LAW OFFICES
Lightman, Manochi & Christensen
A PROFESSIONAL CORPORATION

GARY P. LIGHTMAN •
GLENN A. MANOCHI *
KRISTINE CHRISTENSEN Δ

Δ MEMBER PA & NJ BARS
• MEMBER PA NJ DC & FL BARS
* MEMBER PA NJ NY & CT BARS

1520 LOCUST STREET
TWELFTH FLOOR
PHILADELPHIA, PA 19102-4401

(215) 545-3000
TELECOPIER (215) 545-3001

NEW JERSEY OFFICE
20 KINGS HIGHWAY WEST
HADDONFIELD, NJ 08033

TELEPHONE (856) 795-9669
TELECOPIER (856) 795-9339

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May 15, 2001

George Pangburn, Director of Division
of Nuclear Material Safety
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

VIA TELECOPY (610) 337-5269

Re: Response (in opposition) to an Apparent Violation Inspection Conducted on December 31, 1997 and NRC Office of Investigations Report No. 1-97-050

Dear Mr. Pangburn:

This letter is in response to your letters of April 16, 2001, addressed to our clients, Craig P. Sanford, individually and as President of SMI East Coast Medical Waste, Inc. ("SMI") (your letter refers to SMI as non-licensee EA No. 01-064). In your letter, you indicate that an apparent violation has been identified and is being considered for escalated enforcement, under 10 CFR §30.3, based upon what you claim was SMI's possession, receipt and transfer of several barrels which contained tritium and/or tritium contaminated objects. You indicated that the alleged violation may be categorized as a severity level III and may result in the proposal of a Notice of Violation, a Civil Penalty, or an Order, or some combination thereof. Our clients, SMI and Mr. Sanford dispute that they are guilty of any violation.

We respectfully request a predecisional enforcement conference, which is one of the options which you set forth in your April 16th letter as available to our clients.

We also desire to review the OI Report 1-1997-050, as well the underlying documents comprising the OI investigation. Our clients dispute several of the (purported) factual findings set forth in the Summary of Findings of OI Report 1-1997-050. For example, SMI denies that either alone or "acting in concert with the DHS official, improperly transferred/disposed of the radioactive material". SMI also disputes that it "made false statements to the NRC during the investigation regarding invoices and consultation

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with an expert in the area of radioactive waste."

We also request that SMI's records be returned to SMI, so that we can review those records as well. As you may be aware, the NRC seized SMI's records in 1997. Despite repeated requests made by SMI to the NRC to return those records, to date, they have not been returned. We request that SMI's records be returned to SMI, forthwith.

You should be aware that SMI needs its records in order to aid in preparing its opposition and defenses to the alleged violation set forth in your April 16th letter. Our clients also need access to the entire OI Report 1-1997-050, as well as the source documents considered or reviewed in connection or in advance of that report, to aid us in our clients' defense. We request that someone from your counsel's office contact us at their convenience, so that arrangements can be made for us to obtain the requested documents, and to discuss the scheduling of the conference (which may be as early as 2-3 weeks after we have been afforded access to the requested documents).

Finally, we respectfully request that you inform us of the proposed enforcement decision which the NRC desires to impose upon our clients. While our clients dispute any liability, it may be more cost effective and/or make more business sense for our clients to agree to a stipulated penalty, in lieu of contesting the NRC's enforcement action

We request that the appropriate NRC representative contact us at your convenience, so arrangements can be made to schedule the pre-decision enforcement conference, and to obtain the requested documents, as well as to discuss a stipulated penalty in lieu of contesting this matter.

Very truly yours,

Gary P. Lightman

GPL:kdt

cc: NRC, Attn: Judith A. Joustra, Sr. Health Physicist
SMI East Coast Medical Waste, Inc.
Attn: Mr. Craig Sanford, President