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HEALTH

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To: Hospitals and Clinical Laboratories

From: New York State Department of Health (NYSDOH)

The Center for Disease Control (CDC) and Department of Transportation (DOT) recently provided guidance to hospitals and healthcare providers with information about the safe handling, disposal and transportation of medical waste generated from the care of persons diagnosed with or suspected of having Ebola virus disease (EVD). The New York State Department of Health (NYSDOH) is distributing this notice to remind facilities of New York State requirements for regulated medical waste (RMW) and requirements for autoclaves used to treat RMW.

Requirements for RMW are described in Part 70 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (10 NYCRR Part 70). These regulations apply to hospitals, residential health care facilities, diagnostic and treatment centers and clinical laboratories. Subpart 70-3 of these regulations describes requirements for autoclaves used to treat RMW. Pursuant to these regulations, before using an autoclave to treat RMW, a facility must perform validation testing that demonstrates that an autoclave can effectively treat RMW at the site where the autoclave is installed. Further, the facility must request and obtain NYSDOH approval for such. The request for approval must include an operation plan that includes the results of the validation testing.

The enclosed document has been prepared to assist facilities seeking to obtain approval to use an autoclave to treat RMW and describes the requirements that must be met. If your facility is currently approved by NYSDOH to use an autoclave to treat RMW, please review the enclosed document and your current policies and procedures for the use of autoclaves to ensure that autoclave operation is properly monitored.

For additional information regarding this document, please contact the NYSDOH's Regulated Medical Waste Program by email at rmwp@health.ny.gov, or by phone at (518) 402-4781.

Useful Documents

New York State Department of Environmental Conservation New York State Ebola Waste Disposal Fact Sheet:
http://www.dec.ny.gov/chemical/99119.html

Center for Disease Control Ebola Medical Waste Management:
http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html

Department of Transportation Guidance for Transporting Ebola Contaminated Items, A Category A Infectious Substance:
http://phmsa.dot.gov/portal/site/PHMSA/menuitem.6f23687cf7b00b0f22e4c6962d9c8789/?vgnextoid=4d1800e36b978410VgnVCM100000d2c97898RCRD&vgnextchannel=d248724dd7d6c010VgnVCM10000080e8a8c0RCRD&vgnext

10 NYCRR § 70 Regulated Medical Waste:
http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c004a59f3?OpenDocument&Highlight=0,70

Requirements for Autoclaves Used to Treat Regulated Medical Waste

Requirements for regulated medical waste (RMW) are described in Part 70 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (10 NYCRR Part 70). These regulations apply to hospitals, residential health care facilities, diagnostic and treatment centers and clinical laboratories. Subpart 70-3 of these regulations describes requirements for autoclaves used to treat RMW. This document describes requirements that need to be met before a facility can use an autoclave to treat RMW. Department of Health (DOH) regulations relating to regulated medical waste may be found at: http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c004a59f3?OpenDocument&Highlight=0,70

Autoclave Operation Plan

Prior to using an autoclave, the facility seeking to operate the autoclave must submit an operation plan to NYSDOH for review and approval. The goal of the operation plan is to ensure the safe and effective operation of the autoclave. The operation plan must include all of the following information:

1. Provide the name and address of the facility seeking approval and contact information for the individual(s) that is authorized to communicate with DOH. Please include the contact's name, email, phone number and fax number.

2. A description of the validation testing protocol that was used to demonstrate that the autoclave can effectively treat RMW and a summary of the supporting data from a study that demonstrates its effectiveness. Additional guidance on validation testing is provided below.

3. Procedures that describe how the facility will ensure that appropriate types of waste are being treated. Only those types of waste that have been evaluated by validation testing can be treated. As described in 10 NYCRR § 70-2.3(b), autoclaves cannot be used to treat RMW containing hazardous waste, toxic drug waste, radiological waste or recognizable human body parts.

4. Procedures that describe how the facility will ensure that each load of RMW is treated using the appropriate time, temperature and pressure, and how this information will be documented.

5. Procedures that describe how the facility will monitor the operation of the autoclave to ensure that the autoclave is effectively treating RMW. Procedures should include the frequency of preventative maintenance that is performed on engineering and electronic controls and the monitoring of autoclave operations through the use of parametric controls or challenge testing. Additional guidance on the monitoring of autoclave operations using parametric controls and challenge testing is provided below.

6. Safety procedures that describe how occupational exposure is minimized and physical injury to operators is prevented during the loading, the cycle, and unloading of the autoclave.

7. Procedures that describe training programs for staff operating the autoclave. Procedures must reflect initial and annual retraining on how to operate the autoclave, and training on emergency procedures for handling malfunctioning systems and untreated waste.

Validation Testing

Prior to using an autoclave to treat RMW, validation testing must be performed to demonstrate, under pre-established operating parameters, that an autoclave can effectively treat RMW at the site where the autoclave is installed. Surrogate waste loads, consisting of non-infectious waste that would normally be found in the facilities waste stream, must be autoclaved in the presence of biological and thermal indicators. Effectiveness of the autoclave is demonstrated by showing that the treatment protocol effectively kills bacterial spores within the biological indicators. To demonstrate reproducibility, a minimum of three separate runs (preferably run on separate days) using three distinct loads must be performed. The protocol used for validation testing, and supporting data demonstrating that the autoclave effectively treats RMW, must be submitted to NYSDOH for review and approval.

The following information must be included as part of the validation testing study:

1. A description of the surrogate waste load.

Surrogate waste loads are non-infectious loads consisting of material that would normally be found in the facilities RMW stream. The waste load composition should be documented, including relative percentages of inorganic to organic and fluid to solid components, and a relative breakdown of solid components such as blood culture bottles, plastics (including suction canisters), microbiological waste, and sharps. Ideally, the surrogate waste load should be the worst case scenario of the most difficult waste to treat.

2. Verification that the surrogate loads are equal to the autoclave's treatment capacity.

Validation testing must be performed at the autoclave's full capacity. For example, if the autoclave manufacturer claims the model undergoing validation has the capacity to treat 200 lbs. of medical waste per cycle, then validation testing must be conducted with a surrogate load consisting of 200 lbs. The method used to determine the weight of the surrogate load must also be described and documented.

3. A description of the biological indicators used in the validation testing and the procedures that were used to determine effective treatment.

10 NYCRR 70-3.1 requires that validation testing be performed using spores of *Geobacillus stearothermophilus* at a minimum concentration of 6 log 10 spores per biological indicator. Effective treatment is demonstrated by a 4 log 10 reduction of viable *Geobacillus stearothermophilus* spore concentration after autoclaving.

Two types of biological indicators are commercially available including spore strips and self-contained biological indicators.

<u>Spore strips</u>

Spore strips consist of friable material inoculated with bacterial spores. Spore strips are placed into the surrogate load and autoclaved. The spore strips are retrieved from the treated surrogate load. To determine if there was a 4 log 10 reduction of viable *Geobacillus stearothermophilus* spore, treated and untreated spore strips (from the same manufacturer lot as the treated spore strips) are cultured for a minimum of five days and bacterial growth quantitated.

If spore strips are used for validation testing, the following information must be included:

- Name of the manufacturer
- Product name and copy of the package insert
- Documentation that the spore strip contains at least 6 log 10 spores per indicator
- Steps that will be taken to ensure proper storage
- Steps that will be taken to monitor expiration dates
- Evidence that the same lot numbers were used to evaluate each run
- The expiration dates of indicators used
- Procedures used to quantitate bacterial growth and determine 4 log 10 reduction of viable spores
- Name and address of the laboratory conducting the quantitative analyses, as well as an attestation from the analyst or supervisor of the laboratory that a 4-log reduction was achieved based on an incubation period of 5 days.

Self-contained biological indicators

Self-contained biological indicators consist of a sealed ampoule containing bacterial spores, growth medium and a growth indicator. The self-contained biological indicators are placed into the surrogate load, autoclaved and the indicators retrieved from the treated surrogate load. After autoclaving, treated and untreated indicators (from the same manufacturer lot as the treated indicator) are crushed to expose the spore to the culture media, incubated as instructed by the manufacturer and the indicator used to determine the presence or absence of bacterial growth. Effective treatment is demonstrated by growth in the untreated indicator and no growth in the treated indicator. Facilities using self-contained biological indicators for validation testing must provide documentation from the manufacturer that lack of growth in the autoclaved indicator corresponds to a 4 log 10 reduction of viable *Geobacillus stearothermophilus* spores.

If self-contained biological indicators are used for validation testing, the following information must be included:

- Name of the manufacturer
- Product name and copy of the package insert
- Documentation that the indicator contains at least 6 log 10 spores per indicator
- Steps that will be taken to ensure proper storage
- Steps that will be taken to monitor expiration dates
- Documentation from the manufacturer that lack of growth in the autoclaved indicator corresponds to a 4 log 10 reduction of viable spores
- Evidence that the same lot numbers were used to evaluate each run
- The expiration dates of indicators used
- Procedures used to determine 4 log 10 reduction of viable spores

4. The name and manufacturer of thermal indicators used in the validation testing.

Thermal indicators contain heat sensitive inks that change color when exposed to high temperature over time.

5. A description of the number of biological and thermal indicators used for each run of the validation testing.

The number of indicators used when autoclaving the surrogate load is dependent on the maximum capacity of the autoclave. The number of indicators to be used for each run can be determined by referring to the following chart:

Weight of Surrogate Load (lbs)	# of Treated Biological Indicators	# of Treated Thermal Indicators	# of Untreated Biological Indicators
0-110	4	4	2
111-550	6	6	2
551-1100	8	8	4
1101-1650	10	10	6
>1650	≥12	≥12	≥12

As indicated above, a minimum of three separate runs (preferably run on separate days) using three distinct loads must be performed to demonstrate reproducibility. The numbers in the table represent the number of indicators used per run.

6. A description of how the biological indicators are packaged.
Biological indicators must be packaged in manner that maintains the integrity of the indicator unit during validation testing. Indicators may be wrapped in a paper towel and encased in cotton batting before placement into the package to be treated with the surrogate waste. Materials used to hold the indicator units should be similar to the waste to be treated, provide effective protection from breakage, or otherwise being compromised and be easily retrievable/recoverable at the end of the validation run. Note that metal containers are not recommended for containment of indicators, because steel conducts heat and, as a result, may produce erroneous results.

7. A description of the placement of biological and thermal indicators.
Include a narrative or drawing describing the location of each biological and thermal indicators within the surrogate load and autoclave chamber relative to the location of the coldest spot in the chamber (as identified by the manufacturer) and the location of internal temperature measurement devices.

- For a static autoclave (i.e., the load does not move during the cycle), the location of each indicator pack must be recorded before running through a cycle.
- For a rotary autoclave (i.e., the load is mixed during treatment), the final location of indicators must be recorded and a protocol for their safe retrieval must be included.

8. A description of the autoclave operating parameters used for validation testing.

- Include the temperature (degrees Centigrade), the pressure (psig) and time (minutes of residence time for the entire cycle). The operating parameters used for validation testing must be those that the facility intends to operate the autoclave unit. If parameters are <u>greater than</u> the generally accepted parameters (see below), provide an explanation of why those parameters were selected.
- Include a description of procedures for monitoring accuracy of parametric devices' settings during validation runs to ensure that gauge or electronic read-out (e.g., use of thermocouples) is a true reflection of conditions inside autoclave chamber.
- For vacuum autoclaves, include the number of times the systems air was fully evacuated by pre-vacuum prior to each validation run.

<u>Generally Accepted Operating Parameters</u>
10 NYCRR 70-3.3 describes the generally accepted operating parameters for gravity-feed and vacuum-displacement autoclaves.

Gravity-feed autoclaves:

- at least sixty (60) minutes residence time at a temperature at least one hundred twenty-one (121) degrees Celsius and a pressure of fifteen pounds per square inch (15 psig)

-OR-

- at least forty-five (45) minutes residence time at a temperature at least one hundred thirty-five (135) degrees Celsius and a pressure of thirty-one pounds per square inch (31 psig).

Vacuum-displacement autoclaves:

- at least forty-five (45) minutes residence time at a temperature at least one hundred twenty-one (121) degrees Celsius and a pressure of fifteen pounds per square inch (15 psig)

-OR-

- at least thirty (30) minutes residence time at a temperature at least one hundred thirty-five (135) degrees Celsius and a pressure of thirty-one pounds per square inch (31 psig).

9. A description of the validation testing results including a summary of the data generated demonstrating that the proposed treatment protocols will effectively treat the RMW generated by your facility.

Monitoring Autoclave Operation

As described above, the facility's operation plan must include procedures to monitor the operation of the autoclave, to ensure that the autoclave is effectively treating RMW. 10 NYCRR 70-3.29(f) provides that autoclaves can be monitored using parametric controls or, in the absence of parametric controls, by the performance of challenge testing every forty (40) hours of autoclave operation or once a week, whichever occurs first.

Monitoring Autoclaves Using Parametric Controls

Parametric controls are electronic or other devices designed to accurately monitor the performance of a RMW treatment system and/or regulate continuously the system's operation to achieve and maintain pre-set operating parameters. If parametric controls must be used, procedures need to include a description of how the parametric controls will be used to monitor the operation of the autoclave and how they will be documented on a daily basis**.** ***It is strongly recommended that monitoring of autoclave operation through parametric controls be supplemented with the use of biological and thermal indicators every forty (40) hours of autoclave operation or once a week (whichever occurs first).***

Monitoring Autoclaves Using Challenge Testing

If an autoclave is not equipped with parametric controls, monitoring must be achieved by:

1) Including thermal indicators each time a RMW load is treated.

-and-

2) Performing challenge testing, every forty (40) hours of autoclave operation or once a week, whichever occurs first, using the conditions described in the facilities validation testing protocol. Placement of indicators must be consistent with the approved validation testing protocols and should be documented for each challenge run. Challenge testing must use biological and thermal indicators as follows:

Pounds of Waste Load	# of Treated Biological Indicators	# of Treated Thermal Indicators	# of Untreated Biological Indicators
0-550	2	2	2
551-1100	3	3	3
1101+	5	5	4

If you have any questions, please contact the Wadsworth Center Regulated Medical Waste Program by email at rmwp@health.ny.gov.