

August 16, 2001

EA No. 01-064

SMI East Coast Medical Waste, Inc.
Attn: Craig P. Sanford, President
1307 South Pennsylvania Avenue
Morrisville, PA 19067-1275

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection 99990001/1997023, and NRC Office of Investigations Report
No. 1-97-050)

Dear Mr. Sanford:

This refers to the inspection conducted on October 30, 1997, and November 20, 1997 at the Arthur Brisbane Child Treatment Center (Brisbane) in Farmingdale, New Jersey, to review the circumstances associated with an event which occurred at that facility on October 29, 1997, wherein an exit sign, containing 12 curies of tritium, was broken and resulted in radioactive contamination of a portion of the facility. Brisbane was authorized to possess and use such exit signs pursuant to a general license contained in 10 CFR 31.5. Subsequent to the inspection, the NRC Office of Investigations (OI), Region I, initiated an investigation to determine if Brisbane, which is operated by the State of New Jersey Department of Human Services (DHS), willfully and improperly disposed of the broken generally licensed exit sign (along with contaminated asbestos floor tiles and other contaminated objects) by improperly transferring the material to your company, SMI, East Coast Medical Waste, Inc. (SMI), a medical waste broker who was not authorized to receive radioactive waste.

We informed you of the results of the OI investigation in a letter, dated April 16, 2001, and also provided you the opportunity to address the apparent violations by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. Based on the OI investigation, the NRC found, in part, that on December 4, 1997, SMI removed one barrel of waste from Brisbane which contained approximately 12 curies of tritium in a broken generally licensed exit sign and stored that barrel and its contents at its Morrisville, Pennsylvania facility awaiting proper disposal. SMI also removed several other barrels from Brisbane which contained tritium contaminated objects which were shipped to Safety Disposal Systems, Inc., a medical waste incinerator located in South Carolina, that was not authorized to accept radioactive material. SMI's possession, receipt, and transfer of this material was an apparent violation of 10 CFR 30.3. 10 CFR 30.3 requires, in part, that except for persons exempted, no person shall transfer, receive, acquire, possess, or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

OI also concluded that SMI provided false statements to the NRC during the investigation regarding invoices and consultation with an expert in the area of radioactive waste. Specifically,

you advised OI that you had provided original documents of all information in your files, including bills of lading (previously referred to as invoices), as a result of an NRC subpoena. You also advised the State of New Jersey Department of Environmental Protection (NJDEP) that you had provided copies of all documents to them, including bills of lading. Despite this claim of compliance with both investigative entities, the bills of lading provided to OI and NJDEP were different. In particular, a bill of lading dated December 4, 1997, which identified the broken exit sign, was given to NJDEP but was not provided to OI. When questioned by OI regarding the missing bill of lading, you stated that it was created by mistake and the original no longer existed. In addition, the OI report indicated that you made the decision to dispose of the radioactive material as medical waste only after you had consulted with "your expert" in the field. However, that individual denies providing advice to you that the waste could be disposed of as medical waste.

We received a written response from your lawyer, dated June 26, 2001, that stated SMI did nothing wrong and denied that SMI violated NRC requirements. That letter also stated that SMI desired to have a predecisional enforcement conference. A predecisional enforcement conference was held with your company on July 25, 2001. At the conference, you stated that SMI officials did not know about the NRC requirements and that you believed SMI handled all material from the clean-up in a correct manner. A summary of the meeting is attached.

Notwithstanding your disagreement with our findings, the NRC has concluded, after reviewing all information in this case, that two violations of NRC requirements occurred. With respect to the first violation, 10 CFR 30.3 states, in part, that no person shall transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license. However, SMI received material it was not authorized to possess and attempted to improperly transfer the material for disposal. The NRC determined that this action was taken with careless disregard of NRC requirements because you, as the president of SMI, knew that the waste was radioactive, were aware that the NRC has requirements regarding the appropriate handling of radioactive material, and knew that there were issues regarding whether SMI could possess or transfer the material, but nevertheless possessed and transferred the material to the disposal facility that was not authorized to receive such waste. As such, this was done in complete disregard of the NRC regulations that prohibited such actions.

With respect to the second violation, 10 CFR 30.10(a)(2) states, in part, that any licensee, or licensee employee, or contractor, may not engage in deliberate misconduct that causes or would have caused, if not detected, a licensee to be in violation of any rule, regulation, or any term, condition, or limitation of any license issued by the Commission; and that such individual may not deliberately submit to the NRC, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC. You, as the president of SMI, deliberately provided inaccurate information to the NRC regarding the existence of a bill of lading for the waste shipment. You stated at the predecisional enforcement conference that you did not know how NJDEP obtained the erroneous copy of the bill of lading because it should have been destroyed. However, the document was not destroyed prior to the time that NJDEP obtained copies of the records as evidenced by the copy in the possession of NJDEP. Therefore, the NRC believes that the document existed, SMI removed the document from the files after the time that NJDEP obtained copies of the records, and SMI intentionally did not provide all documents to the NRC. This information was material to the NRC because it had the capability to influence the NRC follow-up review of the attempted improper disposal of radioactive material. The violation is of concern because we rely upon

licensees and individuals to be forthright and honest in dealing with the NRC. In reference to the other apparent false statement regarding the consultation with an expert in the area of radioactive materials, the NRC does not plan to cite this as a violation.

Therefore, although the safety significance of these violations was low because there were no dose to individuals or potential doses to individuals that would create a serious health risk, and the broken exit sign was eventually disposed of properly by SMI, the cited violations are classified as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC enforcement actions," (NUREG-1600). The violations are described in the enclosed Notice of Violation (Notice).

The NRC has also concluded that information regarding the reason for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence, were already described adequately during the predecisional enforcement conference, in this letter, or in the letter from your lawyer, Gary P. Lightman, to Mr. Fewell dated June 26, 2001. 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 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures, and any response will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Reading Room).

Sincerely,

/RA/ James T. Wiggins Acting For

Hubert J. Miller
Regional Administrator

Docket No. 030-03111
License No. 37-09016-01

Enclosures: 1. Notice of Violation
2. Predecisional Enforcement Conference Summary

cc w/encls: State of New Jersey
Commonwealth of Pennsylvania
State of South Carolina

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* Concurrence by J. Luehman per telecon with J. Lubinski

ENCLOSURE

NOTICE OF VIOLATION

SMI East Coast Medical Waste, Inc.
Morrisville, PA

EA 01-064

During an NRC inspection conducted on October 30, 1997, and November 20, 1997 at the Arthur Brisbane Child Treatment Center in Farmingdale, New Jersey, as well as a subsequent investigation conducted by the NRC Office of Investigation, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

- A. 10 CFR 30.3 states that no person shall transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license.

Contrary to the above, on December 4, 1997, SMI East Coast Medical Waste, Inc (SMI) received, acquired, owned, or possessed byproduct material which was not authorized in a general or specific license. Specifically, SMI took possession of a broken generally licensed device (containing approximately 12 curies of tritium) and other objects contaminated with radioactive material, but the company did not hold a specific license issued pursuant to 10 CFR Parts 30 and 32 or a license from an Agreement State. By subsequently transferring this material to Safety Disposal Systems, Inc. (SDS, formerly known as Chambers Medical Technologies of South Carolina), SMI acted in careless disregard of NRC requirements because the president of SMI knew that the waste was radioactive, was aware that NRC has requirements regarding the appropriate handling of radioactive material, and knew that there were issues regarding whether SMI could possess or transfer the material, but nonetheless possessed and transferred the material to SDS knowing that SDS could only accept medical waste.

- B. 10 CFR 30.10 (a)(2), in part, prohibits any contractor of a licensee from deliberately submitting information to the NRC that the person knows to be incomplete or inaccurate in some respect material to the NRC.

Contrary to the above, on January 21, 1998, SMI deliberately provided the Commission information that SMI knew was not complete and accurate in all material respects. Specifically, when questioned regarding an invoice that was provided to the State of New Jersey but not provided to the NRC, you stated that it was not an official document and it did not really exist. This statement is inaccurate because the document did exist as evidenced by the copy provided to the State of New Jersey. This information was material to the NRC because it had the capability to influence the NRC follow-up review of the attempted improper disposal of radioactive material.

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

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence are already adequately addressed on the docket in the letter transmitting this NOV or in the response from Mr. Gary Lightman to Mr. J. Bradley Fewell dated June 26, 2001. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. 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 U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated this 16th day of August 2001

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

ENFORCEMENT CONFERENCE SUMMARY

EA No. 01-064
License No. Non-Licensee
Docket No. Non-Licensee
Non-Licensee: SMI East Coast Medical Waste, Inc.
1307 South Pennsylvania Avenue
Morrisville, PA 19067-1275
Facility Name: 1307 South Pennsylvania Avenue
Morrisville, PA
Conference Date and Time: July 25, 2001 at 10:00 am
Conference Location: NRC Region I, King of Prussia, Pennsylvania

Inspectors:

/RA/ 08/01/01
Judith A. Joustra date
Senior Health Physicist

/RA/ Pamela J. Henderson 08/01/01
Sheri Minnick date
Health Physicist

Approved By: /RA/ Pamela J. Henderson 08/01/01
John Kinneman, Branch Chief date
Nuclear Material Safety Branch 2

CONFERENCE SUMMARY

SMI East Coast Medical Waste, Inc.
NRC Enforcement Conference Report No.99990001/97-023

Mr. Costello opened the meeting by stating the purpose. He explained that the NRC was there to listen to what Mr. Sanford had to say regarding the apparent violations listed in the letters dated April 16, 2001.

Mr. Nick explained the enforcement options available to the NRC. Mr. Nick explained that the conference was not open to the public.

Mr. Sanford on behalf of SMI East Coast Medical Waste, Inc. (SMI) described the events that occurred following the October 29, 1997 tritium contamination event at Arthur Brisbane Child Treatment Center. He specifically ran through the process by which he inquired into being able to properly classify and dispose of the waste from this event. He stated that he does not understand what he did that was inappropriate. He stated that he never described or documented the waste as "medical waste", and, therefore, was not trying to deceive anyone by shipping the waste to the waste incinerator located in South Carolina.

NRC staff asked Mr. Sanford what made him feel that it was acceptable to provide a waste disposal service for radioactive material. Mr. Sanford replied by stating that he knew the waste was radioactive, but he thought the quantities were exempt and therefore not regulated. NRC staff explained that SMI would need to be licensed as a radioactive waste broker in order to arrange for, possess, transfer, and transport, radioactive waste. Radioactive material contained in the exit sign and the resulting contamination were not exempt from NRC regulations.

In closing, Mr. Costello expressed to Mr. Sanford the NRC's appreciation for taking the time to come in and discuss the circumstances surrounding this case.

The meeting was adjourned.

LIST OF PERSONS ATTENDING

Non-Licensee

Craig P. Sanford, President, SMI East Coast Medical Waste, Inc.
Gary P. Lightman, Esquire, Lightman, Manochi & Christensen

NRC

Francis M. Costello, Deputy Director, Division of Nuclear Materials Safety
J. Bradley Fewell, Regional Counsel, Office of the Regional Administrator
John D. Kinneman, Chief, Nuclear Materials Safety Branch 2
Daniel Holody, Team Leader, Office of the Regional Administrator
Joseph Nick, Enforcement Specialist, Office of the Regional Administrator
Kevin Ramsey, Enforcement Specialist, NRC Headquarters
Judith A. Joustra, Senior Health Physicist, Division of Nuclear Materials Safety
Sheri Minnick, Health Physicist, Division of Nuclear Materials Safety
Mark Anderson, Office of Investigations