Meeting Code & Keeping Healthcare Workers Safe: In-Hospital Pharmacy Upgrades

Building codes. They're important standards that almost all industries have to meet in order to keep people safe, remain efficient, and ensure an environmentally conscious setting. Codes are constantly evolving in order to stay ahead of trends, right size issues, and account for changing environments. These changes often have compounding effects—from prompting slight updates to warranting major redesigns and, in the most extreme cases, rebuilds.

A major code change (or a change in the interpretation or enforcement of a code) hits hospitals in particular every few years, causing many hospitals to rush to make the necessary updates to meet the code requirements. Allen & Shariff has partnered with several hospitals to not only ensure they get up to code when a change occurs, but also to help them stay on top of trends and a step ahead of future changes. A recent hot button issue concerning hospital code is how in-hospital pharmacies handle hazardous drugs (HDs) such as chemotherapy medications. While the code in question is extensive and has implications in areas beyond MEP engineering design, here's everything you need to know from an MEP standpoint.

THE HISTORY OF USP800

The code in question—USP800—was introduced in 2017 to promote patient safety, worker safety, and environmental protection. According to The National Institute for Occupational Safety and Health (NIOSH), more than 8 million U.S. healthcare workers are exposed to hazardous drugs every year. In response, the United States Pharmacopeia (USP) developed USP800, which builds on previous codes that focus on minimizing risks to healthcare workers and patients related to the handling of and exposure to HDs.

While the code affects all entities that store, transport, prepare, and administer HDs, Allen & Shariff has seen the biggest effect in pharmacies located within hospitals. The main areas that need upgrades because of the code update are storage areas, compounding areas, and plumbing systems.

Atlantic General Hospital partnered with Allen & Shariff to upgrade its main hospital pharmacy, as well as design a new pharmacy in its satellite cancer center.

STORAGE

USP800 mandates that antineoplastic HDs requiring manipulation (other than counting or repackaging final dosage forms) be stored separately from non-HDs. They must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). For hospital pharmacies that do not already have a separate room or for those who do but don't meet the other requirements, new or upgraded HVAC must be introduced.

In addition, climate control within storage spaces is paramount. CSPs (compound sterile preparations) must be stored in a room/appliance where the temperature does not exceed the warmest label limit of the compound. If the temperature exceeds the label limit by 4 hours, the entire compound will typically have to be discarded. Storage rooms may have refrigerators, freezers, and incubators that need to be accounted for within design calculations.

DRUGS ARE CLASSIFIED AS HAZARDOUS IF THEY HAVE ONE OR MORE OF THE FOLLOWING CHARACTERISTICS[1]:

- Impact or damage DNA/genes
- Cause cancer
- Contribute to infertility
- Impact a developing embryo or fetus
- Cause developmental abnormalities
- Cause organ damage
- Have a similar structure or function to drugs that are determined to be hazardous

[1] http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

COMPOUNDING

USP800 also requires sterile and nonsterile HDs to be compounded within a C-PEC (containment primary engineering control) located within a C-SEC (containment secondary engineering control). The C-SEC used for both sterile and nonsterile compounding must be externally vented, physically separated from other preparation areas, have an appropriate air exchange, and maintain a negative pressure between 0.01 and 0.03 inches of water column (WC) relative to all adjacent areas. This is a change from previous code, which required negative air pressure of *at least* 0.01 inch WC. Remaining within the newly mandated 0.01 and 0.03 range requires sophisticated and precise HVAC design[2].

The new code also requires that HD compounding be vented directly outside, whereas previous standards allowed some HD compounding hoods to be vented into an adjacent room if the air in that room was then vented outside. This change may also require HVAC upgrades.

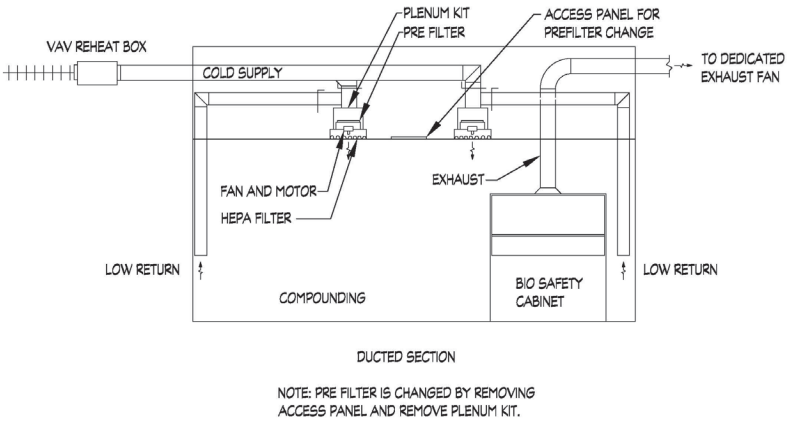


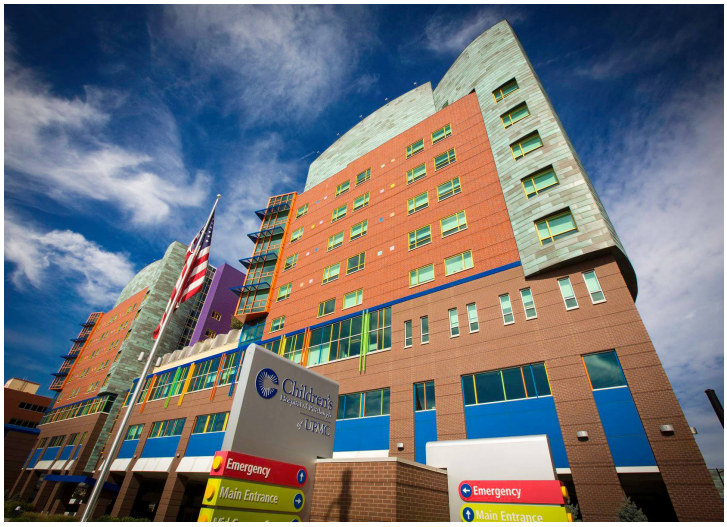
Diagram of air-flow design that has been upgraded to meet USP800 standards.

ENGINEERING CONTROLS FOR CONTAINMENT ARE DIVIDED INTO THREE CATEGORIES[3]:

- The containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs.
- The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed.
- Supplemental engineering controls, such as a closed-system drug-transfer device (CSTD), are adjunct controls to offer additional levels of protection.

One of the biggest challenges for hospitals like Atlantic General and Beebe Healthcare, who are both partnering with Allen & Shariff to upgrade some of their in-hospital and satellite cancer center pharmacies, is that USP800 has more stringent requirements for the room where the hood is located. Because of the updated requirements of the new code, the C-SEC is required to be ISO class 7 (HEPA filtered) with a minimum of 30 ACPH plus filter loading and include an ante room in order to meet the more stringent USP800 standards.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5398627/
[3] http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf



Allen & Shariff is currently designing a USP800 upgrade for five in-hospital pharmacies for UPMC Children's Hospital of Pittsburgh. Photo credit: UPMC Children's Hospital of Pittsburgh Facebook page

PLUMBING

Allen & Shariff has also helped in-hospital pharmacies upgrade their plumbing systems in order to meet USP800 standards. In addition to the change in standards regarding ventilation and temperature control, a sink must be available for hand washing, along with an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations. Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. To mitigate the risk of contamination, water sources and drains must be located at least 1 meter away from the C-PEC.

GOING THE EXTRA MILE

It's important to spend time up front investigating and investing in the systems serving the project areas to ensure they are properly integrated into the project requirements. The more a facility is aware of and plans for up front, the more prepared they'll be for evolving codes and standards.

That's where Allen & Shariff comes in, as a strategic partner our clients trust to help keep them up to code. With 25 years in business, our engineers, designers, and project managers have the knowledge and expertise to not only know the codes and standards that apply to a project at the time of design and construction, but also to stay ahead of trends so that when changes are needed, their scope is mitigated by previous measures, planning, and research. In addition to our history and proven track record in the field, Allen & Shariff designs allow for a flexibility that is crucial for future code changes. If new HVAC equipment is required, it will be designed to have additional capacity, allowing for the expansion of services suites while still being able to meet the current demands.

Allen & Shariff is different from other firms in that we don't provide "cookie cutter" solutions. We evaluate the infrastructure system for each facility and tailor the pharmacy design to the ability of the existing structure. The firm is currently upgrading pharmacies in several UPMC facilities, including UPMC Children's Hospital of Pittsburgh, UPMC Montefiore, and UPMC McKeesport, and each one is different. New pharmacies can be designed with redundant supply and exhaust systems. For existing pharmacies with existing infrastructure, it can be difficult to incorporate redundant air systems. Each design is unique and tailors to the needs and abilities of the existing infrastructure within each facility. Our expertise is not only in understanding and implementing new and changing codes but in making the right updates to each specific facility.

Allen & Shariff ENGINEERING, LLC

Whether you're in the beginning stages of design and construction, you're dealing with a code change, or you just want to set your facility up for success by getting ahead of future changes, Allen & Shariff is a knowledgeable, experienced partner that understands the need—and how to meet it.

ADDITIONAL RESOURCES:

http://www.usp.org/

https://www.cdc.gov/niosh/topics/hazdrug/

HEADQUARTERS

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