

October 14, 2005

EA-04-215

L. K. Thompson
Administrator
The Milton S. Hershey Medical Center
The Pennsylvania State University
P.O. Box 850
Hershey, PA 17033

SUBJECT: Notice of Violation and Confirmatory Order (Effective Immediately)
(NRC Office of Investigations Report Nos. 1-2004-038; -037; -026; -039)

Dear Mr. Thompson:

In a letter dated May 18, 2005, the NRC provided you with the results of four investigations conducted by the NRC Office of Investigations (OI), Region I Field Office, between May 11, 2004 and March 16, 2005, to determine whether licensed byproduct material was improperly used by employees of the Milton S. Hershey Medical Center (MSHMC). Our letter noted, in part, that based on the evidence developed during these investigations, OI concluded that (1) in the 1996 - 1997 time frame, an authorized user deliberately administered byproduct material to an individual, with no medical reason, for the sole purpose of comparing images from two cameras, (2) in 2002, a former MSHMC employee deliberately used byproduct material to perform an unauthorized bone scan on himself, (3) in 2004, a MSHMC employee deliberately used byproduct material to perform an unauthorized brain scan on herself, and (4) an unauthorized nuclear medicine scan of a worker's lower extremities in the early 1990s could not be substantiated. In addition, our letter informed you that after further review of all the available evidence regarding the first investigation noted above, the NRC staff concluded that the authorized user's administration of byproduct material to perform a comparison of images from two cameras violated NRC requirements, but that deliberateness was not substantiated. A Factual Summary of the OI investigations was enclosed with our May 18, 2005 letter.

In our letter dated May 18, 2005, we informed you that as a result of these OI investigations, two apparent violations were identified and were being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The first apparent violation involved an authorized user administering byproduct material with no medical reason, contrary to 10 CFR 35.11. The second apparent violation involved the deliberate use of byproduct material by the staff of the MSHMC to perform unauthorized nuclear medicine tests, without the supervision of an authorized user, on two separate occasions, contrary to 10 CFR 35.27(a).

As a result of these findings, we understand that the MSHMC took several actions to ensure that these events do not recur. These actions included (1) immediately conducting training with each nuclear medicine technician emphasizing the proper procedure for administering licensed material and the need to obtain authorization from a physician or an Authorized User (AU) prior to each administration, (2) reviewing this event with appropriate MSHMC staff members, and (3) modifying training procedures to include review of this event in new student training and required periodic retraining of current employees.

In addition, our letter offered you a choice to (1) attend a Predecisional Enforcement Conference, or (2) request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve any disagreement on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party, and the NRC currently has a pilot program for using ADR. The technique that the NRC decided to employ during the pilot program, which is now in effect, is mediation.

At your request, an ADR mediation session was held between the MSHMC and the NRC in King of Prussia, PA, on August 23, 2005, and a settlement agreement was reached regarding this matter. The elements of the settlement agreement are as follows:

1. The NRC determined that one Severity Level III problem with three examples occurred involving the use of byproduct material to perform unauthorized nuclear medicine tests, during the 1996 - 1997 time frame, in October 2002, and on April 29, 2004, in violation of 10 CFR 35.27(a). Specifically: (1) a Nuclear Medicine Technologist (NMT), formerly employed at the Milton S. Hershey Medical Center (MSHMC), was injected without the authorization of an Authorized User (AU) in violation of NRC requirements; (2) an NMT, formerly employed at the MSHMC, deliberately had himself injected with licensed radioactive material by another NMT for the purposes of conducting a bone scan without the authorization of an AU in violation of NRC requirements; and (3) an NMT, formerly employed at the MSHMC, deliberately directed a student technologist to inject her with licensed radioactive material for the purpose of conducting a brain scan without the authorization of an AU, in violation of NRC requirements.
2. The MSHMC agreed that there were three unauthorized administrations of licensed material in violation of 10 CFR 35.27(a) and agreed that examples (2) and (3) described in paragraph 1, were deliberate.
3. The MSHMC will take the following actions to ensure that similar violations will not recur: (1) the Radiation Safety Officer (RSO) will prepare an article to be published in the Journal of Operational Radiation Safety addressing the topics listed in paragraph 4; (2) the RSO and the Chief Nuclear Medicine Technologist will prepare an article and submit it for publication in the Journal of Nuclear Medicine Technology addressing the topics listed in paragraph 4; (3) the RSO will prepare and submit abstracts for presentation at a meeting of the Health Physics Society and a meeting of the American Association of Physicists in Medicine addressing the topics listed in paragraph 4; (4) the Chief of Nuclear Medicine will submit an agenda item for presentation to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) to determine whether additional actions need to be taken to address instances of unauthorized use of licensed material by licensee employees; and (5) the RSO will prepare and submit scenarios on the list server for the Association of Radiation Safety Officers. The MSHMC will advise NRC upon completion of these items, which are to be completed not later than one year from the date of this agreement.
4. The articles, abstracts, presentations and scenarios must address the following: (1) acknowledgment that a condition occurred that put MSHMC in violation of NRC requirements; (2) the need to establish an environment and culture that promotes regulatory compliance through the implementation of controls and processes; (3) the need to ensure that all employees, including new employees and students, are trained and oriented in NRC requirements; (4) the importance of continued self-assessment of programs and processes to ensure that these programs and processes are delivering

- the desired outcomes; and, (5) the need to promptly address any employee performance issue to avoid actions that could lead to violations of NRC requirements.
5. The MSHMC agreed to include in its orientation for students and new employees information describing the violation that is the subject of this agreement. In addition, this violation will be a topic in periodic retraining for current employees.
 6. The MSHMC agreed to provide the NRC with a final written report once all items have been completed.
 7. In light of MSHMC's agreement to the items described in paragraphs 1 and 2, and the actions that MSHMC will take as described in paragraphs 3, 4, 5 and 6, the NRC agreed to issue one Notice of Violation at Severity Level III, with no Civil Penalty. The NRC will place the Notice of Violation, which will be publically available in ADAMS, on the NRC "Significant Enforcement Actions " website. The Notice of Violation will remain on the "Significant Enforcement Actions " website no longer than one year.
 8. You agreed to issuance of a Confirmatory Order confirming this agreement.

Enclosed with this letter is the Notice of Violation (Notice) and the Confirmatory Order (Order). By letter dated October 5, 2005, the MSHMC consented to issuance of the Notice of Violation and Confirmatory Order and waived the right to request a hearing on all or any part of the Confirmatory Order. You are not required to respond to this letter or Notice. However, in accordance with the settlement agreement, you are required to respond to the Order. Your written response to the Order, and your response to the Notice, if you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Open by Addressee Only", within 30 days of the date of this letter.

A copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter on its website for a period of 1 year at www.nrc.gov; select **What We Do, Enforcement, Significant Enforcement Actions**. In addition, a press release announcing this enforcement action will be issued by the NRC. Your response, if you choose to provide one, will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301.

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 03003203
License No. 37-13831-01

Enclosures: As Stated

L. K. Thompson

4

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DATE	09/13/05		09/13/05		09/13/05		09/13/05		09/13/05	
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NAME	KFarrar		SCollins (MLD for)		GMorell *		BJones (GML for)		MJohnson	
DATE	09/13/05		09/22/05		9/20/05		9/16/05		09/27/05	

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*** Concurrence via e-mail to J. Wray from S. Merchant, OE.**

NOTICE OF VIOLATION

The Milton S. Hershey Medical Center
Hershey, Pennsylvania

Docket No. 03003203
License No. 37-13831-01
EA-04-215

During four separate investigations conducted at the Milton S. Hershey Medical Center (MSHMC) by the NRC Office of Investigations between May 11, 2004, and March 16, 2005, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.27(a), requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b)(1), shall require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, written regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, on three separate occasions, licensee individuals used byproduct material to perform unauthorized nuclear medicine tests without the supervision of an authorized user. Specifically:

1. In the 1996 - 1997 time frame, a Nuclear Medicine Technologist (NMT), formerly employed at the MSHMC, was injected with byproduct material by another NMT, without the supervision of an authorized user.
2. In October 2002, a NMT, formerly employed at the MSHMC, deliberately directed another NMT to inject byproduct material into his body, without the supervision of an authorized user.
3. On April 29, 2004, a NMT, formerly employed at the MSHMC, deliberately directed a student to inject byproduct material into her body, without the supervision of an authorized user.

This is a Severity Level III problem (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in the letter forwarding this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, your written response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Open by Addressee Only" within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation, EA-04-215."

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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.

Dated this 14th day of October 2005.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)	Docket No. 030-03203
)	Licence No. 37-13831-01
Milton S. Hershey Medical Center)	EA-04-215
)	

CONFIRMATORY ORDER
(EFFECTIVE IMMEDIATELY)

The Milton S. Hershey Medical Center (MSHMC) is the holder of Byproduct Material License 37-13831-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. This broad scope medical license authorizes possession and use of a wide variety of radionuclides for medical diagnosis, therapy, and research in humans; research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in vitro studies. The license further authorizes possession and use of iridium-192 sealed sources for medical use permitted by 10 CFR 35.600 in a high dose rate remote afterloader, depleted uranium for shielding in a linear accelerator, and barium-133 sealed sources for use in a device for patient attenuation correction during S.P.E.C.T. imaging. The license, originally issued on October 16, 1970, was renewed on August 4, 1995, and is currently under timely renewal.

II

In a letter dated May 18, 2005, the NRC provided MSHMC with the results of four investigations conducted by the NRC Office of Investigations (OI), Region I Field Office, between May 11, 2004 and March 16, 2005, to determine whether licensed byproduct material was improperly used by its employees. This letter stated that, based on the evidence developed during these investigations, the NRC concluded that (1) in the 1996 - 1997 time frame, the authorized user's administration of byproduct material to perform a comparison of images from two cameras violated NRC

requirements, but that deliberateness was not substantiated, (2) in 2002, a former MSHMC employee deliberately used byproduct material to perform an unauthorized bone scan on himself, (3) in 2004, a MSHMC employee deliberately used byproduct material to perform an unauthorized brain scan on herself, and (4) an unauthorized nuclear medicine scan of a worker's lower extremities in the early 1990s could not be substantiated.

III

In response to the NRC's May 18, 2005, letter, MSHMC immediately took several actions to ensure that these events do not recur. These actions included: (1) conducting training with each nuclear medicine technician emphasizing the proper procedure for administering licensed material and the need to obtain authorization from a physician or an Authorized User (AU) prior to each administration; (2) reviewing this event with appropriate MSHMC staff members; and (3) modifying training procedures to include review of this event in new student training and required periodic retraining of current employees.

MSHMC also requested the use of Alternative Dispute Resolution (ADR) to bring closure to this matter. The NRC uses ADR, a process in which a neutral mediator, with no decision-making authority, assists the NRC and a regulated party (in this case, MSHMC), to resolve disagreements as to whether a violation has occurred, the appropriate enforcement action to be taken, and the appropriate corrective actions to be taken. An ADR session was held between the NRC and MSHMC in Region I, King of Prussia, PA, on August 23, 2005. The ADR session was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. During that ADR session, a settlement agreement was reached. The elements of the settlement agreement consist of the following:

9. The NRC determined that one Severity Level III problem with three examples occurred involving the use of byproduct material to perform unauthorized nuclear medicine tests, during the 1996 - 1997 time frame, i.e., in October 2002, and on April 29, 2004, in violation of 10 CFR 35.27(a). Specifically: (1) a Nuclear Medicine Technologist (NMT), formerly employed at the Milton S. Hershey Medical Center (MSHMC), was injected without the authorization of an Authorized User (AU) in violation of NRC requirements; (2) an NMT, formerly employed at the MSHMC, deliberately had himself injected with licensed radioactive material by another NMT for the purposes of conducting a bone scan without the authorization of an AU in violation of NRC requirements; and (3) an NMT, formerly employed at the MSHMC, deliberately directed a student technologist to inject her with licensed radioactive material for the purpose of conducting a brain scan without the authorization of an AU, in violation of NRC requirements.
10. The MSHMC agreed that there were three unauthorized administrations of licensed material in violation of 10 CFR 35.27(a) and agreed that examples (2) and (3) described in Item I of this part, were deliberate.
11. The MSHMC will take the following actions to ensure that similar violations will not recur. These actions include: (1) the Radiation Safety Officer (RSO) will prepare an article to be published in the Journal of Operational Radiation Safety addressing the topics listed in Item 4 of this section; (2) the RSO and the Chief Nuclear Medicine Technologist will prepare an article and submit it for publication in the Journal of Nuclear Medicine Technology addressing the topics listed in Item 4 of this section; (3) the RSO will prepare and submit abstracts for presentation at a meeting of the Health Physics Society and a meeting of the

American Association of Physicists in Medicine addressing the topics listed in Item 4 of this section; (4) the Chief of Nuclear Medicine will submit an agenda item for presentation to the ACMUI to determine whether additional actions need to be taken to address instances of unauthorized use of licensed material by licensee employees; and (5) the RSO will prepare and submit scenarios on the list server for the Association of Radiation Safety Officers. The MSHMC will advise NRC upon completion of these items, to be completed not later than one year from the date of this agreement.

12. The articles, abstracts, presentations and scenarios must address the following: (1) acknowledgment that a condition occurred that put MSHMC in violation of NRC requirements; (2) the need to establish an environment and culture that promotes regulatory compliance through the implementation of controls and processes; (3) the need to ensure that all employees, including new employees and students, are trained and oriented in NRC requirements; (4) the importance of continued self-assessment of programs and processes to ensure that these programs and processes are delivering the desired outcomes; and, (5) the need to promptly address any employee performance issue to avoid actions that could lead to violations of NRC requirements.
13. The MSHMC agrees to include in its orientation for students and new employees information describing the violation that is the subject of this agreement. In addition, this violation will be a topic in periodic retraining for current employees.
14. The MSHMC agrees to provide the NRC a final written report once all items have been completed.

15. In light of MSHMC's agreement to Items 1 and 2, and the actions that MSHMC will take as described in Items 3, 4, 5 and 6, the NRC agrees to issue one Notice of Violation at Severity Level III, with no Civil Penalty. The NRC will place the Notice of Violation, which will be publically available in ADAMS, on the NRC "Significant Enforcement Actions " website. The Notice of Violation will remain on the "Significant Enforcement Actions " website no longer than one year.

By letter dated October 5, 2005, the MSHMC consented to issuance of the Notice of Violation and this Confirmatory Order with the commitments, as described in Section IV. The MSHMC further agreed in its October 5, 2005, letter that this Order is to be effective upon issuance and that it has waived its right to a hearing.

I find that the MSHMC's commitments as set forth in Section IV are acceptable and necessary, and that the NRC's concerns can be resolved by confirming the MSHMC's commitments as outlined in this Confirmatory Order. I conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments be confirmed by this Order. Based on the above and the MSHMC's consent, this Confirmatory Order is immediately effective upon issuance.

IV

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR § 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, THAT BY AUGUST 23, 2006:

- 1) The MSHMC will take the following actions to ensure that similar violations will not recur. These actions include: (1) the Radiation Safety Officer (RSO) will prepare an article to be published in the Journal of Operational Radiation Safety addressing the topics listed in Item 2 of this section; (2) the RSO and the Chief Nuclear Medicine Technologist will prepare an article and submit it for publication in the Journal of Nuclear Medicine Technology addressing the topics listed in Item 2 of this section; (3) the RSO will prepare and submit abstracts for presentation at a meeting of the Health Physics Society and a meeting of the American Association of Physicists in Medicine addressing the topics listed in Item 2 of this section; (4) the Chief of Nuclear Medicine will submit an agenda item for presentation to the ACMUI to determine whether additional actions need to be taken to address instances of unauthorized use of licensed material by licensee employees; and (5) the RSO will prepare and submit scenarios on the list server for the Association of Radiation Safety Officers. The MSHMC will advise NRC upon completion of these items, to be completed not later than one year from the date of this agreement.
2. The articles, abstracts, presentations and scenarios must address the following: (1) acknowledgment that a condition occurred that put MSHMC in violation of NRC requirements; (2) the need to establish an environment and culture that promotes regulatory compliance through the implementation of controls and processes; (3) the need to ensure that all employees, including new employees and students, are trained and oriented in the requirements; (4) the importance of continued self-assessment of programs and processes to ensure that these programs and processes are delivering the desired outcomes; and, (5) the need to promptly address any employee performance issue to avoid actions that could lead to

violations of NRC requirements.

3. The MSHMC agrees to include in its orientation for students and new employees information describing this violation that is the subject of this agreement. In addition, this violation will be a topic in periodic retraining for current employees.
4. The MSHMC agrees to will advise NRC upon completion of these items, to be completed not later than one year from the date of this agreement.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above conditions upon a showing by MSHMC of good cause.

V

Any person adversely affected by this Confirmatory Order, other than the MSHMC, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, D.C. 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, to the Director of the Division of Regulatory Improvement Programs at the same address, and to MSHMC. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the

Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to hearingdocket@nrc.gov and also to the Office of the General Counsel by means of facsimile transmission to 301-415-3725 or e-mail to OGCMailCenter@nrc.gov. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.309 (d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR A REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Michael Johnson, Director
Office of Enforcement

Dated this 14th day of October 2005