INDUSTRY UPDATE

PHYSICAL ENVIRONMENT PROVISIONS OF USP <797>
“Pharmaceutical Compounding—Sterile Preparations” (Second Edition)

ASHE.Org

ASHE General Chapter <797>, “Pharmaceutical Compounding—Sterile Preparations,” of the U.S. Pharmacopeia addresses policies and practices for preparation, packaging, and storage of compounded sterile preparations (CSPs) before they are administered to patients. The standard applies to all places where CSPs are prepared (e.g., hospitals, clinics, pharmacies, and emergency rooms) and to all persons, regardless of profession, whose work involves preparation of CSPs. Contact is the most likely source of clinically significant microbial contamination during pharmaceutical compounding, and proper hand hygiene is critical. The standard also stresses the need for environmental sampling as part of comprehensive quality management. This ASHE monograph discusses only the physical environment aspects of USP <797> and is intended for the use of health care facility managers.
1. Defining CSPs
2. Explaining enforceability
3. Describing environmental quality and control
4. Discussing physical environment considerations including HVAC layout
5. Reviewing initial certification process and ongoing compliance requirements
6. Providing an operational checklist

LIFE SAFETY DECOMMISSIONING TOOL
ASHE.Org

ASHE’s new “Life Safety Decommissioning Tool” breaks down a number of life safety features no longer required by code, as well as recommendations to either decommission or maintain these features. This tool is available for download at the link provided.

Demystifying the Process for Decommissioning Life Safety Features

Where possible, it is always preferred to remove existing life safety features not required by code, but when it is very difficult or not possible what should be done? This tool aids in evaluating what life safety features are deemed obsolete by the public by NFPA 101 (2012) Section 4.6.12.3 which requires that existing life safety features, if not required by the code, shall be either maintained or removed. The presence of a life safety feature, such as sprinklers or fire alarm devices, creates a reasonable expectation by the public that these safety features are functional. When systems are inoperable or taken out of service but the devices remain, they present a false sense of safety.

NOTE: This tool should not be the sole source for determining if non-required life safety features can remain in place. Before taking any life safety features out of service, extreme care needs to be exercised to ensure that the feature is not required, was not originally provided as an alternative or equivalent, or is no longer required due to other new requirements in the current code. For example: it’s important to note which codes your building is required to meet. CMS mandates compliance to NFPA 101 (2012); however, your local or state AHJ might additionally require compliance with the International Building Code (IBC) or International Fire Code (IFC). This is important because IFC (2018) 901.6 mandates that nonrequired fire protection systems and equipment shall be inspected, tested and maintained or removed. IBC defines a fire protection system as approved devices, equipment and systems or combinations of systems used to detect a fire, activate an alarm, extinguish or control a fire, control or manage smoke and products of a fire or any combination thereof. Further, this tool does not account for insurance company requirements such as FM Global or Zurich standards.

HOSPITALS TO SUBMIT ATTESTATIONS OF 2030 SEISMIC SAFETY DEADLINE TO OSHPD BY DEC. 31
CALHOSPITAL.ORG

The California Building Standards Commission certified emergency building standards proposed by the Office of Statewide Health Planning and Development (OSHPD) to implement CHA’s sponsored bill from last year, Assembly Bill (AB) 2190 (Chapter 673, Statutes of 2018). That legislation granted specified hospitals the opportunity to apply for an extension of the Jan. 1, 2020, seismic compliance deadline. It also required general acute care hospitals with buildings that do not substantially comply with seismic safety standards to attest that their board of directors is aware that the buildings are required to meet the Jan. 1, 2030, compliance deadline.
INDUSTRY UPDATE

The California Society for Healthcare Engineering, Inc.

MAINTAINING SAFETY OF HOLIDAY DECOR

For those responsible for their hospital’s compliance with The Joint Commission’s Environment of Care Chapter, the most dreaded season may be the winter holidays. It is the season when the desire of well-meaning staff to celebrate and decorate often clashes with the rules and regulations facilities and safety professionals are responsible to uphold. Often, the safety officer must be “the Grinch” while walking the halls and units within the health care facility. NFPA 101®, Life Safety Code®, 2012 section 19.7.5.6 states: “Combustible decorations shall be prohibited in any health care occupancy unless they are flame retardant. Exception: Combustible decorations, such as photographs and paintings, in such limited quantities that a hazard of fire development or spread is not present.” How the facility applies this is based on hospital-specific policies and procedures, but some of the universal applications are:

- Decorations may not be hung from the sprinkler heads or pipes or impede the flow of water from the sprinkler system.
- Ceiling tiles function as a smoke barrier; items should not be hung from the ceiling tiles or grid.
- No decorations on fire doors or on doors in fire corridors.
- No decorations on fire doors or on doors in fire corridors.
- Fire doors, hallway doors and patient room doors shall not be wrapped.
- Decorations should not block views through windows and vision panels.
- No garland or tinsel.
- A visual inspection of all electrical cords must take place prior to use to ensure no frayed ends or exposed wires.
- Do not place electrical cords or light strings such that they create a trip hazard.
- Electrical cords can never be daisy chained.

What is the balance between supporting the holidays that bring cheer to those receiving care while also ensuring that those decorations are not creating a hazard with severe consequences?

The American Society for Health Care Engineering created a video to help staff understand these regulations and allow everyone to be a holiday-loving Grinch.

THE JOINT COMMISSION APPOINTS NEW DIRECTOR TO STANDARDS INTERPRETATION GROUP

The Joint Commission announces the appointment of Herman McKenzie, MBA, CHSP, to director of the Department of Engineering, Standards Interpretation Group. McKenzie reports to Executive Vice President and Chief Medical Officer Ana Pujols McKee, MD. In his new role, McKenzie will lead standards interpretation and customer support activities relative to the Life Safety and Environment of Care standards. His previous roles at The Joint Commission prepared him for his new responsibilities. McKenzie joined The Joint Commission in 2017 as a staff engineer, and in January 2019, he was promoted to senior engineer. McKenzie rose to acting director of the Department of Engineering in February. McKenzie previously served in facilities management and biomedical engineering roles at several health care facilities in the Chicago area. He has more than 25 years of experience in health care, having held managerial and directorial roles in clinical engineering, plant operations and facilities services during his career.
ASHE ADDRESSES DEFINITION OF HIGH-EFFICIENCY FILTERS

Advocacy leaders within the American Society for Health Care Engineering encourage health care facilities professionals to adhere to ASNI/ASHRAE/ASHE Standard 170-2017 Ventilation of Health Care Facilities in regard to air filter requirements. The standard already requires a MERV (Minimum Efficiency Reporting Value) 14 filter for most areas, particularly within patient areas at a hospital or outpatient facility. HEPA (High Efficiency Particulate Air) filters are also sometimes referred to as a high-efficiency filter. However, HEPA filters are tested and classified using a different standard than a MERV 14 and are typically only required in a protective environment, such as a bone marrow transplant unit. In most cases, a well maintained MERV 14 filter coupled with the correct air exchange requirements will produce the necessary environment. Health care facilities professionals can refer to ASNI/ASHRAE/ASHE Standard 170-2017 for more information on ventilation requirements.

FREEZER MALFUNCTION AT CHILDREN'S HOSPITAL DESTROYS STEM CELLS FOR 56 PATIENTS

Fifty-six patients' blood stem cells have been destroyed after a freezer malfunction at the Children's Hospital Los Angeles, CNN reports. The freezer's temperature sensors and safeguards both failed, causing the loss of stem cells in long-term storage, according to a Sept. 25 statement from the hospital. Since the malfunction, the hospital has replaced the freezer, upgraded the alert system and is reviewing all power sources. The hospital apologized for the incident, which has not put any child's health at risk. Stem cells, often used to replenish living cells, can still be harvested from patients if needed, James Stein, MD, CMO of Children's Hospital Los Angeles, told ABC affiliate KABC. The hospital also apologized for their initial notification of the malfunction, delivered via letter addressed to the young patients. The hospital said it is reviewing the notification process and has set up a phone line for parent questions.

PUBLIC RESOURCES FOR UTILITY FAILURE PLANNING

The Utility failure risks in the physical environment can include electricity, lighting, domestic water, medical gases, vacuum, HVAC, air pressure, domestic water, fire sprinkler and alarm, nurse call, security and access control, computer networks, refrigeration, steam, natural gas, sewer and wastewater, vertical transportation, medical equipment and myriad other specialty systems all needed to properly care for patients and to perform daily operations. These failures can not only have a significant impact on patients but also on the ability of staff to perform patient care. While risks of utility failures are inherent due to the mechanical nature of the systems, equipment and environments that are necessary to provide patient care, one of the best ways to manage these risks is to assess and evaluate the potential risks with a multidisciplinary team. By identifying individuals who can help develop failure response plans — especially in relation to clinical services — and cooperatively working together to develop the necessary actions needed during a failure, facility professionals and their teams can be more confident that they have minimized any potential harm for patients. There are also several tools and websites available to assist in the development of utility failure plans. One site that is available from the Department of Health & Human Services is TRACIE, developed and maintained by the Office of the Assistant Secretary for Preparedness and Response. TRACIE was created to meet the information and technical assistance needs of individuals who work in health care emergency preparedness. It serves as an information gateway to improve preparedness, response, recovery and mitigation efforts. While many of the resources on this website are directed toward emergency preparedness and response, a search of the word utility on the website provides dozens of results regarding utility failure. One in particular is the “Planning for Power Outages: A Guide for Hospitals and Healthcare Facilities” document. This document provides guidance for how to prepare for power outages and gives a good format for the development of other utility failure tools.
Seven Steps to Creating a Water Management Program

ASHRAE Standard 188: Legionellosis: Risk Management for Building Water Systems establishes minimum legionellosis risk management requirements for building water systems. Creating a water risk management plan can help hospitals comply with this standard and mitigate risk as much as possible.

Here are 7 steps for creating a water risk management plan.

1. **Create a team.** [ASHRAE 188](https://www.ashrae.org) requires a team — called the "Designated Team" — to write water management programs and procedures, and to oversee the implementation of the water risk management plan. Who should be at the table? A hospital executive, facility manager and infection preventionist should be on the team. Consider adding team members from nursing management, occupational and environmental safety or other areas.

2. **Map the water system.** The Designated Team should develop a water system flow diagram of the entire building's water system. This map will help the team identify potential hazard conditions and high-risk patient care areas. You can consider using up-to-date plumbing drawings if available, but those are often too complicated for the team to use for risk assessments. Simplified drawings are often more practical. A helpful example can be found in the publication [Water Management in Health Care Facilities: Complying with ASHRAE Standard 188](https://www.ashrae.org/store/).

3. **Identify risks.** The Designated Team should systematically evaluate the water flow diagram to identify potential risks. Look for areas where there is slow or stagnant water. Consider areas with patient populations that have reduced immunity levels. Identify control locations and limits. It is important to identify both the patient populations at risk and the equipment and systems at risk to get a full picture.

4. **Develop strategies to mitigate the risks.** The Designated Team should use a risk management approach to identify control locations and limits. Control limits could refer to characteristics such as water flow rate, water temperature, disinfectant residual, concentration of pathogen or any other identified measurements.

5. **Monitor and respond.** The Designated Team must develop monitoring procedures to keep an eye on the control limit data. If there are deviations outside of the set control limits, the Designated Team can consider response methods, such as disinfectant, heating, cooling, filtering or flushing water. A full list of treatment options is available in the [Water Management in Health Care Facilities](https://www.ashrae.org/store/) publication. The team should develop standard operating procedures to help reduce risks.

6. **Review periodically.** The Designated Team should create procedures that will confirm that the risk management plan is working. This confirmation can be as simple as a spreadsheet that shows specific steps of the water management plan that are reviewed with the team whenever anomalies occur.

7. **Document, document, document.** From the first step through the last, all activities should be documented. Documentation should include all parts of the plan, and must be maintained and kept current. 2013.

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