

Decontamination

Responsible Official Webinar Series

September 15, 2021



What is Decontamination?



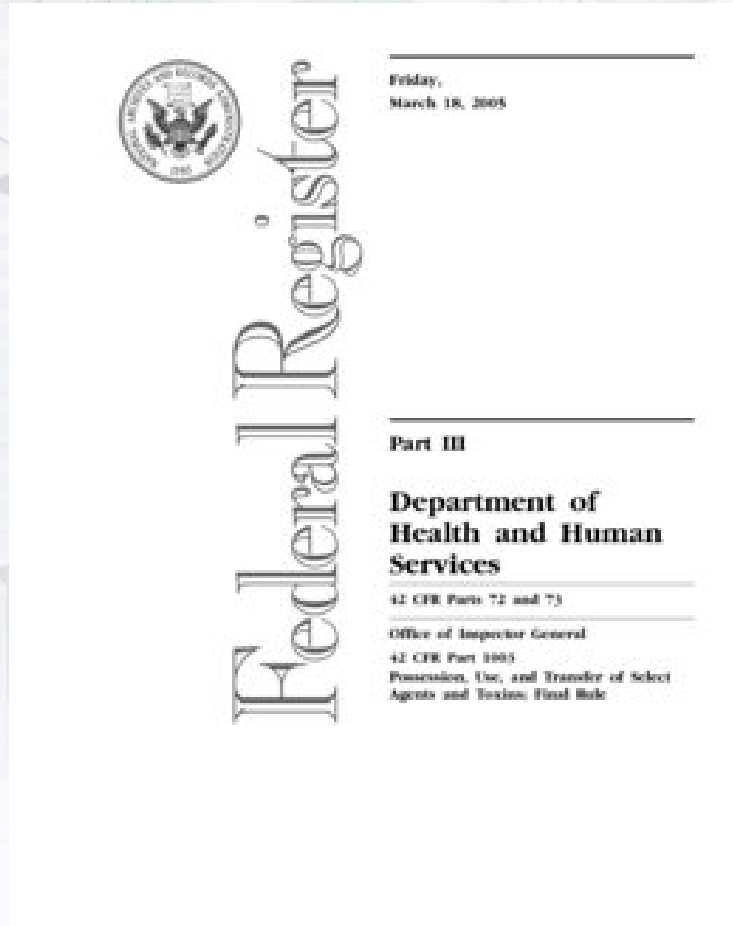
Decontamination

- Disinfection or sterilization of articles contaminated with toxins or agents to make the articles safe for use or disposal*
- At a minimum, disinfection
- Physical (e.g., steam sterilization) and chemical methods (e.g., hypochlorites)

[*https://www.selectagents.gov/compliance/guidance/biosafety/appendix1.htm](https://www.selectagents.gov/compliance/guidance/biosafety/appendix1.htm).



How do the Select Agent Regulations discuss Decontamination?



- No formal definition
- **Exclusions:** Biological select agents and toxins (BSAT) subjected to decontamination or destruction procedure, waste generated from patient (once decontaminated or transferred for destruction)
- **Section 14(d)(12):** “The incident response plan must also contain the following information: Decontamination procedures.”
- **And...Section 12(a)(3)**



Section 12(a)(3)

- An entity's biosafety plan must include written procedures for each validated method used for disinfection, decontamination, or destruction
- Contaminated or presumptively contaminated material includes (but is not limited to):
 - Cultures and other materials related to BSAT propagation
 - Items related to the analysis of BSAT
 - Personal protective equipment (PPE)
 - Laboratory surfaces and equipment
 - Effluent material
 - Animal caging systems and bedding
 - Animal carcasses or extracted tissues and fluids



Decontamination vs. Inactivation

- Unlike inactivation, decontamination does not produce material for further use
- Although the biosafety plan must include written procedures for each validated method of decontamination, unlike inactivation, an entity does not have to validate the method in-house
 - For example, with commercial products entities can use prescribed concentrations and conditions (from manufacturer, BMBL, other regulations)
- Inspectors will evaluate consistency between written decontamination procedures and those implemented, and whether procedures address key considerations



Autoclaves



Autoclaves (Steam Sterilizers)

- Method most often used to decontaminate infectious material
- Autoclaves use heat and pressure to kill microorganisms and denature toxins*
 - 121 degrees Celsius or greater
 - 15 psi
- Range of sizes
 - Tabletop to walk-in

*BMBL 6th Edition Appendix I



What are the phases of an autoclave cycle?

- **Conditioning Phase**
 - Air removed from chamber and steam introduced to increase temperature and pressure
 - Air can be removed by vacuum or gravity
- **Exposure Phase**
 - Chamber held at sterilization temperature and pressure for a predetermined amount of time
- **Exhaust Phase**
 - Steam is removed and pressure relieved

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===== PREVAC =====
===== PREVAC =====
CYCLE START AT 15:14:55
ON 0/11/09

CYCLE COUNT 8675
OPERATOR MM
STERILIZER: 421
CYCLE TYPE PREVAC
CYCLE NO. 4

STER TEMP = 132.2C
CONTROL TEMP = 133.2C
STER TIME = 4 MIN
DRY TIME = 40 MIN

V=Intlg
- TIME T= C P=psig
C 15:15:17 35.3 0.0P
C 15:16:18 107.6 12.1P
C 15:17:43 85.5 11.1P
C 15:19:19 129.1 26.0P
C 15:21:05 92.7 14.0V
C 15:22:24 130.2 26.1P
C 15:24:09 94.5 15.0V
C 15:25:26 130.2 26.1P
C 15:27:11 95.6 16.0V
S 15:29:45 132.2 28.3P
S 15:30:45 133.5 29.3P
S 15:31:45 133.1 29.1P
S 15:32:45 133.2 29.0P
E 15:33:45 133.2 29.1P
E 15:34:34 105.6 3.6P
E 15:14:35 40.2 28.1V
Z 16:14:11 40.9 1.9V

LOAD 081106

TEMP MAX=133.5C
TEMP MIN=132.2C

CONDITION = 0:14:28
STERILIZE = 0:04:00
EXHAUST = 0:42:26
TOTAL CYCLE = 1:00:54

=====
* READY TO UNLOAD *
=====
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Validation of Autoclave Cycle

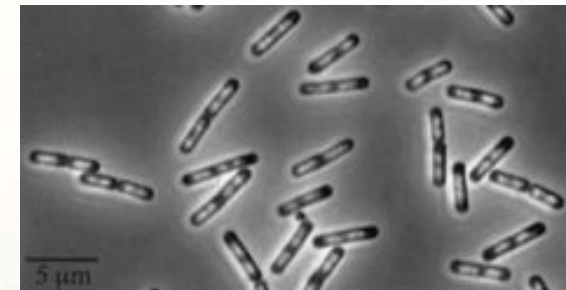
- Considerations
 - Type of material
 - Amount of material
 - Appropriate validation indicators



Autoclave Validation Considerations

- **Type of Material**

- Dry laboratory waste such as PPE
- Infectious waste such as plates, flasks, and vials
- Animal caging
- Animal carcasses
- Temperature of waste (frozen, refrigerated, room temperature)
- BSAT characteristics (spores, toxins)



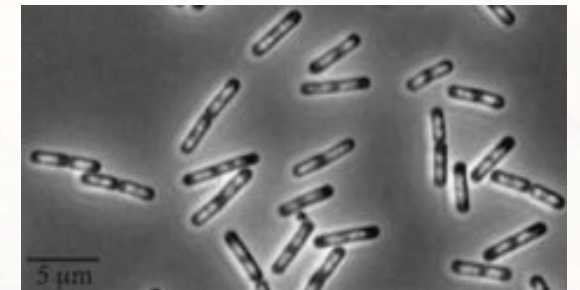
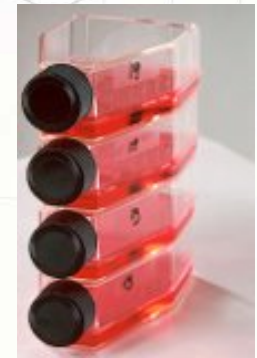
Autoclave Validation Considerations (cont'd.)

- Amount of Material

- Volume and density
- Parameters may differ by type of material

- Validation Indicators

- Biological Indicators
- Chemical Indicators



Surface Decontamination



Considerations for Choosing a Disinfectant

- Toxins or agents that may be present
- Contact time
- Method (e.g., gas or chemical wipe down)
- Surface area (e.g., whole room vs. biological safety cabinet)
- Surface material (e.g., stainless steel vs. plastic)
- Sensitivity of equipment (e.g., electronics)



Procedure Description

- Procedures in biosafety plan should describe*
 - Method used
 - Contact time
 - Chemical concentration, if applicable
 - Whether chemicals used must be freshly prepared or can be stored
 - When decontamination should occur and how staff will be notified of status of spaces and equipment
- If equipment will be opened, ensure the procedure is effective at decontaminating internal components that may be accessed
- For fumigation procedures, biological indicators should be used to verify decontamination

*<https://www.selectagents.gov/regulations/interpretations/waste.htm>



Terminal Decontamination



Terminal Decontamination Equipment/Facilities

- Autoclaves, tissue digesters, renderers, effluent decontamination systems (EDS)
- An EDS is a system that sterilizes biohazardous liquid waste generated from a biocontainment laboratory or other facility prior to discharge from the entity.
- If the entity has an EDS, recommended practices:
 - Create and maintain documentation that the decontamination procedure is validated for specific BSAT
 - Validate the EDS system under actual in-use conditions
 - Ensure that procedures are in place for the cleanup and decontamination of a spill from the EDS
 - Maintain training records that the EDS operation staff have been trained on how to respond to leaks and spills
 - Have systems in place to contain more liquid than the EDS system would process in the event of a spill



Effluent Decontamination System Policy

- An EDS is not required to be listed on an entity's registration as long as:
 - Room housing the EDS is not otherwise used for storage and/or work with BSAT
 - The biosafety, security, and incident response plans address effluent with the potential to contain BSAT such that plan procedures are sufficient to prevent the theft, loss, release or unauthorized access to BSAT
- The entire EDS is considered an extension of the registered space(s) where effluent originates
- The FSAP reserves the right to inspect the EDS, including in unregistered areas



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301- 851-2070

