IREDELL HEALTH SYSTEM

Use and Maintenance of Proper Engineering Controls for HAZARDOUS DRUGS	
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P&T Committee	Date: 04/2020

Purpose
To promote patient safety, worker safety and environmental protection in the use and maintenance of facilities and equipment involved in the use of hazardous drugs (HD).

Policy
A Containment Secondary Engineering Control (C-SEC) or buffer room shall be a negative pressure room in which HDs are compounded. Containment Primary Engineering Controls (C-PECs) are equipment that shall use negative pressure to avoid exposing workers and the environment with HDs while compounding. This entity shall utilize Compounding Aseptic Containment Isolators (CACIs) as closed system C-PECs in which HDs are manipulated by workers through gloves built into the device. The airflow within the CACI allows for sterile compounding.

The C-SEC shall be used for sterile compounding and shall:

- Provide ISO class 7 air quality
- Be externally vented
- Be physically separated
- Have an appropriate air exchange (at least 30 ACPH)
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- Not exceed room temperature of 68°F (20°C)
- Not exceed humidity of 60%

The C-PEC shall operate continuously. If repair or moving of the C-PEC occurs, all work surfaces shall be decontaminated, cleaned and disinfected as well as, allowed for manufacturer-specified recovery time prior to resumption of use.

The C-SEC shall have fixed-walls with smooth, impervious, crack-free walls. Seamless floor covering shall be present. This entity shall utilize High Efficiency Particulate Air (HEPA) filtered supply air of which is designed to remove 99.7% of airborne particles measuring 0.3 microns or greater in diameter passing through.

The temperature and humidity in the Negative Pressure Buffer Room shall be monitored and recorded each day compounding is performed, by a continuous reading device.

Containment Supplemental Engineering Controls, such as Closed-System Transfer Devices (CSTDs), shall provide an additional level of protection during compounding and administration. Refer to *Compounding Hazardous Drugs* and *Administration and Post-Administration of Hazardous Drugs* policy.

Procedure
The listed equipment shall be maintained and certified as described in the chart below:

Equipment	Schedule
CACI	Semi-Annual Certification
Airflow Characteristics of C-SEC	Semi-Annual Certification
HEPA filters	Semi-Annual Certification
Temperature and Humidity monitoring device	Annual Certification
CACI Gloves	Changed daily or when visibly damaged
CACI Sleeves	Changed every 6 months or when visibly damaged

INITIAL EFFECTIVE DATE: 05/2020
DATES REVISIONS EFFECTIVE:
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