action. Specifically, the minutes of the July 19, 2021, RSC meeting recorded that two individuals exceeded the ALARA I level and one individual exceeded the ALARA II level; however, there was no investigation recorded in the minutes and the inspector was informed that the individuals were simply informed of their exposure.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

I. 10 CFR 20.1201(a) requires, in part, that licensees shall control the occupational dose to individual adults to the following dose limits: (1) An annual limit, which is the more limiting of (i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or (ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv). (2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are: (i) A lens dose equivalent of 15 rems (0.15 Sv), and (ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

   Contrary to the above, between April 13, 2021, and March 2, 2022, the licensee did not control the occupational dose to individual adults to the annual dose limits referenced above. Specifically, the licensee did not add exposure from lost/not returned badges to the individuals exposure records to assure the exposure did not exceed the occupational limits. The RSC committee meeting minutes from January 2021, April 2021, July 2021, October 2021, and January 2022, report the number of late, unused and missing dosimeters; however, no action was taken to assure that the missing dose was reconstructed and added to the individuals' exposure records to verify that the occupational dose limits were not exceeded. Additionally, two physicians, who were determined to potentially exceed 10% of the occupational exposure limit and authorized to perform Y-90 microsphere therapies, were not issued dosimetry to evaluate their occupational dose.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

J. 10 CFR 35.75(a) requires, in part, that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

   Contrary to the above, between April 13, 2021, and March 2, 2022, the licensee authorized the release from its control an individual who had been administered unsealed byproduct material or implants containing byproduct material without determining if the total effective dose equivalent to any other individual from exposure to the released individual would not likely exceed 5 mSv (0.5 rem). Specifically, a Y-90 therapy was performed on May 13, 2021, without performing release calculations to verify that the released patient would not pose an exposure risk to any other individual in excess of 5 mSv total effective dose equivalent.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

K. 10 CFR 35.67(b)(2) requires the license shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Contrary to the above, as of April 2021, the licensee did not test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. Specifically, the licensee possessed Ge-68 sealed sources greater than 100 µCi mounted in the PET camera which were not leak tested between April 2021 and March 2, 2022.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

L. Condition 14 of NRC License No. 06-00843-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated February 20, 2014.

The letter dated February 20, 2014, requires in part, that the licensee include the treatment site on the written directive.

Contrary to the above, on May 13, 2021, the licensee did not conduct its program in accordance with the procedures contained in the letter dated February 20, 2014. Specifically, the licensee performed a Y-90 microsphere treatment and did not indicate the target organ where the intended dose should be delivered.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already addressed on the docket in Inspection Report No. 03001245/2022001 and your letter dated September 26, 2022. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a Reply to a Notice of Violation, and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406, and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above through one of the following two methods:

1. Submit the payment with the enclosed invoice for Civil Penalty EA-22-048, issued to St. Vincent’s Medical Center, to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

OR

2. Submit the payment in accordance with NUREG/BR-0254.

The Licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, or Answer to a Notice of Violation, should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406, and the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 13th day of December, 2022.

The resource of this report item is

Address/Customer Information

St. Vincent's Medical Center
ST. VINCENT'S MEDICAL CENTER
2800 MAIN STREET
BRIDGEPORT, CT 06606

Customer Codes

Account Code: L00000711/1

Bill Information

Bill Number: EA-22-048
Amount Due: $8,000.00
Due Date: 01/11/2023

Contact Us

Phone Number: 301-415-7554
Fax Number: 301-415-4135
Email Address: Fees.Resource@nrc.gov

Remit to Address

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

Bill Summary

Initial Charges	$8,000.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	$8,000.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	$8,000.00

Credit Summary

Applied Credit	$0.00
Unapplied Credit	0.00
Credit Total	$0.00

Comments:

For questions, contact (301) 415-7554 or by email at Fees.Resource@nrc.gov. For NRC debt collection procedures, including interest and penalty provisions, see 31 U.S.C. 3717, 4 CFR 101-105, AND 10 CFR 15.
For questions, contact (301) 415-7554 or by email at Fees.Resource@nrc.gov. For NRC debt collection procedures, including interest and penalty provisions, see 31 U.S.C. 3717, 4 CFR 101-105, AND 10 CFR 15.
Invoice for Civil Penalty EA-22-048, St. Vincents Medical Center

Customer Information

L00000711/1
St. Vincent's Medical Center
ST. VINCENT'S MEDICAL CENTER
2800 MAIN STREET
BRIDGEPORT, CT 06606

Change of Address:

Phone:

Remittance Information

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

This Payment References the following Bill:

EA-22-048

Outstanding Amount Due: $8,000.00

Amount Enclosed:

QUESTIONS?

If you have questions, please visit https://www.nrc.gov and search for “License Fees.”

Questions may also be directed to the NRC Accounts Receivable Help Desk by e-mail at nrc@fiscal.treasury.gov, by phone at (301) 415-7554, or by writing to the address below:

U.S. NUCLEAR REGULATORY COMMISSION
OCFO/DOC/ARB
Mail Stop T9-E10
Washington, DC 20555-0001

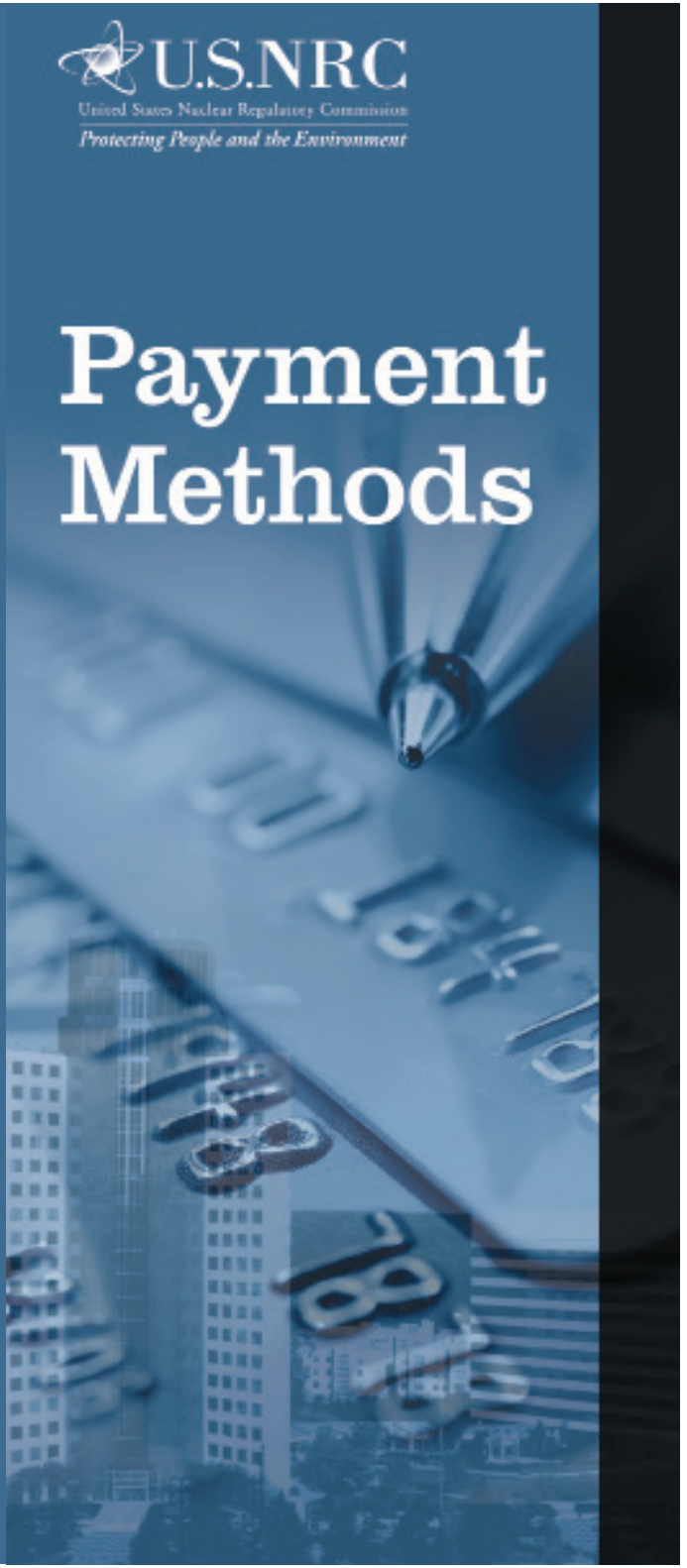
U.S. NUCLEAR REGULATORY COMMISSION
OCFO/DOC/ARB
Mail Stop T-9-E10
Washington, DC 20555-0001
PH (301) 415-7554

NUREG/BR-0254, Rev. 9
June 2019

Blog @NRCgov YouTube

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Payment Methods



APPROVED BY OMB: NO. 3150–0190

Estimated burden per response to comply with this voluntary collection request: 10 minutes. This brochure provides information about available payment methods. Forward comments about to burden estimate to the Records Management Branch (T6-F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0190), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

NRC accepts the methods described below.

PAYMENT BY AUTOMATED CLEARINGHOUSE

To pay by Automated Clearinghouse/Electronic Data Interchange (ACH/EDI), provide a copy of NRC Form 628 to your financial institution. You may obtain a copy of NRC Form 628 from the NRC Web site at http://www.nrc.gov by searching for "NRC Form 628." You can also obtain a form by calling the NRC Accounts Receivable Help Desk at (301) 415-7554.

PAYMENT BY CREDIT CARD

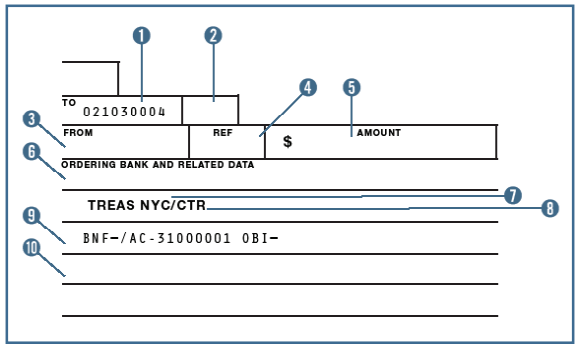
The NRC is currently accepts credit card payments of up to $24,999.99. For payment by credit card, go to Pay.gov, search for ,"U.S. Nuclear Regulatory Commission Fees" and enter the required information.

You may also mail or fax NRC Form 629 following the directions on the form. To obtain a copy of NRC Form 629 go to http://www.nrc.gov and search for "NRC Form 629" or call the NRC Accounts Receivable Help Desk at (301) 415-7554.

PAYMENT BY FEDWIRE DEPOSIT SYSTEM

The NRC can receive funds through the U.S. Department of the Treasury (Treasury) Fedwire Deposit System. The basic wire message format below complies with the Federal Reserve Board's standard structured third-party format for all electronic funds transfer (EFT) messages.

See the sample EFT message to Treasury below. Each numbered field is described below.



❶ **RECEIVER-DFI# –** Treasury's ABA number for deposit messages is 021030004.

❷ **TYPE-SUBTYPE-CD –** The sending bank will provide the type and subtype code.

❸ **SENDER-DFI# –** The sending bank will provide this number.

❹ **SENDER-REF# –** The sending bank will insert this 16-character reference number at its discretion.

❺ **AMOUNT –** The transfer amount must be punctuated with commas and decimal point; use of the "$" is optional. The depositor will provide this item.

❻ **SENDER-DFI-NAME –** The Federal Reserve Bank will automatically insert this information.

❼ **RECEIVER-DFI-NAME –** Treasury's name for deposit messages is "TREAS NYC". The sending bank will enter this name.

❽ **PRODUCT CODE –** A product code of "CTR" for customer transfer should be the first item in the reciever text field. Other values may be entered, if appropriate, using the ABA's options. A slash must be entered after the product code.

❾ **AGENCY LOCATION CODE (ALC) –** THIS ITEM IS OF CRITICAL IMPORTANCE. IT MUST APPEAR ON THE FUNDS TRANSFER DEPOSIT MESSAGE IN THE PRECISE MANNER AS STATED TO ALLOW FOR THE AUTOMATED PROCESSING AND CLASSIFICATION OF THE FUNDS TRANSFER MESSAGE TO THE AGENCY LOCATION CODE OF THE APPROPRIATE AGENCY. The ALC identification sequence can, if necessary, begin on one line and end on the next line; however, the field tag "BNF=" must be on one line and cannot contain any spaces. The NRC's 8-digit ALC is: BNF=/AC-31000001

❿ **THIRD-PARTY INFORMATION –** The Originator to Beneficiary Information (OBI) field tag "OBI=" signifies the beginning of the free-form third-party text. All other identifying information intended to enable the NRC to identify the deposit—for example, NRC annual fee invoice number, description of fee, 10 CFR 171 annual fee, and licensee name—should be placed in this field.

The optimum format for fields 7, 8, 9, and 10 using an 8-digit ALC is as follows:

TREAS NYC/CTR/BNF=/AC-31000001 OBI=

The optimum format, shown above, will allow 219 character positions of information following the "OBI=" indicator.

If the licensee's bank is not a member of the Federal Reserve System, the nonmember bank must transfer the necessary information and funds to a member bank, which then must transfer the information and funds to the local Federal Reserve Bank.

For a transfer of funds from local Federal Reserve Banks to be recorded on the same day, the transfer must be received at the New York Federal Reserve Bank by 4 p.m., EST. Otherwise, the deposit will be recorded on the next workday.

PAYMENT BY CHECK

Checks should be made payable to the U.S. Nuclear Regulatory Commission with the invoice number, Enforcement Action number, or other information that identifies the payment, written on the check. Mail the check to the following address:

U.S. Nuclear Regulatory Commission
U.S. Bank
P.O. Box 979051
St. Louis, MO 63197-9000

FedEx or overnight mailings must be delivered to the following address:

U.S. Nuclear Regulatory Commission
U.S. Bank Government Lockbox
SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101

TAXPAYER IDENTIFICATION NUMBER

You must file your Taxpayer Identification Number (TIN) with the NRC. Use NRC Form 531 to provide your TIN. You may obtain NRC Form 531 from the NRC Web site at http://www.nrc.gov by searching for "NRC Form 531" or by calling the NRC Accounts Receivable Help Desk at (301) 415-7554.