Several resources provide guidance on how to manage hazardous drugs. However, there is limited information on how to decommission primary engineering controls, including biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs) that have reached the end of the equipment life cycle.

Should the BSC or CACI be reused, recycled, or discarded? What is the process to decontaminate the BSC or CACI? How clean is “clean?” Should the decommission process be handled in-house or by an external vendor or consultant? What is the role of the Occupational Environmental Health and Safety (OEHS) Professional such as an industrial hygienist or safety professional in this process?

Figure 1 shows the steps to decommission a BSC or CACI that has been used to compound hazardous drugs.

This fact sheet does not address BSCs used to compound biological or radioactive agents. Per the National Sanitation Foundation Standard 49–2019 (NSF, 2019), the decommissioning process for a BSC used in a laboratory with biological agents includes gas decontamination and other steps to address the biological hazards. The decommissioning and decontamination needs of a BSC or CACI used to compound hazardous drugs differ due to the nature of the chemical hazards.

**Step 1. Assemble Team**

Typically, a BSC or CACI is replaced during a renovation project that is led by a project manager. However, it is important to include the following partners in the decommissioning process, as each partner contributes a different type of expertise:

- Pharmacy: Identifies drugs compounded within the BSC or CACI
- Facility maintenance: Provides ventilation records and diagrams
- OEHS professional: Provides guidance on workplace safety, decontamination, and surface wipe sampling

Although decontamination and surface wipe sampling can be done in-house by an OEHS professional, decontamination is typically conducted by an external vendor that conducts semiannual certification of the BSC or CACI. To avoid potential conflicts of interest, the external consultant conducting the surface wipe sampling should be independent of the vendor conducting the BSC or CACI certification. As such, it is important to include external vendors and consultants in conversations to manage the disposition of primary engineering controls.
Step 2. Review Hood History

An initial review of the BSC’s or CACI’s history will aid in the disposition determination (e.g., reuse, recycle, discard) and decontamination method and will determine whether surface wipe sampling is needed as part of the decommissioning process. This type of review is typically conducted by the pharmacy and includes identification of the types and compounding frequency of hazardous drugs, and the protocols and records associated with cleaning, semiannual certification, and equipment maintenance.

Information from this review will help the OEHS professional or person(s) conducting the decontamination to determine the appropriate deactivation agent to render the hazardous drug(s) inert, especially if there are multiple hazardous drugs present. (See Step 4 for additional information on decontamination.)

In addition, this detailed review will help identify the appropriate surface wipe sampling and analytical methods to detect residue from hazardous drugs compounded in the BSC or CACI. (See Step 5 for additional information on surface wipe sampling.)

Step 3. Determine Disposition

Reuse and recycling are the most common disposition options for a BSC or CACI. Reuse is a viable option if the BSC or CACI is in good condition and serviceable, and if parts are still available. From a liability perspective, it is important to consider the end user prior to reuse. For example, donation of a BSC or CACI (even though decontaminated) to a school may not be a suitable option for young children due to the perceived or actual risk of residual contamination. However, reuse may be acceptable at a research facility, graduate school, or academic department that is familiar with hazardous drugs.

If reuse is not an option, consider recycling (e.g., salvaging) the metal and components from the BSC or CACI. Consult with the department in your state that manages either universal or hazardous waste to identify local vendors that will recycle or accept the BSC or CACI for scrap metal.

Prior to the reuse or recycling of BSCs or CACIs used for compounding hazardous drugs, the standard practice is to have the high-efficiency particulate air (HEPA) filters removed, bagged, and disposed of by incineration. The basis for incineration would be as either (1) regulated medical waste, which may be referred to as trace chemotherapy waste, which is discarded into yellow containers designated for chemotherapy waste, or (2) hazardous waste disposed via a Resource Conservation Recovery Act (RCRA) disposal contractor.

HEPA filter removal should be conducted in a designated area as determined by the OEHS professional due to the contamination of the filter with chemotherapy drugs. The HEPA filter is typically removed by a vendor who is a trained hood certification technician.

The technician should be wearing appropriate personal protective equipment (PPE), such as double nitrile gloves that have been tested in accordance with ASTM International “Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs,” (ASTM, 2019), appropriate eye and face protection, a protective gown, and appropriate respiratory protection. A HEPA vacuum is also used to vacuum any debris dislodged from the HEPA filter.

If reusing the BSC or CACI, components such as the pressure gauges, lighting, and circuit boards will remain intact for the next user. However, if salvaging the BSC or CACI, consult with the hazardous waste vendor to determine whether removal of these components is necessary. Many times, these components contain precious metals that are of commercial value—or they may contain mercury, which is
considered toxic and requires universal or hazardous waste disposal. Typically, the vendor will remove these components if this is within its scope of work. If it is not, local engineering may be assigned this task after completion of decontamination wearing appropriate PPE such as double nitrile gloves (ASTM, 2019), appropriate eye and face protection, a protective gown and appropriate respiratory protection.

When in doubt, the BSC or CACI can be discarded as RCRA-like hazardous waste. However, this is a very costly option.

Step 4. Decontaminate Hood

Once the HEPA filters have been removed, all “accessible” surfaces should be cleaned and decontaminated with a multistep process. Accessible surfaces include the front sash, sides and work surface; the area under the work surface; plenum; exhaust collars; and connections.

Decontamination of internal plenums is difficult and controversial. Despite decontamination efforts, in most situations contamination may still be present on hard-to-reach surfaces such as the internal mechanisms of the BSC or CACI, plenum, and ductwork. Best practice dictates that service personnel should presume that all internal components are contaminated (Connor, Eckel, McDiarmid, et al., 2013).

The terms decontamination and cleaning are commonly thought of as interchangeable. However, they have different meanings that are important to understand as part of the entire decontamination process. The USP Convention General Chapter 800 (USP <800>) provides an overview of these terms and their role in the decontamination process (USP, 2020).

• Deactivation is the process of rendering the compound inert or inactive. There does not appear to be a universal agent to deactivate all types of hazardous drugs. USP <800> states that “if no specific information [is] available, sodium hypochlorite or other Environmental Protection Agency (EPA) registered oxidizer” may be used (USP, 2020). Deactivation is a critical step to ensure that active hazardous drugs are not transferred to other surfaces during subsequent decontamination, cleaning, or disposal.

• Decontamination is the removal of the inactivated residue using sterile alcohol, sterile water, peroxide, or sodium hypochlorite. It is important to deactivate the hazardous drug first; otherwise you could be transferring the active drug from one surface to another.

• Cleaning is the removal of organic and inorganic material using a germicidal detergent and sterile water.

• Disinfection is the destruction of microorganisms using sterile alcohol or another EPA-registered disinfectant appropriate for use.

The OEHS professional should make a waste determination regarding any wipes used during decontamination and associated personal protective equipment waste. Decontamination waste is typically disposed of by incineration as regulated medical waste (trace chemotherapy waste) that is discarded into yellow containers designated for chemotherapy waste. Disposal of decontamination waste as RCRA-like hazardous waste is also an option but more costly.

The Controlled Environment Testing Association also has a document, “Servicing Hazardous Drug Compounding Primary Engineering Controls,” which provides guidance for the decommissioning and disposal of a hazardous BSC or CACI (CETA, 2007).

The 2013 Pan American Health Organization guideline “Safe Handling of Hazardous Chemotherapy Drugs in Limited-Resource Settings” recommends the following:
A 2% sodium hypochlorite solution with detergent may be wiped onto contaminated surfaces, allowed to dwell in accordance with the manufacturer’s specifications, and then rinsed; this is followed by a neutralizing solution of 1% sodium thiosulfate, wiped on and off, followed by a rinse solution of water, then alcohol. (Connor, Eckel, McDiarmid, et al., 2013)

The sodium thiosulfate neutralizes the bleach or ammonium chloride to prevent pitting the stainless steel. A wipedown with isopropyl alcohol or a mild soap solution, following cleaning with any bleach-containing surfactant, is suggested to further prevent pitting of the BSC or CACI. This step is necessary only if reusing the BSC or CACI.

**Step 5. Conduct Surface Wipe Sampling**

Once the HEPA filters have been removed and all accessible areas decontaminated, surface wipe sampling can be conducted to determine the amount of residual hazardous drugs. Although the facility OEHS professional may conduct the surface wipe sampling, prudent practice is to have the surface wipe sampling performed by an independent consultant with no financial ties to the vendor performing the decontamination work.

While surface wipe sampling is currently not required by USP <800>, it is recommended to be performed routinely, at least every 6 months (USP, 2020). However, if surface wipe sampling is pursued, the types of drugs compounded in the BSC or CACI will need to be identified, followed by determination of whether a laboratory analysis protocol is available for those drugs.

If the laboratory analyses provide a result above the limit of detection, interpretation of the results will be necessary. There are no consensus standards for acceptable limits for surface contamination for comparison. In general, the most conservative approach is to achieve nondetectable hazardous drug levels from decontaminated surfaces.

However, if a concentration is detected, prudent practice recommends that all accessible surfaces should be decontaminated to as low as reasonably achievable (ALARA) or compared against benchmark surface wipe sampling, if available.

Conducting surface wipe sampling is highly recommended if reusing the BSC or CACI. If the BSC or CACI will be recycled (e.g., salvaged), consult with the waste vendor to determine if it requires surface wipe sampling. If it does, determine whether the waste vendor has an acceptable limit for surface contamination. The article “Surface Wipe Sampling for Antineoplastic (Chemotherapy) and Other Hazardous Drug Residue in Healthcare Settings: Methodology and Recommendations” provides an overview of how to conduct surface wipe sampling (Connor, Zock, and Snow, 2016). From a liability perspective, documentation is necessary to verify that proper decontamination has been performed. Documentation should include the following:

- BSC or CACI make, model, and serial number
- hazardous drugs used within the BSC or CACI
- decontamination methods and date of decontamination (e.g., removal and disposition of HEPA filter, multistep cleaning, and decontamination of accessible surfaces with 2% sodium hypochlorite)
- limit of detection for analytical method and the results of surface wipe sampling (post-decontamination phase only)
- approved disposition of BSC or CACI (e.g., scrap recycling, disposal in sanitary landfill, disposal at RCRA facility, reuse at another facility)

If discarding the BSC or CACI as hazardous waste, the use of surface wipe sampling may not be of value because the equipment is considered hazardous.
Conclusion
In conclusion, collaboration with key stakeholders is crucial to ensure that BSCs and CACIs used to compound hazardous drugs are properly decommissioned. Knowing which hazardous drugs have been used within a BSC or CACI is essential to determine both appropriate decontamination methods and the availability of sampling and analytical methods for surface wipe sampling. Once a disposition method has been determined, maintain appropriate documentation that supports decontamination methods and surface wipe sampling results, if applicable.

References


Additional Resources


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- Shelley Rae Carry, MPH, CHMM, CSP, CIH (lead author)
- Pier-George A. Zanoni, PE, CIH
- John Martinelli, CDPH I/A, CHRT, CHCPEW
- J. Nick Rice, MSOH, CIH, CSP
- Martin L Jones, PhD, FAIHA, CIH, CSP, EIT

Reviewers
- Christopher Kolbash, CIH
- Paul H. Lilley, CIH
- Stephanie Caler, MPH, CIH, CSP, REHS
- Teresa Fisk, CIH, CSP, CHSP