



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

November 5, 2013

Docket No. 03031963  
EA-13-059

License No. 52-25127-01

José Soltero, M.D.  
Centro de Medicina Nuclear  
Centro de Institutos Diagnósticos  
1801 Avenida Ponce de León, Suite 411  
Santurce, PR 00909

SUBJECT: NOTICE OF VIOLATION AND PROPOSED CIVIL PENALTY \$7,000 –  
NOTIFICATION OF THE POTENTIAL IMPOSITION OF ADDITIONAL DAILY  
CIVIL PENALTIES

Dear Dr. Soltero:

This letter is in reference to the continued failure by Centro de Medicina Nuclear (CDM) to respond to an Order Revoking License (Order) issued on August 7, 2012 (ML12220A598)<sup>1</sup>, for nonpayment of its NRC annual licensing fee. The Order, which required a response from CDM within 20 days of the date of the Order, specified that if the fee was not paid within that timeframe, the license was to be revoked and CDM was to perform a number of actions. Because CDM did not pay the fee within the allotted 20 days, CDM's license was, in fact, revoked on August 28, 2012 (ML12248A416), and CDM was required to perform the specified actions, which included: (1) arranging for disposal or transfer of any licensed material possessed under the license; (2) within 5 days after disposal, providing the NRC written reports describing how, where, and when such disposition took place; (3) within 60 days from the date of revocation, initiating site decommissioning; and (4) no later than the date of revocation, submitting to the NRC a written report that includes: (a) a listing of all licensed materials disposed of, transferred, or still in possession; (b) a description of the conditions of storage of retained materials and actions being taken to control access to the material; and (c) for any licensed material not disposed of or transferred, a description of the actions taken to attempt to dispose of or transfer the licensed material and why those actions were unsuccessful.

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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<sup>1</sup> 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.

After CDM did not respond to the Order, a Region I inspector conducted a site visit on January 17, 2013, and, with the assistance of CDM's contract Radiation Safety Officer, confirmed that CDM's radioactive sources were secured and that the inventory was unchanged from the inventory last performed on June 1, 2012. During that visit, you informed the inspector that you did not have definite plans for future activities at the facility and no specific timeframe to take action. In a May 16, 2013, letter (ML13141A430), Region I documented the observations from the January site visit, and provided CDM thirty days to provide the information required by the Order. The letter informed CDM that continued failure to respond would result in further enforcement action (which could include daily civil penalties). To date, CDM has not responded to either the NRC letter or to telephone messages left by Region I staff.

Based on the above, the NRC has concluded that CDM is in violation of NRC requirements. The violation, which is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), involves CDM's failure to respond to the Order and take the actions currently required (initiating site decommissioning and submitting a written report with the status of CDM's licensed materials and actions taken to dispose of or transfer the materials). Given that CDM has neither responded to NRC communication attempts nor given any indication that it intends to comply with NRC requirements, the NRC is proceeding with its enforcement action.

In assessing the significance of this violation, the NRC considered that CDM has failed to comply with the NRC Order for more than a year and has taken no action to initiate decommissioning of its site or arrange for transfer or dispose of its licensed material. Additionally, CDM's continued failure to provide the required information to, and communicate with, the NRC has impeded the NRC from carrying out its regulatory mission of protecting public health and safety and the environment, and has resulted in additional, unplanned site visits to CDM's facility to verify the security of CDM's licensed material. Therefore, the NRC has assessed this violation at Severity Level (SL) III, in accordance with the NRC Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because CDM was issued an escalated enforcement action within the last two years (the August 7, 2012, Order), 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. Credit for identification is not warranted because the NRC identified the violation. Credit for corrective action is also not warranted because CDM has failed to address the violation or to communicate with the NRC. Therefore, to emphasize the importance of compliance with NRC requirements, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice and Proposed Imposition of Civil Penalty in the amount of \$7,000 (twice the amount of the base civil penalty).

If, after 60 days from the date of this letter, CDM continues to remain in violation of the Order, in addition to the \$7,000 civil penalty proposed for the violation in the attached Notice, the NRC intends to impose additional daily civil penalties of \$100 per day. Daily civil penalties are justified because CDM has been informed that it is in violation of NRC requirements, yet has failed to take effective corrective action. Daily civil penalties will continue to be assessed until CDM corrects the violation by performing the previously-described actions currently required by the Order.

The NRC's primary interest in this matter is to ensure that CDM meets its obligation to decommission its facility and ensure the proper transfer or disposal of the licensed material in its possession. Accordingly, the NRC will provide CDM a grace period of 60 days from the date of this letter before imposing the \$7000 civil penalty. If, during this 60 day grace period, CDM properly transfers or disposes of its material, as described below, the NRC will forgo imposition of any civil penalty, and will terminate CDM's license by written notice upon NRC verification that the licensed material has, in fact, been transferred or disposed.

If CDM transfers or disposes of its licensed material as described above within 60 days of the date of this letter, it must provide us the following information:

1. At least two business days prior to the date of transfer or disposal, notify Jim Dwyer, Chief, Medical Branch, NRC Region I, by telephone (610-337-5309).
2. Within five business days following completion of the transfer or disposal, provide to the Regional Administrator, NRC Region I, in writing: a) confirmation, using NRC Form 314 (enclosed), that the material has been transferred or disposed; b) a copy of the certification from the authorized recipient that the material has been received; and (c) a copy of the radiation survey performed in accordance with 10 CFR 30.36(j)(2).

You are required to respond to this letter and to follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

**/RA/**

William M. Dean  
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NRC Form 314
3. NUREG/BR-0254

cc w/enclosures:

David M. Rhoe, Radiation Safety Officer  
Commonwealth of Puerto Rico

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Sincerely,  
**/RA/**  
 William M. Dean  
 Regional Administrator

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3. NUREG/BR-0254

cc w/enclosures:

David M. Rhoe, Radiation Safety Officer  
 Commonwealth of Puerto Rico

Distribution: see next page

DOCUMENT NAME: S:\Enf-all\Enforcement\Proposed-Actions\Region1\Centro de Medicina NOV-III EA-13-059.docx

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DATE	9/03/13	9/03/13		10/3/13	
OFFICE	FSME	OE	OGC	RI/DNMS	RI/RA
NAME	M Burgess	N Hilton	C Hair	J Clifford/	W Dean
DATE	10/23/13	11/1/13	10/3/13	11/04/2013	11/05/2013

\* See previous concurrence page

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ENCLOSURE

NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Centro de Medicina Nuclear  
Santurce, Puerto Rico

Docket No. 03031963  
License No. 52-25127-01  
EA-13-059

Following the August 7, 2012, issuance of an NRC Order Revoking the License of Centro de Medicina Nuclear, 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 particular violation and associated civil penalty are set forth below:

10 CFR 2.202(b) requires, in part, that a licensee to whom the NRC has issued an Order must respond to the Order by filing a written answer under oath or affirmation in which the licensee specifically admits or denies each allegation or charge made in the Order.

NRC "Order Revoking License Within 20 Days," dated August 7, 2012 (Order), specified that if Centro de Medicina Nuclear (CDM) did not pay its NRC annual licensing fee within 20 days of the date of the Order, the license was to be revoked and CDM was to perform a number of actions. Because CDM did not pay the fee within the allotted 20 days, CDM's license was, in fact, revoked on August 28, 2012, and CDM was required to perform the specified actions, which included: (1) arranging for disposal or transfer of any licensed material possessed under the license; (2) within 5 days after disposal, providing the NRC written reports describing how, where, and when such disposition took place; (3) within 60 days from the date of revocation, initiating site decommissioning; and (4) no later than the date of revocation, submitting to the NRC a written report that includes: (a) a listing of all licensed materials disposed of, transferred, or still in possession; (b) a description of the conditions of storage of retained materials and actions being taken to control access to the material; and (c) for any licensed material not disposed of or transferred, a description of the actions taken to attempt to dispose of or transfer the licensed material and why those actions were unsuccessful.

Contrary to the above, as of the date of this Notice, CDM has not: (1) submitted an answer to the Order (which was required by August 27, 2012); (2) paid the license fee (which was required by August 27, 2012); (3) begun decommissioning its site (which was required by October 26, 2012); or (4) submitted to the NRC the required written report regarding the amount, condition, and status of its licensed material (which was required by August 27, 2012).

This is a Severity Level III violation (Enforcement Policy Examples 6.9).  
Civil Penalty - \$7,000

Pursuant to the provisions of 10 CFR 2.201, CDM is hereby required to submit a written statement or explanation within 60 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; (EA-13-059)" and should include for each alleged violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective

steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved.

In addition to submitting its reply, within 60 days of the date of this Notice, CDM must either: (a) pay the civil penalty proposed above; (b) protest imposition of the civil penalty in whole or in part, or (c) transfer or dispose of its licensed material as described in the letter enclosing this Notice. CDM must inform the NRC in writing as to which of these actions it is taking by following the directions provided below. Any such answer should be set forth separately from the "Reply to the Notice of Violation," but may incorporate parts of the reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition.

To pay the civil penalty, CDM must follow the instructions in NUREG/BR-0254 (enclosed) and also submit a statement indicating when and by what method payment was made. To protest imposition of the civil penalty, as provided in 10 CFR 2.205, CDM should prepare a written answer that: (1) denies the violation listed in this Notice, in whole or in part; (2) demonstrates extenuating circumstances; (3) shows error in this Notice; or (4) shows other reasons why the penalty should not be imposed. CDM may also request remission or mitigation of the penalty and, in doing so, should address the factors in Section 2.3.4 of the NRC Enforcement Policy. CDM should clearly mark its answer as an "Answer to a Notice of Violation." If CDM transfers or disposes of its licensed material, CDM must follow the directions provided in the letter enclosing this Notice.

The responses noted above, i.e., Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Roy Zimmerman, 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, 2100 Renaissance Boulevard, King of Prussia, PA, 19406, and the Document Control Desk, US Nuclear Regulatory Commission, Washington, DC 20555-0001.

Should CDM fail to answer within 60 days of the date of this Notice, the NRC will issue an Order imposing the civil penalty. Additionally, if, after 60 days, CDM continues to remain in violation of the Order, the NRC will consider imposing additional daily civil penalties of \$100 per day, as described in the letter enclosing this Notice. 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.

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 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 may be required to post this Notice within two working days of receipt.

Dated this 5<sup>th</sup> day of November, 2013