

Emergency Plumbing Fixtures in Classified Areas of Aseptic Processing Facilities (APFs) at NIH

Introduction

The safety of our workers is paramount to the NIH, but there are certain hazards inherent to the work performed in our Aseptic Processing Facilities (APFs), including the ubiquitous, persistent risks associated with accidental exposure to the various eye-damaging cleaning and sanitizing agents used to maintain these facilities as aseptic environments. There is a tension, however, between regulations which require the presence of emergency plumbing fixtures for worker safety and other regulations which discourage the introduction of biologically active potable water for patient safety related to potential product contamination.

Regulations Regarding Emergency Plumbing Fixtures

APFs are those facilities engaged in the production and/or testing of sterile and non-sterile drugs using aseptic processes, inclusive of sterile and non-sterile pharmaceuticals and biologics for human use, in NIH owned and leased facilities. These facilities include rooms and spaces that are International Organization for Standardization (ISO) Class 8, or better, classified areas. Entry into these areas requires donning appropriate Personal Protective Equipment (PPE) for two reasons: to protect the product being produced from contamination, and to provide a barrier to protect the worker from the products and components of manufacture, as well as from exposure to cleaning chemicals. Eye-protection PPE mitigates the risk of exposure, but does not eliminate it, and the need for readily accessible eye flushing fluid is recognized by regulation.

To maintain an appropriate environment for production, all surfaces, including ceilings, walls, floors, and all other exposed surfaces and components, are subject to regular cleaning and sanitization using chemicals demonstrated to be effective at removing and deactivating surface contaminants, including molds, spores, fungi, bacteria, etc. To achieve the required log reduction of viable particles on these surfaces, they are wiped and/or mopped with immediately successive passes, each utilizing different chemicals and disinfecting mechanisms in order to be impactful against a broad spectrum of potential pathogens. With near uniformity, these chemicals are characterized by an association of exposure with severe eye injury. With a few exceptions, these cleaning and sanitizing chemicals pose the greatest risk to worker safety in these facilities.

The U.S. Code of Federal Regulations 29 CFR 1910.151 states, "Where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use." These requirements are further defined and quantified in the ANSI/ISEA standard Z358.1 for Emergency Eyewash and Shower Equipment. More specifically, as implemented, this generally requires a plumbed eyewash within the room where the hazard exists, with no intervening doors.

This regulation predates the advent of NIH APFs and similar facilities, where each room, regardless of size, shall be equipped with a plumbed

emergency eyewash/facewash/shower, depending on the site-specific nature of the risk. Monthly emergency fixture testing is performed to provide assurance that the fixture is ready for use in an emergency. NIH recognizes that the accepted method of providing emergency drenching and flushing of the eyes and body is through plumbed eyewash stations/emergency showers that meet the current ANSI Z358.1 standard. However, in addition to space and other practical considerations, this poses two unintentional consequences which, in APFs, increase the risk of product contamination and potential impact on patient safety via the product being produced. These consequences are:

- During monthly testing, emergency fixtures are discharged, spraying large volumes of tepid, potable water into the air and across surfaces. This water is significantly less sterile than these surfaces, which must be maintained clean. The droplets and aerosols from monthly flushing can contaminate surfaces well away from the fixture, depending on airflows and personnel movement.
- Drain openings are connected to traps which harbor and sustain diverse microflora, including persistent biofilms. During drain usage, these microflora aerosolize and discharge from the drain trap body into the air around the trap, contaminating the air nearby, settling onto surfaces and personnel. Regular trap maintenance cannot effectively mitigate the microbiologic activity here.

Regulations that govern aseptic environments, including Good Manufacturing Practice (GMP) and Good Practice (GxP), United States Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding – Sterile Preparations, and others, prohibit the introduction of such insanitary conditions within APF production spaces to prevent contamination of the product being produced within the APF. Thus, there is a tension between the regulations, which respectively require and prohibit these fixtures in the ISO-8 or better classified spaces of the APFs.

Effective July 2nd, 2020, NIH Manual Chapter 1407 seeks to mitigate that tension and the inherent associated risks by excluding plumbed emergency fixtures from these areas; ensuring other areas of the APF conform to the ANSI/ISEA Z358.1 standard; providing a conventional, plumbed emergency eyewash/facewash and showers, as required, as close to the point of entry/exit from the APF's ISO classified areas as practicable; and providing and maintaining sterile, sealed, dual eyewash bottle stations nor more than one per room, and not more than 40'-0" apart in the ISO-8 or better spaces.

It is our belief that this approach is the appropriate balance to meet the intent of these otherwise conflicting regulations and standards for keeping workers and patients safe.

Reference

1407 - Emergency Eyewash and Shower Equipment in Classified Areas of Aseptic Processing Facilities

<https://policymanual.nih.gov/1407>

