

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 Post Office Square, Suite 100
Boston, MA 02109-3912

February 1, 2012

Lynn A. Shea, R.Ph.
Pharmacist, IV Service
Pharmacy Services
The Miriam Hospital
164 Summit Ave.
Providence RI 02906

Re: Inquiry regarding satellite accumulation in hospital patient rooms

Dear Ms. Shea:

Thank you for your recent inquiry regarding the management of pharmaceutical hazardous wastes generated in hospital patient rooms. This correspondence addresses the question you raise in your email to Janet Bowen dated November 29, 2011 asking if hospital patient rooms can be used as satellite accumulation areas for pharmaceutical hazardous wastes if the containers used in the collection of such waste are locked and mailbox-type design that would prevent hand access. As your request relates to Resource Conservation and Recovery Act (RCRA) regulatory policy, it has been forwarded to my office for response.

As background, the federal satellite accumulation area provisions at 40 CFR 262.34(c) and the analogous state requirements of the Rhode Island Department of Environmental Management (RIDEM), Rules and Regulations for Hazardous Waste Management, Section 2.2 (incorporating federal regulations by reference) and Section 3.0 (definition of "satellite accumulation" including regulatory citations referenced therein) allow large and small quantity generators of hazardous waste to accumulate up to 55 gallons of hazardous waste (or 1 quart of acutely hazardous waste) in containers that are (1) at or near each point of generation where wastes initially accumulate which is (2) under the control of the operator/key staff individual responsible for the process generating the waste, so long as (3) the generator complies with certain container management standards and marking/labeling requirements. Within 3 days of satellite accumulation limits being met, the wastes must be managed in compliance with applicable central storage accumulation area requirements and are typically removed from the satellite accumulation area and brought directly to the central storage area(s).

Note that the RIDEM satellite provisions are more stringent than the federal provisions in that they have additional container marking/labeling requirements in section 5.4.C of RI's hazardous waste regulations. In addition, RI's hazardous waste regulations do not provide an exemption for conditionally exempt small quantity generators as does the federal requirement at 40 CFR 261.5; see section 5.0 Generators of RI's hazardous waste regulations. Thus, in Rhode Island the same regulations generally apply to all generators, even those generating only small quantities of hazardous waste.

In a recent regulatory interpretation by Region 1, EPA stated that hospital patient rooms should not be used as satellite accumulation areas for hazardous wastes since the waste would not be under the control of the operator (e.g., nurses) at all times, a key condition which defines a satellite area. Due to concerns of possible patient/visitor contact with such wastes, we also recommended that these wastes should be managed in nearby secure (locked) satellite storage areas that are typically established in each hospital medical unit and within large units on each floor, as described in a May 2, 2007 guidance document issued by the Massachusetts Department of Environmental Protection. (See T. Dresser regulatory interpretation dated February 24, 2011 and related MassDEP May 2, 2007 guidance document, attached). In addressing EPA's concern, you present an alternative scenario in which the collection and management of pharmaceutical hazardous wastes within patient rooms would occur in locked, mailbox-type units (designed to prevent hand access) and thus suggest that these specially designed locking containers could satisfy the key condition which defines a satellite accumulation area, i.e., that hazardous waste be "under control of the operator." (See 40 CFR 262.34(c).)

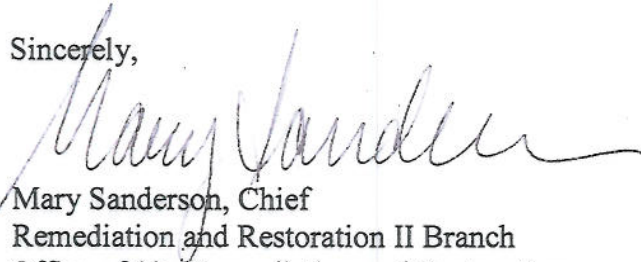
After consideration of the scenario you describe, EPA believes that your proposal to use locked, specially designed mailbox-type units to manage hazardous waste in hospital patient rooms as a satellite accumulation area would generally meet the intent of the satellite requirement that hazardous wastes be under control of the operator. In addition to using these specially designed locking containers, we believe an additional protocol is needed to be fully protective of public health and the environment and to meet the intent of the regulations while managing hazardous wastes in satellite accumulation areas within patient rooms. This protocol should include items, such as, (1) containers must be locked when not in use or when the operator (e.g., attending nurse) is not within the line of sight of such containers; (2) containers must be secured (e.g., mounted to a wall, preferably in an out-of-the-way place) to prevent unauthorized access/accidental spillage of its contents or unauthorized removal of the container; (3) incompatible wastes must be managed in separate containers to avoid potential harmful consequences (e.g., heat, pressure, fire/explosion, violent reaction, toxic gases, or flammable gases), etc.

In summary, with regard to the scenario you present as described above, i.e., using locked, secured, specially designed mailbox-type units for the collection of pharmaceutical hazardous wastes in patient rooms, we believe that the patient rooms would be a suitable satellite accumulation area only if managed in accordance with the safe waste management protocol enumerated above and in compliance with the applicable state hazardous waste regulations.

Pursuant to RCRA section 3006, EPA Region 1 has authorized the RIDEM's hazardous waste program. Under this authorization, the state program provisions are in effect and enforceable by RIDEM as well as EPA. The regulations applicable to the hospital are part of the Rhode Island authorized state program. We therefore have consulted with the RIDEM to ensure that there is consistency between the EPA and the State in the interpretation of the regulations, and RIDEM concurs with this approach.

If you have any questions with regard to this regulatory interpretation, please contact Robin Biscaia of our RCRA Waste Management and UST Section at 617-918-1642.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary Sanderson", written in black ink.

Mary Sanderson, Chief
Remediation and Restoration II Branch
Office of Site Remediation and Restoration

Attachments

cc: Mark Dennen, RIDEM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Region 1

5 Post Office Square, Suite 100
BOSTON, MA 02109-3912

February 24, 2011

Mr. H. Todd Dresser, CHMM
Senior Environmental Consultant
Mabbett & Associates, Inc.
Environmental Consultants and Engineers
Corporate Offices
5 Alfred Circle
Bedford, MA 01730-2318

Re: Satellite Accumulation in Hospitals Inquiry

Dear Mr. Dresser:

Thank you for your recent inquiry regarding the proper management of pharmaceutical hazardous wastes generated in a hospital setting. This correspondence addresses questions you raised in your email to Janet Bowen dated November 30, 2010 regarding satellite accumulation areas. As your request relates to Resource Conservation and Recovery Act (RCRA) regulatory policy, it has been forwarded to my office for response. Specifically, the scenario you describe involves the collection and management of pharmaceutical hazardous wastes in sealed plastic containers that currently are being stored in patient rooms or treatment areas. These wastes typically include used IV bags, used injection vials, and plastic and glass bottles which contain residual material after administering dosages to patients.

EPA has issued a proposed rule on the management of hazardous pharmaceutical wastes applicable to hospitals on December 2, 2008 (73 FR 73520). Currently, the Agency is evaluating options to move forward, but that rule has not yet been finalized. Our response below thus reflects our regulatory interpretation of how the current full RCRA requirements apply to the particular situation outlined above.

The federal satellite accumulation area provisions at 40 CFR 262.34(c), and analogous state requirements of Massachusetts Department of Environmental Protection (MassDEP) at 310 CMR 30.340(6) and 310 CMR 30.351(4), allow large and small quantity generators of hazardous waste to accumulate up to 55 gallons of hazardous waste (or 1 quart of acute hazardous waste) in containers that are (1) at or near each point of generation where wastes initially accumulate that are (2) under the control of the operator/key staff individual responsible for the process generating the waste, so long as (3) the generator complies with certain container management standards and marking and/or labeling requirements, including weekly inspections. (Note, the MassDEP's satellite provisions are more stringent than the federal provisions as is the fact that Massachusetts has additional similar satellite accumulation requirements for conditionally exempt small quantity generators (CESQGs) which MassDEP refers to as very small quantity generators (VSQGs) at 310 30.353(6)(i). MassDEP requirements also prohibit VSQGs from generating or accumulating acute hazardous wastes at 310 CMR 30.352, resulting in any entity accumulating such wastes needing to be regulated as a LQG or SQG).

In the scenario described above, we believe that the patient rooms and treatment areas which are often left unattended and not within sight of the key person responsible for maintaining control over that waste would have difficulty meeting the specified condition which defines a satellite accumulation area. Having unattended hazardous waste in these areas raises the concern that persons other than those trained and familiar with the nature of the hazardous wastes, i.e., patients or their visitors, possibly children, could potentially come into contact with these wastes. Therefore, to reduce the risk of potential unwanted exposure to hazardous wastes, we recommend that wastes generated in these areas be brought to an appropriate nearby satellite storage areas upon generation. Secured (locked) satellite areas may be established in each hospital medical unit, and within large units on each floor, as described in the attached Mass DEP regulatory interpretation dated May 2, 2007.

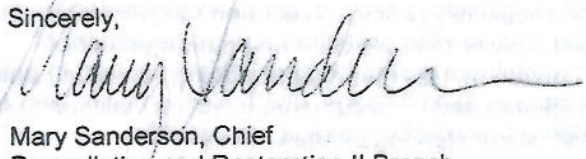
We understand the hospital's concern that having to move wastes to secure satellite areas takes time and staff resources, but we believe that the need to ensure safe handling of the wastes outweighs this concern. Any burden can be reduced by establishing multiple nearby secure satellite areas in accordance with the MassDEP guidance cited above. The practice of storing hazardous wastes in patient rooms and treatment areas without complying with the satellite management, labeling and inspection requirements is not allowed. Also, given the absence of the required continuous control by the key staff individual responsible for generating waste in a satellite area, it would be difficult for these areas to meet the conditions which define a satellite storage area. Therefore, we would not recommend hazardous wastes be managed within patient rooms and treatment areas as satellite storage areas.

Pursuant to RCRA section 3006, EPA Region 1 has authorized the MassDEP's hazardous waste program. Under this authorization the state program provisions are in effect and enforceable by MassDEP as well as EPA. The regulations applicable to the hospital are part of the Massachusetts authorized state program. We therefore have consulted with the MassDEP to ensure that there is consistency between the EPA and the State in the interpretation of the regulations.

If you have any questions with regard to this regulatory interpretation, please contact Robin Biscaia of our RCRA Waste Management and UST Section at 617-918-1642.

Thank you.

Sincerely,



Mary Sanderson, Chief
Remediation and Restoration II Branch
Office of Site Remediation and Restoration (OSRR)

Attachment

cc: James Paterson, MassDEP



COMMONWEALTH OF MASSACHUSETTS
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Secretary

ARLEEN O'DONNELL
Commissioner

May 2, 2007

Paul Hartman
Vice President
Environmental Safety & Health
Stericycle, Inc.
369 Park East Drive
Woonsocket, RI 02895

Dear Mr. Hartman,

As follow-up to our meeting on April 18, 2007, this letter provides clarification on the applicability of the satellite accumulation provisions of 310 CMR 30.000 to listed or characteristic pharmaceutical wastes ("hazardous pharmaceutical waste") generated in a hospital.

Regarding the issue of placing multiple, small containers of hazardous pharmaceutical waste into a single 17-gallon satellite accumulation container for each hospital unit, MassDEP would consider the 17-gallon container a single container. Therefore, having more than one small container of the same pharmaceutical waste in the satellite container would not conflict with the "one container per waste stream" provision described at 310 CMR 30.340(6)(c). The generator must label the 17-gallon satellite container, "Hazardous Waste" and "Waste Pharmaceuticals," and ensure that incompatible wastes are managed in separate containers [see 310 CMR 30.688(4)].

With respect to labeling the satellite accumulation container with the names of the specific hazardous wastes in the container and their associated hazards, the key staff individuals responsible for providing 24-hour oversight of the accumulation area may use a log securely attached to the satellite container at all times instead of a label to describe the specific contents of the container. The log would need to list the names of the pharmaceutical wastes inside and their associated hazards. Since there are so many different types of hazardous pharmaceutical wastes in a hospital, the log could list just the hazardous pharmaceutical waste generated in that unit of the hospital (e.g. the oncology unit or dialysis unit) with their associated hazards. As each waste is added to the container, the key staff individual could check off the applicable waste pharmaceutical and its associated hazards on the log until the container is moved to the central hazardous waste accumulation area for sorting and shipping.

This information is available in alternate format. Call Donald M. Gomes, ADA Coordinator at 617-556-1057. TDD Service - 1-800-298-2207.

MassDEP on the World Wide Web: <http://www.mass.gov/dep>

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Please note that if a medical unit is especially large and, for example, occupies several floors, then additional satellite accumulation areas (SAA) may need to be set up in order to ensure that each SAA is at or near the point of waste generation and is conveniently accessible to the key staff individuals. Each 17-gallon satellite container must be moved from its SAA to the central accumulation area as quickly as possible within three days of the date the container becomes full and cannot be stored at some intermediate location.

As we discussed, if the satellite container is in a room that is not within the line of sight of the key staff individual, the room would have to be locked except when access to the satellite accumulation area is required. Also, hazardous pharmaceutical waste must be shipped off-site by a licensed transporter on a manifest to a licensed hazardous waste storage, treatment or disposal facility. If Stericycle chooses to transport this waste stream itself, it must obtain a hazardous waste transporter's license before doing so.

Finally, please note that this guidance applies to the satellite accumulation requirements cited in 310 CMR 30.340, 30.351 and 30.353 for Large, Small and Very Small Quantity Generators, respectively.

If you have any additional questions, please contact me at 617.556.1096.

Sincerely,



James Paterson
Business Compliance Division
Bureau of Waste Prevention

cc: William Sirull, DEP Boston
James Miller, Boston
✓ Jeff Fowley, US EPA
Ernie Waterman, US EPA
John Kronopolus, MassDEP
John Downes, MassDEP
Gregg Hunt, MassDEP
Ed Pawlowski, MassDEP
Saadi Motamedi, MassDEP