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News to Use
Design Requirements Manual
The formulae $\frac{\partial \rho u_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho u_j u_i)=-\frac{\partial P}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial u_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ for building $\frac{\partial}{\partial x_j}(\rho\overline{u_i}\overline{u_j})=-\frac{\partial P}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu\frac{\partial u_i}{\partial x_j}-\rho\overline{u_i'u_j'}\right)+g_i(\rho-\rho_0)$ state of the art $\frac{\partial}{\partial x_i}(\rho\overline{u_i}\overline{H})=\frac{\partial}{\partial x_i}\left(\lambda\frac{\partial T}{\partial x_i}-\rho\overline{u_i'H'}\right)$ biomedical research facilities.

'Design Requirements Manual (DRM) News to Use' is a monthly ORF publication featuring salient technical information that should be applied to the design of NIH biomedical research laboratories and animal facilities. NIH Project Officers, A/E's and other consultants to the NIH, who develop intramural, extramural and American Recovery and Reinvestment Act (ARRA) projects will benefit from 'News to Use'. Please address questions or comments to: shawm@mail.nih.gov

BSL-3 Planning Part 3: Autoclave Fundamentals

As outlined in the previous two issues of News to Use[1], defining the barriers is fundamental to the planning of a safe and functional BSL-3 facility. Primary barriers are the biological safety cabinets and other devices in which infectious agents are manipulated; the secondary barrier is the physical enclosure of the laboratory.

The autoclave is an essential component of the secondary barrier. It allows waste and other material to safety leave the containment environment, and maintains the physical enclosure that constitutes the secondary barrier.

Autoclave Function and Types

Autoclaves use steam to kill infectious agents, and render hazardous material safe for ordinary handling and disposal. Saturated water vapor is a very dependable method of sterilization, and is faster and more effective than dry heat, ultraviolet or ionizing radiation or other common methods. Autoclaves are pressure vessels, inside of which material is subject to steam at a predetermined pressure and temperature and prescribed time duration to ensure sterility. Due of the high temperature some plastics, sealed vessels and other items cannot be autoclaved and must be sterilized by an alternate method.

Autoclaves are available as steam and electric. Steam autoclaves operate using a central steam source. Electric autoclaves produce steam using an integral steam generator. Steam autoclaves are preferable, if central steam is available, because of reduced cycle times, maintenance and operating cost. Clean steam is generally not required.

There are three basic types of autoclaves. The primary differences are the way air is removed from the sterilization chamber:

- **Gravity Displacement:** Steam is introduced into the chamber as it is produced, which displaces air by gravity until the sterilization process begins. Some air remains in the chamber, which defines the cycle times.

- **Positive Pressure Displacement:** Steam is held in a separate chamber. When sufficient steam has been accumulated it is released into the main chamber in a pressurized burst, beginning the sterilization process. This process removes more air and decreases cycle times.

- **Negative Pressure Displacement:** Air is removed from the chamber using a vacuum pump prior to the introduction of steam. This process removes the most air and further reduces cycle times.

Note that all air exhausted from the chamber prior to the completion of the sterilization cycle must be HEPA filtered or otherwise decontaminated. Autoclaves should be selected with cycles for dry goods, liquids and other functions required by the lab. Color-changing autoclave tape is used to confirm the efficacy of cycles, and records must be kept of cycles, maintenance and testing.

Autoclave Planning

Autoclaves used in BSL-3 labs generally are double-door pass-through units, installed as part of the secondary barrier. This eliminates the need to wrap or protect items to be autoclaved. Doors are interlocked and programmed to the completion of the sterilization cycle, thereby maintaining the integrity of the barrier. The size of the autoclave should be determined based on anticipated throughput, considering such factors as load capacity and cycle duration. Redundant autoclaves or alternate sterilization methods may be considered to maintain operations during maintenance and other outages.

Autoclaves are both large and heavy. Clear paths have to be identified for the installation and replacement of units. Paths must include height, width, turning radii and vertical components from the loading dock to the final location. Weight should be confirmed for both the final location and the installation/replacement path. Weight calculations must consider that units may be required to undergo periodic hydrostatic testing, where all chambers are filled with water.

Autoclaves are generally installed with only the door section protruding into the BSL-3 lab, enabling most mechanical components and maintenance tasks to be performed outside of the secondary barrier. The junction between the unit and the barrier shall be a bioseal. The bioseal is usually stainless steel, fully welded to the outer steam jacket and sealed to the wall surfaces comprising the secondary barrier. The seal incorporates a flexible component at the wall designed to maintain integrity through differential movement and expansion. Adequate space must be provided for all mechanical components, including sufficient space for access and service activities.

A room or alcove shall be provided at the unloading side of the autoclave so that materials are not unloaded directly into a corridor. This space shall have a sink for the disposal of liquid, and space for carts, waste receptacles and other required items. A canopy-type steam capture hood shall be installed above each door. Exhaust air shall be at a minimum rate of 0.254 m/s (50 fpm) capture velocity, and a drip edge provided to collect steam condensate, and the condensate must be drained to a drain or receptor on the same side of containment as the respective hood. Consideration should be given to how steam and heat may affect smoke and heat detectors. The area immediately around the autoclave shall have finishes resistant to heat and humidity, and must have lighting which is sealed, gasketed and with a minimum UL damp rating.

The sterilized effluent from the BSL-3 autoclave may discharge through the sanitary waste or lab waste system as indirect connection through a floor sink, located within the service area on the non-containment side.

References:

[1]Februaryand March 2014 News to Use, POLICIESANDGUIDELINES/Pages/DRM_News_to_Use

Further details on this month's topic are available on the DRM website
PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManualPDF
DRM Chapter 2, Section 2-5 BSL3 Contaminent Laboratories at the BSL3 Level