3/1/92

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
DEPARTMENT OF VETERANS AFFAIRS, MEDICAL CENTER,	)	[MWTA] RCRA Docket No. I-90-1084
	)	
	)	
Respondent	)	

1. Consolidated Rules of Practice - Burden of Proof - Burden of Persuasion - 40 C.F.R. § 22.24: Complainant has the initial burden of establishing a prima facie case, the burden of proof and the ultimate burden of persuasion with respect to violations alleged in a complaint. Once Respondent comes forward with rebutting evidence, the entire record must be evaluated to determine whether Complainant has established by the preponderance of the evidence that Respondent committed the alleged violations.

2. Consolidated Rules of Practice - Preponderance of Evidence - 40 C.F.R. § 22.24: Preponderance of the evidence, with respect to the burden of proof in an administrative action such as this case, means the greater weight of evidence, evidence which is more convincing than the evidence which is offered in opposition to it or such evidence as, when weighed against that opposed to it, has the more convincing force that something is more likely so than not so.

Appearances:

For Complainant:
Douglas Luckerman, Esquire
William L. Parker, Esquire
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For Respondent:
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District Counsel
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Before: Henry B. Frazier, III
Chief Administrative Law Judge

INITIAL DECISION

I. Background - Complaint and Answer:

This proceeding was initiated when an administrative complaint was filed by the U.S. Environmental Protection Agency (EPA, Agency or Complainant) pursuant to Section 11005 of the Solid Waste Disposal Act, as amended by the Medical Waste Tracking Act of 1988 (MWTA or the Act), 42 U.S.C. § 6992d. The complaint alleges that the United States Department of Veterans Affairs Medical Center in West Haven, Connecticut (DVA, Medical Center, facility or Respondent), violated Section 11003 of the MWTA, 42 U.S.C. § 6992b and the regulations promulgated thereunder, 40 C.F.R. Part 259.

More specifically, the complaint alleges that unincinerated regulated medical waste (RMW) was placed outside Respondent's incinerator building on the paved area next to the loading dock in approximately 10 household-type uncovered aluminum trash cans. As a result, Respondent is alleged to have:

i. failed to store RMW in a manner and location that maintains the integrity of the packaging and provides protection from water, rain and wind as required by 40 C.F.R. § 259.42(a);

ii. failed to lock the outdoor storage area containing RMW to prevent unauthorized access as required by 40 C.F.R. § 259.42(c); and

iii. failed to store the RMW in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents as required by 40 C.F.R. § 259.42(e).

EPA seeks an order directing Respondent to comply with the applicable requirements of 40 C.F.R. Part 259. EPA also seeks the payment by Respondent of a civil penalty in the amount of $6,500.00 for the alleged violations based upon the waiver of sovereign immunity found at 42 U.S.C. § 6992e(a).

In answer to the complaint, Respondent denies that any RMW was placed outside of the incinerator building at the Medical Center. Respondent maintains that the material in the uncovered aluminum trash cans was not RMW but was unregulated incinerator ash. The Medical Center also contends that the assessment of a civil penalty is not only unwarranted by the facts in this matter but also is contrary to the EPA's own regulations, in particular, the Federal Facilities Compliance Strategy, commonly known as the "Yellow Book," for which notice was published in the Federal Register.[1]

II. Background - Processing of the Case:

Following unsuccessful attempts by the parties to settle this matter, a hearing was held in Hartford, Connecticut on July 23, 1991. Initial post-hearing submissions were filed by Respondent and Complainant on November 14, 1991 and November 15, 1991, respectively. Replies to these submissions were filed by Respondent on November 27, 1991 and by Complainant on December 16, 1991.

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[1] 53 Fed. Reg. 50568 (November 8, 1988).

III. Discussion, Findings and Conclusions:

The MWTA became law on November 1, 1988. The Act amended the Solid Waste Disposal Act, commonly referred to as the Resource Conservation and Recovery Act (RCRA), to require the Administrator of EPA to promulgate regulations that establish a demonstration tracking system for medical waste. Among other things, the Act was designed to prevent careless management of medical waste by establishing tracking and storage requirements and subjecting violators to administrative (as well as civil and criminal) penalties.[2]

Section 11001 of the Act,[3] describes the geographic scope of the demonstration program; Connecticut is included among the covered states. Section 11003(c) of the Act[4] recognizes that some RMW may be incinerated on site by the generator and, hence, would not be subject to the requirements for tracking RMW from the generator's facility to the disposal facility. Such on-site incinerators are subjected to storage requirements as well as recordkeeping and reporting requirements. Section 11004 of the Act[5] authorizes EPA inspections of any establishment or place where any person, inter alia, generates or disposes of medical waste. Section 11006(a) of the Act[6] subjects Federal Government facilities

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[2]134 Cong. Rec. S15328 (October 7, 1988).

[3]42 U.S.C. § 6992.

[4]42 U.S.C. § 6992b(c).

[5]42 U.S.C. § 6992c.

[6]42 U.S.C. § 6992e(a).

to the requirements of the Act[7] and Section 11006(b) of the Act[8] defines person as including each department, agency and instrumentality of the United States.

EPA has issued regulations, 40 C.F.R. Part 259, to provide standards for the tracking and management of medical waste. The MWTA does not authorize or require EPA to establish regulations that address the actual treatment, destruction, or disposal of RMW.[9] Medical waste is defined in the regulations as "any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or

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[7]Section 11006(a) provides, in pertinent part:

> Each department, agency, and instrumentality of the executive, legislative, and judicial branches of the Federal Government in a demonstration State (1) having jurisdiction over any solid waste management facility or disposal site at which medical waste is disposed of or otherwise handled, or (2) engaged in any activity resulting, or which may result, in the disposal, management, or handling of medical waste shall be subject to, and comply with, all Federal, State, interstate, and local requirements, both substantive and procedural (including any requirement for permits or reporting or any provisions for injunctive relief and such sanctions as may be imposed by a court to enforce such relief), respecting control and abatement of medical waste disposal and management in the same manner, and to the same extent, as any person is subject to such requirements, including the payment of reasonable service charges.

See also, 54 Fed. Reg. 12326, 12364-12365 (March 24, 1989).

[8]42 U.S.C. § 6992e(b).

[9]54 Fed. Reg. at 12357 and 12359.

animals, in research pertaining thereto, or in the production or testing of biologicals."[10] Regulated medical waste (RMW) is a subset of medical waste; it is defined as "those medical wastes that have been listed in § 259.30(a) of this part and that must be managed in accordance with the requirements of this part."[11] Section 259.30(a) lists seven classes of RMW: (1) cultures and stocks; (2) pathological wastes; (3) human blood and blood products; (4) sharps; (5) animal waste; (6) isolation wastes; and (7) unused sharps.

Respondent is a person as defined in the Act and in the course of its operations at the Medical Center generates RMW.[12] Respondent operates an on-site incinerator which is used to incinerate the RMW.[13] The Medical Center is located within a state covered by the MWTA. Respondent is subject to the requirements of the MWTA and to 40 C.F.R. Part 259.[14] Therefore, Respondent is subject to the requirements of 40 C.F.R. § 259.42 which states, in pertinent part:

> Any person who stores regulated medical waste prior to treatment or disposal on-site (e.g., landfill, interment, treatment and destruction, or incineration), or transport off-site, must comply with the following storage requirements:

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[10]40 C.F.R. § 259.10(b); 42 U.S.C. § 1004(40).

[11]40 C.F.R. § 259.10(b).

[12]Complaint at 2-3; Answer at 1.

[13]Complaint at 3; Answer at 1.

[14]Complaint at 3; Answer at 2.

> (a) Store the regulated medical waste in a manner and location that maintains the integrity of the packaging and provides protection from water, rain and wind;
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> * * * * * * *
>
> (c) Lock the outdoor storage areas containing regulated medical waste (e.g., dumpsters, sheds, tractor trailers, or other storage areas) to prevent unauthorized access;
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> * * * * * * *
>
> (e) Store the regulated medical waste in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents.

Respondent is charged with having violated these provisions of the regulations by placing unincinerated RMW outside the incinerator building on the paved area next to the loading dock in approximately 10 household-type uncovered aluminum trash cans.

There is no dispute between the parties that waste was placed outside the incinerator building on the paved area next to the loading dock in approximately 10 household-type uncovered aluminum containers.[15] The only question is whether the waste was RMW or ash remaining after incineration of RMW.

This question is central to the decision in this case because "[a]sh from incineration of regulated medical waste is not regulated medical waste once the incineration process has been completed."[16] In addition, "[r]esidues from treatment and destruction processes are no longer regulated medical waste once

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[15]Complaint at 3-4; Answer at 2-3.

[16]40 C.F.R. § 259.30(b)(1)(iii).

the waste has been both treated and destroyed."[17] Treated regulated medical waste is that which "has been treated to substantially reduce or eliminates [sic] its potential for causing disease, but has not yet been destroyed."[18] Destroyed regulated medical waste is that which "has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as medical waste."[19] EPA recognizes that treatment also includes thermal treatment, such as incineration, because it is generally effective in reducing or eliminating the infectious risk posed by RMW.[20] Indeed "incineration and steam sterilization (autoclaving) are the most common treatment methods for medical wastes."[21] Consequently, the residue remaining following incineration would be excepted from regulation under either exclusion: that for incinerator ash or that for treatment/destruction residue since thermal treatment, such as incineration, is specifically recognized to be both a treatment and a destruction process.

The inspection of Respondent's facility was conducted on August 22, 1989, by two employees of Alliance Technologies Corporation (Alliance) which held a contract with EPA to perform

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[17] 40 C.F.R. § 259.30(b)(1)(iv).

[18] 40 C.F.R. § 259.10.

[19] Id.

[20] 54 Fed. Reg. at 12336.

[21] 54 Fed. Reg. at 12343.

MWTA compliance inspections. The regulations which had been promulgated by EPA pursuant to MWTA had gone into effect exactly two months before the inspection.[22]

Ms. Diane Lazarus, who, at the time of the inspection, was employed as an Environmental Scientist by Alliance and who participated in the inspection of Respondent's facility, testified that she observed some RMW that had not been completely incinerated lying in the ash in approximately ten uncovered aluminum trash cans in the paved area outside of and adjacent to the incinerator building. Specifically, she testified that she saw a portion of a red plastic bag and 3 inch by 4 inch piece of blue adult diaper in one trash can; that she observed a common housefly hovering over this particular trash can. She also testified that she and the other Alliance inspector, Ms. Susan Elliott, identified the exposed regulated medical waste to facility personnel upon discovery of this "noncompliance."[23]

Ms. Lazarus testified that they collected no RMW samples from the outside ash cans because EPA had directed them not to do so "unless it was absolutely necessary" and because it was "more important to take photographs because then we could prove what we saw and where we saw it."[24] However, they took no photographs of the alleged RMW in the outside trash cans because they had used the

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[22]40 C.F.R. § 259.2(a).

[23]Tr. 36-37, 39-40, 58-61; Complainant's Exhibit (Compl. Exh.) 1.

[24]Tr. 59-60.

only remaining frame on the roll in the camera earlier inside the building and had failed to bring an extra roll of film with them.[25]

Mr. William A. Howard, a Senior Sanitary Engineer with the Solid Waste Unit of the Connecticut Department of Environmental Protection who accompanied the two EPA contract inspectors from Alliance as an "observer" for "on-the-job training to become more familiar with the implementation of the regulations promulgated under the Medical Waste Tracking Act"[26] testified that he saw RMW that "did not appear to be completely incinerated"[27] in the incinerator ash stored in "several uncovered metal trash receptacles . . . located outside . . . the . . . incinerator building . . . ."[28] Specifically, Mr. Howard testified he saw some paper and cloth fabric materials and bandage wrapping, the unburned portion of which was tan or brown in color.[29] Mr. Howard testified that he did not observe the piece of red bag or the piece of blue diaper which Ms. Lazarus claims to have seen because he did not look into more than four cans.[30]

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[25]Tr. 59-60. The Alliance inspectors also failed to ask DVA officials whether film was available for purchase at the facility. Film was available for purchase. (Tr. 193-94.)

[26]Tr. 92.

[27]Tr. 89.

[28]Tr. 88; Compl. Exh. 7.

[29]Tr. 88-89, 91; Compl. Exh. 7.

[30]Tr. 92, 95, 101-102.

Witnesses for the Respondent who had accompanied the Alliance personnel during the inspection conceded that RMW which had not been completely incinerated was seen in waste cans on the date of the inspection. However, they insisted that this partially burned RMW was in waste cans inside the incinerator building waiting to be reincinerated.

Mr. Jeremiah Clay, the Chief of Building Management Services at the Medical Center who accompanied the inspectors on their inspection, testified that he observed "a can of charred waste in the center of the incinerator room . . . [containing] a piece of red plastic about two-by-two inches and a piece of burnt paper that appeared . . . charred on the outside edges, or other debris or ash in the can."[31]

Mr. Clay explained that the practice at the Medical Center calls for the incinerator operator to remove the ash from the incinerator each morning prior to beginning the burning cycle. "[A]nything that looks like it hasn't been burned to complete the destruction process in again put into a trash can, and that is fed into the incinerator later on during the day to be re-burned."[32]

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[31]Tr. 184-85.

[32]Tr. 180. Testimony was offered by witnesses on both sides concerning the incinerator and whether it had been operating properly just before the time of the inspection. Although Complainant presented one witness who attempted to establish that both the primary and the secondary temperatures in the incinerator were too low for it to operate properly in the days just before the inspection (Tr. 103-113), Complainant now concedes in its Reply to Respondent's Post-Hearing Brief (December 16, 1991) that "[n]either the allegations nor the penalty contained in EPA's complaint were based on whether the Medical Center's incinerator was malfunctioning" (at 7). Respondent offered a witness,

Four cans are kept inside the building for this purpose.[33] "When it's reduced to ash, it's put into the regular trash cans that are stored outside the building, and they are put outside to cool, and during the night shift the cooled ash is put into the regular dumpster where it again goes to the municipal site where it's re-incinerated for the third time."[34]

Mr. Clay testified that while at the incinerator building, he looked at the outside trash cans from the bay door of the incinerator building and did not see any RMW in them.[35] The bay door is about four and a half feet off the ground and the trash cans are close to the bay door.[36] He further testified that the adult diapers used at the Medical Center were white and not blue, but that some bedspreads may be "bluish" in color.[37] He also testified, in refutation of Mr. Howard's allegation that some unburned brown or tan RMW was found in the ash cans, that no tan or

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Mr. Christian Mainka, who testified that the incinerator itself had been functioning properly and that a temperature indicator must have failed a day or two prior to the inspection (Tr. 157-60). Based upon Mr. Mainka's detailed testimony and his professional education, training, experience and resulting expert knowledge of incinerators, I must credit his testimony.

[33]Tr. 180.

[34]Tr. 181.

[35]Tr. 191, 202-203.

[36]Tr. 191.

[37]Tr. 192.

brown material which would constitute RMW is used at the facility.[38]

Mr. Robert Palazzi, who was Chief of Operations at the Medical Center on the date of the inspection and who also accompanied the inspectors, testified that during the inspection he saw a trash can with a mixture of ash and partially destroyed RMW inside the incinerator building.[39] He also testified that from the loading dock of the incinerator building he had a clear, unobstructed view of all the trash cans and he saw nothing but ash or incinerated material in the cans.[40]

Mr. Stephen Hogel, who was Assistant Chief of Engineering Services at the Medical Center on the date of the inspection, and who also accompanied the inspectors, testified that he saw a piece of red bag in the debris in a trash can inside the incinerator room.[41] Mr. Hogel did not go out and look at the trash cans outside the building. Both Mr. Palazzi and Mr. Hogel confirm Mr. Clay's testimony concerning the facility's practice of retaining partially burned RMW in trash cans inside the incinerator room for reincineration.

In support of the testimony of Ms. Lazarus and Mr. Howard, the Complainant introduced several pieces of documentary evidence. One of these was the EPA Inspection Checklist which was completed

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[38]Id.

[39]Tr. 210.

[40]Tr. 212.

[41]Tr. 229.

during the inspection. The Inspection Checklist was prepared by Ms. Susan Elliott, who at the time of the inspection, was an Environmental Analyst with Alliance. Ms. Elliott completed the Inspection Checklist because she was responsible for asking the questions of the facility personnel during the inspection. This was Ms. Elliott's second inspection under the MWTA and her first as "question asker."[42]

There is no mention in this document, prepared contemporaneously with the inspection, of unincinerated RMW being found outside the incineration building in uncovered waste cans. Although the Inspection Checklist consists of eight (8) parts, Ms. Elliott's report consists only of the first four parts. Among the parts which were not completed were those entitled "Part VII Inspectors Comments" and "Part VIII Inspector's Conclusions and Recommendations." Part VII was not used even though the Checklist itself includes the following explicit instruction: "Inspectors are encouraged to include narrative descriptions where appropriate, particularly in describing violations of the regulations. These comments should be numbered to correspond to Inspection Form question number and may be included in Part VII of this Form. Attach additional sheets if necessary."[43] In explanation for not having complied with these instructions, Ms. Lazarus explained that they "removed the nonapplicable portions of the Inspection

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[42]Tr. 63, 83.

[43]Compl. Exh. 6.

Checklist to save on paper"[44] and consequently "did not [note] in our inspection report--that there was a violation, that there was a potential noncompliance . . . ."[45] She testified that she and Ms. Elliott "may have noted that in our handwritten notes. We noted that in our minds and memory."[46] Ms. Lazarus testified that some notes ("not a lot"), other than those on the Inspection Checklist, were taken during the inspection. However, she testified that the notes no longer exist.[47]

A second exhibit introduced by the Complainant was another document prepared by Ms. Elliott and dated September 5, 1989, some fourteen (14) days after the inspection. That document was the "Compliance Evaluation Inspection Trip Report" and it stated in pertinent part: "The incinerator had not been working properly during the preceding day or two, and some RMW had not been completely incinerated and had to be burned again. The partially burned waste, some of which was recognizable, was left outside in approximately 10 household-type uncovered trash cans."[48]

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[44]Tr. 44. Subsequently, Ms. Lazarus testified that Parts VII and VIII were never attached to the Inspection Checklist which was used during the inspection. (Tr. 70.)

[45]Tr. 45.

[46]Id.

[47]Tr. 42.

[48]Compl. Exh. 4.

Following review of this trip report by the EPA, a second version was prepared by Alliance "in response to EPA comments."[49] This second draft, dated November 3, 1989, was prepared by Ms. Lazarus. Ms. Elliott was no longer available to make revisions to her initial report. According to the testimony of Ms. Arlene Levin, Manager of Health and Environmental Sciences Department at Alliance Technologies Corporation, Ms. Elliott, the "question asker" and preparer of the Inspection Checklist and of the initial trip report, left the employment of Alliance about a month after the inspection because of "a mutual parting of the way" and because "her performance on other work conducted at Alliance was not of the technical quality of insightfulness as required."[50]

Ms. Lazarus' revised trip report of November 3, 1989 stated, in pertinent part: "Because the incinerator had not been operating properly the day or two preceding the inspection, some waste had not been completely incinerated and needed to be burned again. The partially burned waste, some of which was recognizable, was stored outside, exposed to wind, rain, water, and insects, in approximately 10 household-type uncovered aluminum trash cans."[51]

Finally, on July 10, 1990, "in response to further EPA comments," Ms. Lazarus again revised the trip report.[52] The pertinent paragraph was rewritten as follows: "Facility

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[49]Tr. 46.

[50]Tr. 83-84.

[51]Compl. Exh. 3.

[52]Tr. 46.

representatives stated that the incinerator had not been operating properly the day or two preceding the inspection. The inspectors and facility personnel observed some waste that had not been completely incinerated. Facility personnel stated that the ash and waste would be burned again in the on-site incinerator. The inspectors and facility personnel observed that the partially burned waste, some of which was recognizable, was placed outside the incinerator building on the paved area near the loading dock, exposed to wind, rain, water, animals and insects, in approximately 10 household-type uncovered aluminum trash cans. Specifically, the inspectors observed a piece of a red bag and an adult diaper in one trash can. The inspectors also observed a common housefly over this particular trash can. The RMW and ash was not stored in a locked outdoor storage area."[53] Thus, nearly eleven (11) months after the inspection, the "piece of a red bag and an adult diaper in one trash can" together with the "common housefly" are, for the first time, mentioned in the trip report.

The Respondent avers that the "ultimate EPA report citing the DVA for violations was based upon inaccurate information and that the EPA inspectors misremembered where they saw the unincinerated material. In fact, they probably observed the same red bags of [sic] remnants observed by the DVA personnel inside the incinerator building."[54]

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[53]Compl. Exh. 2.

[54]Tr. 25.

In her final (July 10, 1990) version of the trip report[55] Ms. Lazarus also inserted the assertion that both "inspectors and facility personnel observed the partially burned waste, some of which was recognizable" in the trash cans outside the incinerator building. Ms. Lazarus testified that after seeing the RMW in the ash in the outside waste can, she and Ms. Elliott told one or two of the facility personnel at the incinerator building that there was some unburned RMW in the ash.[56] However, she does not remember which of the facility personnel were so informed and she cannot recall any response by the facility personnel who are alleged to have been shown the partially burned RMW.[57]

Mr. Howard testified that he did not discuss partially burned RMW in the outside trash cans with facility personnel at the incinerator building and could not recall whether such a discussion took place between the Alliance representatives and the facility personnel.[58]

Mr. Palazzi and Mr. Hogel did recall a discussion with members of the inspection team about RMW in the trash cans inside the incinerator building.[59] Mr. Clay, Mr. Palazzi and Mr. Hogel testified that there was no discussion during the inspection of RMW

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[55]Compl. Exh. 2.

[56]Tr. 35, 58-59. Compl. Exh. 1.

[57] Tr. 37, 59.

[58]Tr. 92-93, 98.

[59]Tr. 210-11, 229, 232-33.

being in the trash cans outside the incinerator building.[60] Each testified that the only mention of the outside waste cans by Alliance personnel, both at the incinerator building and at the exit interview, was a recommendation that the cans be covered so that the ash would not be exposed to wind and rain and to possible dispersal by the elements.[61] In response to two inquiries by Mr. Clay as to whether this was a recommendation or a requirement the Alliance inspectors replied that it was a recommendation.[62] Mr. Howard corroborated their testimony that at the exit interview the Alliance inspectors simply made a recommendation that the outside trash cans be covered.[63]

Each of the three witnesses from the Medical Center who had accompanied Ms. Lazarus on the inspection testified that at the exit interview the Alliance inspectors told them that everything seemed to be fine and the only recommendation that they had was to put covers on the outside ash cans.[64] Nothing was said about partially incinerated RMW.[65] Mr. Howard corroborated their description of the exit interview, testifying that at the exit interview the Alliance personnel told the Medical Center personnel

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[60]Tr. 190, 211, 231.

[61]Tr. 185, 190-91, 193, 211-12, 229-31.

[62]Tr. 185, 193.

[63]Tr. 99-100.

[64]Tr. 185, 193, 212, 231.

[65]Tr. 193, 232.

that "[o]verall, the facility was doing well"[66] and "they were in substantial compliance."[67] He further testified, that "[w]hat was brought to the attention of the facility personnel at the exit interview was the uncovered trash cans and the suggestion or recommendation that they be covered to prevent them from being exposed to the elements, primarily."[68]

Although Ms. Lazarus insisted that she recalled seeing a piece of red bag and a blue adult diaper in the trash cans outside, and not inside the incinerator building, she was unable to recall the specifics of the exit interview. Her vague and somewhat evasive description of the exit interview on cross-examination follows:

> Q. Do you remember the conversation at the exit interview?
>
> A. I do not recall the specific conversation.
>
> Q. Do you have any idea what you were asked; what would people normally ask you at the time?
>
> A. Most people ask, "How are we doing? How do things look?"
>
> Q. Were you asked questions like that?
>
> A. Probably.
>
> Q. And what did you say?
>
> A. We probably told them that everything looked fine and that they should cover the ash out in the -- out by the incinerator building.
>
> Q. Why did you tell them to cover the ash?

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[66]Tr. 93.

[67]Id.

[68]Tr. 99. See also, Tr. 93, 100.

A. It was exposed regulated medical waste.

Q. Would that have been sufficient because it was exposed regulated medical waste that you told them to cover the ash; you just said to cover the ash?

A. They should have covered the regulated medical waste and the ash that was exposed to the wind, water, rain.

Q. Would that be sufficient coverage?

A. Regulated medical waste that was stored is also required to be locked and protected from elements, protected from non-authorized personnel.

Q. Did you tell the VA personnel that that area should be locked?

A. I don't know. I do not recall if I told them that or not.

I find Ms. Lazarus' description of events on the day of the inspection implausible and credit the testimony of other witnesses to the effect that none of the Medical Center personnel saw or were shown partially burned RMW in open waste cans outside the incinerator building. Further, if as Ms. Lazarus testified, this "potential noncompliance" was seen by her and brought to the attention of facility personnel at the site during the inspection, it is implausible that at the exit interview the inspectors would have told the facility personnel that everything was fine and that they only recommended that the outside ash cans be covered. While contract inspectors such as Ms. Lazarus, may be "without authority to make a final determination of violation or to issue compliance

orders,"[69] that is not to say that she was without authority to identify a "potential noncompliance," to use her phrase. Regardless of Ms. Lazarus' authority or her obligation toward Respondent at the exit interview, to have previously identified a "potential noncompliance" on site during the inspection as she testified, and then inform the DVA personnel that everything looked fine at the exit interview is indeed incredulous. Even Ms. Lazarus had testified that the inspectors would discuss "any potential noncompliances that we found" with facility personnel at the exit interview.[70]

In contrast to Ms. Lazarus' testimony, which was often vague and evasive and at times somewhat incredible, I found the testimony of the Medical Center personnel, on the whole, to be direct, forthright and credible.

The doubtful accuracy and questionable reliability of the inspection trip report prepared by the contract inspectors is further evidenced by the content of section "F. MWTA Tracking Form" which alleged that:

> The inspector reviewed a copy of Tracking Form number 1212 which showed that the Medical Center had offered 727 pounds (22 containers) of RMW for transport off-site to Browning Ferris Industries of Connecticut on June 27, 1989. The Tracking Form was signed by the generator and transporter. The Medical Center had not received a copy of the Tracking Form signed by the destination facility. Mr. Clay stated that he was aware of the exception

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[69]Complainant's Reply to Respondent's Post-hearing Brief (December 16, 1991) at 6.

[70]Tr. 34.

> reporting requirements if he did not receive the completed original tracking form back from the destination facility within 35 days of the date the waste was accepted by the initial transporter.
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> The inspector, Ms. Lazarus, called Mr. Clay on November 3, 1989 to ask if he had received the original tracking form back from the destination facility for the June 27, 1989 shipment, Tracking Form number 1212. Mr. Clay said he did not have it in his files. Ms. Lazarus reminded him of the exception reporting requirements. The facility has not submitted an exception report for Tracking Form number 1212 to the CT DEP or the EPA Regional Administrator.[71]

In truth, contrary to Alliance's trip inspection report, there was no Tracking Form dated June 27, 1989, in the files of Respondent. There was a Medical Waste Tracking Form number 001212 for 727 pounds of RMW signed by the representative of the generator and by a representative of the transporter, Browning-Ferris Industries of Connecticut on July 26, 1989.[72] This form had been signed by a representative of the destination facility, Merrimack Valley Medical Services Company, on July 27, 1989.[73]

The Medical Waste Tracking Form consists of five (5) copies; copy 1 is a white copy which is mailed by the destination facility to the generator and copy 4 is a pink copy which is retained by the generator upon shipment.[74] While copy 1, which had been duly signed by representatives of the generator, the transporter and the

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[71]Compl. Exh. 2.

[72]Resp. Exh. 1.

[73]Id., Tr. 52.

[74]Resp. Exh. 1.

destination facility was in Respondent's file, copy 4 was missing. Prior to the inspection, Mr. Clay made a second copy from copy 1 and marked it "Pink Lost, not in file J. Clay"[75] as a replacement for the missing copy 4. During the inspection Mr. Clay explained this to the Alliance personnel.[76]

Based upon the Alliance submissions, EPA continued to pursue the elusive original tracking form for the nonexistent shipment of June 27, 1989, because such a form was required to be returned to the Medical Center by the destination facility. In July 1990 the Medical Center sent a copy of the July 26, 1989, form to EPA. Thereafter, in August 1990 the complaint was issued; the complaint did not allege a violation in regard to the medical waste tracking form requirements.

During cross-examination concerning this error in the trip inspection report, Ms. Lazarus stated that she did "not recall which tracking form . . . [she] saw" during the inspection;[77] that she did "not remember if . . . [she] even requested a copy of the tracking form during the inspection;"[78] that she did not remember the conversation with Mr. Clay on November 3, 1989, which is first described by Ms. Lazarus in her own initial version of the trip inspection report on that date;[79] and that she did "not recall

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[75]Tr. 187-88; Resp. Exh. 1.

[76]Tr. 188.

[77]Tr. 52.

[78]Tr. 54.

[79]Tr. 55; Compl. Exh. 3.

being shown the correct form."[80] Ms. Lazarus' memory and ability to recall matters pertaining to the tracking form proved to be unreliable. Indeed, I seriously question the reliability of Ms. Lazarus' memory concerning the entire inspection.

The question of whether the Respondent placed RMW in uncovered trash containers outside must be resolved in accordance with the provisions of 40 C.F.R. § 22.24 which provides:

> The complainant has the burden of going forward with and of proving that the violation occurred as set forth in the complaint and that the proposed civil penalty, revocation, or suspension, as the case may be, is appropriate. Following the establishment of a prima facie case, respondent shall have the burden of presenting and of going forward with any defense to the allegations set forth in the complaint. Each matter of controversy shall be determined by the Presiding Officer upon a preponderance of the evidence.

Thus, Complainant's case rests on its establishing by the preponderance of evidence that Respondent violated the regulations as alleged. The testimony of Ms. Lazarus and Mr. Howard, standing alone, establishes a prima facie case in that the reasonable inference to be drawn is that the uncovered waste cans outside the incinerator building contained partially burned or partially destroyed RMW. The burden which then shifts to the Respondent after the establishment of the prima facie case is the burden of coming forward with some credible evidence to rebut this inference. Just as the Complainant has the initial burden of establishing a prima facie case, the Complainant has at the outset, and retains

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[80]Tr. 57.

throughout, the burden of proof and the ultimate burden of persuasion with respect to the violations alleged in the complaint.[81] The burden of persuasion does not shift after the Complainant for its case-in-chief has made a prima facie case by producing sufficient evidence to warrant a judgment in its favor and the Respondent has come forward to offer evidence to explain or rebut Complainant's evidence. Once the Respondent has come forward with rebutting evidence, as it did here, the entire record must be evaluated to determine whether Complainant has established by the preponderance of the evidence that Respondent violated the regulations as alleged.

"Preponderance of the evidence, with respect to the burden of proof in civil or administrative actions such as this one, means the greater weight of evidence, evidence which is more convincing than the evidence which is offered in opposition of it."[82] For example, a preponderance of the evidence has been defined by one Federal agency as: "That degree of relevant evidence which a reasonable mind, considering the record as a whole, might accept as sufficient to support a conclusion that the matter asserted is more likely to be true than not true."[83] Or a preponderance of the evidence means, "such evidence as, when weighed against that

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[81]Jackson v. Veterans Admin., 768 F.2d 1325, 1329 (Fed. Cir. 1985).

[82]Hale v. Dept. of Transp., F.A.A., 772 F.2d 882, 885 (Fed. Cir. 1985).

[83]5 C.F.R. § 1201.56(c)(2).

opposed to it, has the more convincing force that something is more likely so than not so."[84]

I conclude that the violations alleged in the complaint are not supported by the requisite preponderant evidence. This conclusion is based upon the demeanor of the witnesses, their credibility and the content and reliability of their testimony and the documentary evidence which was introduced into the record.

Considering the record as a whole, I conclude that Complainant's evidence, when weighed against Respondent's evidence, does not possess that convincing force that it is more likely that Respondent committed the violations as alleged than Respondent did not do so. In other words, Complainant's evidence is not more convincing than Respondent's evidence. I find, therefore, that Complainant has not sustained its burden and that the complaint should be dismissed.

ORDER

It is hereby ordered that the complaint in this proceeding be dismissed.

Henry B. Frazier, III
Chief Administrative Law Judge

Dated: March 11, 1992
Washington, DC

[84]Hopkins v. Price Waterhouse, 737 F. Supp. 1202, 1204 n. 3 (D.D.C. 1990).