

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION IV 1600 EAST LAMAR BOULEVARD ARLINGTON, TEXAS 76011-4511

January 25, 2024

EA-23-070

Shahe Bagerdjian, Chief Executive Officer International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, ID 83401

SUBJECT: INTERNATIONAL ISOTOPES, INC. - NOTICE OF VIOLATION AND

PROPOSED IMPOSITION OF CIVIL PENALTY - \$18,000, NRC INSPECTION

REPORT 030-35486/2023-001

Dear Shahe Bagerdjian:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) limited scope inspection conducted from March 2 through October 2, 2023, of licensed activities performed at your facility in Idaho Falls, Idaho. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the NRC rules and regulations and with the conditions of your license. A final exit briefing was conducted with you telephonically on October 2, 2023. Details of the inspection and associated apparent violation identified during the inspection were provided to you in the subject inspection report, dated October 5, 2023 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23262B447).

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference, participating in alternative dispute resolution mediation, or by providing a written response before we made our final enforcement decision. In a letter dated October 26, 2023 (ML23355A138), you provided your response to the apparent violation.

Based on the information developed during the inspection and the information you provided in your written response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in Enclosure 1, "Notice of Violation and Proposed Imposition of Civil Penalty" (Notice), and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to manufacture and distribute a sealed source in accordance with the Sealed Source and Device registry as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210(f).

The NRC considers the violation to be significant because the failure to seek NRC approval for increasing the maximum activity of a sealed source and then manufacturing and distributing the sealed source caused two other NRC licensees to violate NRC requirements and conditions of their materials licenses. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The 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 NRC Enforcement Policy, a base civil penalty in the amount of \$18,000 is considered for the Severity Level III violation.

Because your facility has been the subject of escalated enforcement actions within the last two inspections (refer to letter dated October 20, 2020, ML20294A080), the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that *Identification* credit is not warranted because the violation was identified by the NRC. The NRC has determined that *Corrective Action* credit is warranted based on the prompt and comprehensive corrective actions you implemented. Your corrective actions to address the violation are documented in NRC Inspection Report 030-35486/2023-001 and in your letter dated October 26, 2023.

Therefore, to emphasize the importance of manufacturing and distributing a sealed source in accordance with regulations and your license, the need to promptly identify violations, as well as recognition of your previous escalated enforcement action, 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 base amount of \$18,000 for the Severity Level III violation. In addition, issuance of this Notice constitutes an escalated enforcement action that may subject you 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 2), 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 "Payment Methods," Enclosure 3 (ML23269A212). When using NUREG/BR-0254 to pay the civil penalty, the bill number, EA-23-070, 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.

If you disagree with this enforcement sanction, you may deny the violation, as described in Enclosure 1, or you may request alternative dispute resolution (ADR) mediation with the NRC to resolve this issue. Alternative dispute resolution 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 neutral 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 issue.

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 at Cornell University has agreed to facilitate the NRC's ADR program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the Institute on Conflict Resolution at 877-733-9415; and (2) Lizette Roldán-Otero at 817-200-1455 within 10 days of the date of this letter. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day period for payment of the civil penalty, as identified in Enclosure 1, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-35486/2023-001 and in your letter dated October 26, 2023. 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 Enclosure 1.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," 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 ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its website at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,

Signed by Monninger, John on 01/25/24

John D. Monninger Regional Administrator

Docket No. 030-35486 License No. 11-27680-01MD

Enclosures:

- Notice of Violation and Proposed Imposition of Civil Penalty
- 2. Civil Penalty Invoice
- 3. NUREG/BR-0254 "Payment Methods"

cc w/Enclosures:

Rikki Waller Radiation Control Program Director Idaho Dept of Health & Welfare Division of Public Health Bureau of Laboratories 2220 Old Penitentiary Rd Boise, ID 83712-8299

Landry Austin State Liaison Officer Idaho Department of Environmental Quality 900 North Skyline Drive, Suite B Idaho Falls, ID 83402 INTERNATIONAL ISOTOPES, INC. - NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$18,000, NRC INSPECTION REPORT 030-35486/2023-001 - DATED JANUARY 25, 2024

DISTRIBUTION:

RidsOeMailCenter Resource;
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RidsEdoMailCenter Resource;
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DPelton, OE SLewman, OE JPeralta, OE Cook, DRSS RErickson, DRSS MBurgess, NMSS LRoldan-Otero, DRSS RAugustus, OGC R4-DRSS-MLB

ADAMS ACCESSION NUMBER: ML24004A223									
SUNSI Review by: JGK		ADAMS	☑ Publicly Available		X	Non-Sensitive	Keyword:		
			□ Non-Publicly Available			Sensitive	MD 3.4		
OFFICE	SES:ACES	C:MIB	TL:ACES	RC		NMSS	OE		
NAME	JKramer	LRoldanOtero	JGroom	DCylkowski		MBurgess	JPeralta		
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E		/RA/ E	/RA/ E		
DATE	01/04/24	01/08/24	01/05/24	01/08/24		01/12/24	01/17/24		
OFFICE	OGC	D:DRSS	RA						
NAME	RAugustus	TBloomer	JMonninger						
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E						
DATE	01/17/24	01/18/24	01/25/24						

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

International Isotopes, Inc. Idaho Falls, Idaho

Docket No. 030-35486 License No. 11-27680-01MD EA-23-070

During an NRC inspection conducted from March 2 through October 2, 2023, a violation of NRC requirements was 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 violation and associated civil penalty are set forth below:

10 CFR 32.210(f) requires, in part, that the person submitting the request for evaluation and registration of safety information about a sealed source or device containing a sealed source shall manufacture and distribute the product in accordance with the provisions of the registration certificate.

License Condition 9.D of NRC Materials License 11-27680-01MD, Amendment No. 39 states, in part, that in accordance with 10 CFR 32.74, the licensee is authorized to manufacture and distribute sealed sources to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or under equivalent licenses of any Agreement State, and to persons licensed in accordance with 10 CFR Part 35 or under equivalent licenses of any Agreement State.

Contrary to the above, on March 18, 2021, the licensee failed to manufacture and distribute a sealed source that was in accordance with the provisions of the registration certificate. Specifically, the licensee manufactured and distributed a sealed source that exceeded the maximum activity specified for the sealed source model number and byproduct material combination (NR-1235-S-102-S, BM06-V5-5715, cobalt-57). The source that was manufactured and distributed contained 17.07 millicurie of cobalt-57 and the maximum activity allowed according to the registration certificate was 15 millicurie.

This is a Severity Level III Violation (Enforcement Policy Section 6.3.c.11.c). Civil Penalty - \$18,000. EA-23-070

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-35486/2023-001 and in your letter dated October 26, 2023. 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 and Proposed Imposition of Civil Penalty (Notice). In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-23-070," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and a copy to

the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, and email it to R4Enforcement@nrc.gov.

You 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-23-070, issued to International Isotopes, Inc. 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.

You may protest the proposed 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 you 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, EA-23-070," and may: (1) deny the violation 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. Should you fail to answer or pay the civil penalty within 30 days of the date of this Notice, the NRC may issue an order imposing the civil 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 the 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 a Notice of Violation, EA-23-070" and "Answer to a Notice of Violation, EA-23-070," 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 IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, and email it to R4Enforcement@nrc.gov.

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy or proprietary 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).

In accordance with 10 CFR 19.11, you are required to post this Notice within 2 working days of receipt.

Dated this 25th day of January 2024

Civil Penalty Invoice



International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, ID 83401



Address/Customer Information

International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, ID 83401 **Customer Codes**

Account Code:

L00000097/1

Bill Information

Bill Number: EA-23-070 Amount Due: \$18,000.00

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	\$18,000.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	\$18,000.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	\$18,000.00

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 the NRC Financial Services and Operations Branch at (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.

If this invoice is related to an Order Imposing a Civil Penalty, International Isotopes, Inc. is required to pay the Civil Penalty within 30 days of the Order date. If payment is in response to a Notice of Violation and Proposed Imposition of a Civil Penalty, please follow the instructions in the Notice. The NRC may consider a request for additional time to pay the Civil Penalty, including the option to enter into an installment agreement, if appropriate. All requests for additional time to pay an invoice must be submitted in writing, with appropriate justification, to NRCCollections.Resource@nrc.gov, and should be submitted sufficiently ahead of time to allow the NRC time to review the request for additional time to pay within the 30-day payment period. This Invoice is related to the Civil Penalty proposed or imposed under EA-23-070 issued to International Isotopes, Inc. Please include this reference number on your payment method (see attached Payments Methods Brochure).

Customer Information L0000097/1 International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, ID 83401 Change of Address: This Payment References the following Bill: EA-23-070 Outstanding Amount Due: Amount Enclosed: Phone:

NUREG/BR-0254 Payment Methods

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 sending an e-mail to nrc@fiscal.treasury.gov, by calling (301) 415-7554, or by writing to the address below:

U.S. NUCLEAR REGULATORY COMMISSION OCFO/DOC/LAFBB Washington, DC 20555-0001





U.S. NUCLEAR REGULATORY COMMISSION OCFO/DOC/LAFBB Washington, DC 20555-0001

PH (301) 415-7554



NUREG/BR-0254, Rev. 11 October 2023

STAY CONNECTED













APPROVED BY OMB NO. 3150-0190

Paperwork Reduction Act This NUREG/BR provides guidance for completing the voluntary information collection in NRC Form 629. The estimated burden per response for completing NRC Form 629 is 10 minutes. This information collection was approved by the Office of Management and Budget (OMB), approval numbers 3150-0190. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, or by e mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0190), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e mail: oira submission@omb.eop.gov.

Public Protection Notification The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

The 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 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 DIGITAL WALLET

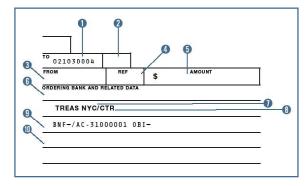
The NRC currently accepts payments of up to \$10,000.00. For payment by PayPal and Amazon Pay, go to Pay,goy, search for "U.S. Nuclear Regulatory Commission Fees." and enter the required information.





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.



- RECEIVER-DFI#—Treasury's ABA number for deposit messages is 021030004.
- 2 TYPE-SUBTYPE-CD-The sending bank will provide the type and subtype code.
- SENDER-DFI#-The sending bank will provide this number.
- SENDER-REF#-The sending bank will insert this 16-character reference number at its discretion.
- **6** AMOUNT-The transfer amount must be punctuated with commas and a decimal point; use of the "\$" is optional. The depositor will provide this item.
- 6 SENDER-DFI-NAME-The Federal Reserve Bank will automatically insert this information.
- RECEIVER-DFI-NAME-Treasury's name for deposit messages is "TREAS NYC". The sending bank will enter this name.
- 8 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.
- 9 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 eight-digit ALC is: BNF=/AC-31000001
- 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 Part 171 annual fee, and licensee name—should be placed in this field,

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

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

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

SL-MO-R1GL

3180 Rider Trail S.

Earth City, MO 63045

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.