NIH Policy Manual

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

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Transmittal Notice

1. **Explanation of Material Transmitted:**

   This new chapter establishes the National Institutes of Health (NIH) policy for the selection, placement, use, maintenance and inspection of emergency eyewash stations in classified areas of Aseptic Processing Facilities (APF) to ensure compliance with regulatory requirements.

2. **Filing Instructions:**

   Insert: NIH Policy Manual, Chapter 1407, dated 06/26/2020

Please Note: For information on:

- Contents of this chapter contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Management Support, OMA on 301-496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose

This Manual Chapter establishes the policy to implement uniform guidelines and procedures for the placement, maintenance, use and inspection of emergency eyewash, facewash, and emergency shower equipment in International Organization for Standardization (ISO) Class 8, or better, classified areas of APFs engaged in the production and/or testing of sterile and non-sterile drugs, pharmaceuticals, and biologics for human use.

The intent of this policy is to maximize worker protection beyond what is afforded by required Personal Protective Equipment (PPE). This is accomplished by providing access to secondary eyewash equipment, as well as minimizing patient risk due to contamination of aseptic processing areas from non-sterile discharges from potable water valves and drains.

Emergency flushing systems for the eye, face, or body are NOT a substitute for the use and proper maintenance of personal protective equipment (PPE) or for the safe and proper

handling of potentially hazardous materials.

B. Scope

This Manual Chapter applies to Aseptic Processing Facilities (APFs) engaged in the production and/or testing of sterile and non-sterile drugs using aseptic processes, inclusive of pharmaceuticals and biologics for human use, in NIH owned and leased facilities.

Also included in the scope are training requirements for staff engaged with the production of products in APFs; the staff/contractors engaged in cleaning APFs; as well as the staff/contractors providing operations and maintenance services to support the APFs.

C. Background

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.”

The NIH recognizes that the preferred 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.

The NIH also recognizes that bottled emergency flushing systems are supplemental to conformant plumbed or self-contained stations, and should not be used unless they are in conjunction with a conformant plumbed or self-contained station in compliance with regulatory policy.

Emergency eyewash, facewash, and showers minimize harm to workers from accidental exposures to chemicals (i.e., injurious corrosive surface disinfectants and sterilants) and other hazardous materials. Materials used in the production and/or testing of pharmaceuticals or biologics are not hazards that require emergency eyewash/safety shower facilities.

Eyewash stations within APFs involved in the manufacturing and/or testing of pharmaceuticals must comply with the Code of Federal Regulations, Title 21 – Food and Drugs, Chapter I – Food and Drug Administration (FDA), Department of Health and Human Services (HHS), Subchapter C – Drugs: General, Part 211 - Current Good Manufacturing Practice (cGMP) for Pharmaceuticals, and Sub-Part 113 - Control of microbiological contamination.

The production of biologics in APFs pose risks for environmental microbiological contamination of the product. To mitigate this risk, regulations that govern include the Good Manufacturing Practice (GMP) and Good Practice (GxP), 21 CFR Part 1271, Section 361 - Minimal Manipulation of Human Cells, Tissues, and Cellular Tissue-Based Products, 21 CFR Part 1271 Section 351 - More Than Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products, and products not subject to Human Cells, Tissues, and

cellular and tissue-based Products (HCT/P).

These requirements are further defined and quantified in the ANSI/ISEA standard Z358.1 for Emergency Eyewash and Shower Equipment. This standard establishes the minimum requirements for emergency eyewash and shower discharge pressure, delivered flushing solution temperature, valve operation, supply line, placement of the emergency equipment and per Appendix B7, a requirement for weekly activation to establish readiness of the equipment.

D. Policy

The NIH APFs will provide equivalent worker protection for potential exposures to injurious corrosive materials, based on risk assessments that take into consideration existing regulations, to minimize sources of waterborne environmental contamination in order to maintain aseptic classified environments used to produce cellular therapeutics for humans:

1. Excluding plumbed emergency eyewashes, facewashes, and showers, within APF, ISO-8, or better, classified areas;
2. Ensuring other areas of APF's conform to the requirements of the current ANSI/ISEA Z358.1 standard;
3. Providing sterile, sealed, dual eyewash bottle stations in APF, ISO-8, or better, classified areas;
4. 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 by
5. Periodically reviewing Standard Operating Procedures, to ensure that operations such as cleaning and decontamination are to be performed in a manner that minimizes splash risk to workers performing these operations.

The NIH will also comply with OSHA standards for workers exposed to injurious corrosive materials, using a combination of strict administrative controls for use of PPE, and both an awareness of and a demonstrated competency to respond to an adverse exposure using portable eye wash stations inside the ISO-8 and 7 areas; guiding the exposed worker through the APF to the nearest plumbed emergency eyewash/shower station, and the proper use of this equipment.

Emergency eyewash, shower and related equipment is not a substitute for proper administrative controls or strict adherence to the use of approved personal protective equipment (PPE).

All personnel working in areas where emergency eyewash, shower or related equipment is located will wear approved eyewear and (as directed) protective clothing/coverings; and follow all Standard Operating Procedures that have been developed to ensure the safety of all personnel working in these areas.

E. Responsibilities

1. The Quality Assurance Director or Manager within each APFs is responsible for:

    a. Ensuring the Quality Assurance (QA) Officer reviews and approves the location type, and installation of eye/face wash fixtures and stations; and
    b. Ensuring the APF Production staff track the expiration date on the sealed bottles to ensure they are replaced prior to that date, and for daily inspection of fixtures and stations to ensure their fitness for use.

2. The Office of Research Services (ORS), Division of Occupational Health and Safety (DOHS) is responsible for reviewing the use of Self-Contained Eye/Facewash Fixtures or Secondary Two-Bottle Eyewash Stations Options identified in Appendix 2 - Emergency Eyewash Equipment Selection and Placement Options.
3. The Director, Office of Research Facilities Development and Operations (ORFDO), has the overall responsibility for design, construction, operation, maintenance, renovation and decommissioning of NIH facilities.
4. The ORFDO, Division of Technical Resources (DTR) is responsible for:

    a. Reviewing design and construction documents associated with APFs; and for
    b. Conducting inspection of APFs for compliance with this policy.

5. The ORFDO, Division of Facilities Operations and Management (DFOM) is responsible for the installation of new emergency eyewash/facewash fixtures and stations when authorized.
6. The ORFDO, Division of Design, Construction and Management (DDCM) is responsible for the installation and/or removal of eyewash/facewash fixtures and stations that are part of a construction project.
7. The ORS, Office of Scientific Resources (SR), has overall responsibility for occupational safety and health of NIH facilities.
8. The ORS, DOHS is responsible for reviewing and approving design and construction submittals associated with this policy.

F. Procedures

1. Eye/Face Exposure Event Response Within the Classified Area of an APF where a Secondary Two-Bottle Eye/Facewash Station is provided:

    a. Stop all work. All employees must work in groups of at least two trained personnel during cleaning operations. No employee should be alone in an area where these stations are required;
    b. Unexposed worker shall guide and assist the exposed worker to the nearest bottle-mounted fixture or plumbed emergency eyewash/shower station;
    c. Commence flushing contaminated skin and/or mucous membranes per SOP;

        i. Begin flushing the affected area of the body immediately

ii. For chemical spills to the eye(s), hold eyes open as wide as possible to permit the water to reach all areas around the eye
iii. Unexposed worker may be needed to assist with holding eye(s) open and/or ensuring that flushing solution is directed to affected eye(s)
iv. Unexposed worker shall hold open any doors between the site of the incident and the nearest plumbed emergency eyewash/shower station, providing the employee a clear, unobstructed pathway to the station, and

d. The unexposed worker shall call for assistance, as specified in Standard Operating Procedure (SOP) for the APF. This shall include notifying Occupational Medical Service (OMS) or activating the NIH Division of Fire and Rescue Services (DFRS) Emergency Medical System (EMS), by dialing 911 from a house phone or (301) 4596-5685 using a cell phone. This notification shall be included in the incident SOP for the APF. This includes paging OMS after normal business hours and activating EMS via a landline or cell phone.

2. Eye/Face Exposure Event Response outside of the ISO 8/7 areas where a plumbed emergency eyewash/shower station is provided:

a. Unexposed worker, who has guided the exposed worker through the portals will assist the exposed worker at the eyewash station/emergency shower.
b. Once at a plumbed station, exposed employee shall continue to flush the affected area of the body for a minimum of 15 minutes or until EMS or OMS has assumed responsibility for treatment of exposed worker.
c. EMS/OMS shall take over care and decontamination of the exposed worker, continuing to flush and remove contaminated/potentially contaminated PPE under the emergency shower, per SOP.
d. As required, the unexposed worker shall initiate further actions per the Clinical Center (CC) Hazardous Spill Management Policy.

G. References

1. NIH Policy Manual, Chapter 1743 *Keeping and Destroying Records*, available at: https://oma1.od.nih.gov/manualchapters/management/1743/
2. NIH Design Requirements Manual, available at: https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/default.aspx, Chapter 13
3. U.S. - Code of Federal Regulations Title 21 , available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1
4. 21 CFR Part 1271, Section 361 - Minimal Manipulation of Human Cells, Tissues, and Cellular Tissue-Based Products
5. 21 CFR Part 1271 Section 351 - More Than Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products, and products not subject to Human Cells, Tissues, and cellular and tissue-based Products (HCT/P)

6. U.S. Code of Federal Regulations 29 CFR 1901.151, Occupational Safety and Health Standards, available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910h
7. American National Standards Organization (ANSI)/International Safety Equipment Association - ANSI/ISEA Z358.1 and ANSI/ISEA Z87.1, available at: https://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2fISEA+Z358.1+%2f+ANSI%2fISEA+Z87.1+-+Eyewash+and+Eye+Protection+Package
8. International Organization for Standardization (ISO) – ISO 14644 Cleanrooms and associated controlled environments, available at: https://www.iso.org/standard/53394.html
9. Standard Operating Procedures (SOP) for APF Cleaning Contractors (Available by request on an as needed basis. Contact the Office of Research Support and Compliance @ http://intranet.cc.nih.gov/orsc/index.html for assistance).
10. Clinical Center (CC) Hazardous Spill Management Policy S-010

H. Definitions

1. **Aseptic Processing Facility (APF):** Facilities which produce drug and/or biologic products for human injection, vascular infusion, implantation, ingestion, inhalation, or absorption. This includes facilities where non-aseptic products are produced using aseptic practices.
2. **ISO Classified Space:** These spaces must satisfy the Food and Drug Administration (FDA), United States Department of Health and Human Services (HHS) requirements for the work being performed. ISO classified spaces are areas where HVAC systems are specifically designed to reduce airborne contaminants below a specified level (as defined in ISO classes) and both temperature and relative humidity (RH) are controlled more tightly than in the ambient environment. These areas must be performance verified/qualified to meet the requirements of ISO Classification, specifically for Class-8, 7, or 5.
3. **Conventionally Plumbed Emergency Fixture:** May reference eyewash, facewash, emergency shower, and combination fixtures which conform to the normally applicable DRM, ABA/ADA, OSHA, and NIOSH requirements for placement, capacity, and function. These fixtures are tested weekly, releasing potable water, and constitute a known environmental risk of contamination to ISO Classified spaces.
4. **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**: Is a system developed by the United Nations for standardizing and harmonizing the classification and labelling of chemicals globally. More specifically, the UN GHS Document (known as UN GHS Purple Book) which defines physical, health and environmental hazards of chemicals and harmonizes classification criteria; and standardizes the content and format of chemical labels and Safety Data Sheets.
5. **Injurious corrosives:** Chemicals, upon eye exposure resulting in serious eye damage that doesn't heal in 20+ days, shall be designated with pictograms and labels as described in Global Harmonized System, specifically. Serious eye damage products are labeled "Danger."

6. **Irritant:** Chemicals, upon eye exposure resulting in serious eye damage that heals quickly, shall be designated with pictograms and labels as described in Global Harmonizing System,specifically.Irritant eye damage products are labeleded "Caution."
7. **ISO Class:** An air quality classification from the International Organization for Standardization, per ISO 14644-1 standards, which specify the cleanliness of spaces by airborne particulate via decimal logarithm of the number of particles 0.1 μm or larger permitted per cubic meter of air.
8. **Secondary Two-Bottle Eye/Facewash Station**: A bracket and holder with a minimum of two (2) sealed bottles, 946 ml (32 oz.) or larger each of preserved water, preserved buffered saline solution or other medically acceptable flushing solution.

Appendix 1: Good Manufacturing Practice (GMP) Risk Analysis

If supported by a GMP Risk Analysis, and upon the direction of the APF's Quality Assurance (QA) Officer, existing, or new installations of plumbed emergency eyewash and shower equipment within APF ISO classified spaces, are not required to conform to this interpretation – e.g. plumbed stations may be installed/maintained, where it can be established that doing so does not create unacceptable levels of risk of contamination of the products being produced.

1. The detailed limitations and requirements applicable to APF's and the staff follows:

    a. APF staff engaged in the operation of the processing or testing of products in the APF shall be trained, experienced, and wearing full body PPE (which may include, but is not limited to booties, Tyvek coveralls, gloves, hair nets, and safety goggles/full face shields), in accordance with site-specific SOP, within classified areas of the APF;
    b. APF staff and/or cleaning contractors engaged in the cleaning of APF's shall be trained, experienced, and wearing single use full body PPE, including, but not limited to booties, Tyvek coveralls, gloves, hair nets, respirators, and safety goggles/full face shields, in accordance with site-specific SOP, within classified areas of the APF; and
    c. Operations and Maintenance staff and contractors engaged in the operations and maintenance of the facility shall be trained, experienced, and wearing full body PPE (which may include, but is not limited to booties, Tyvek coveralls, gloves, hair nets, and safety goggles/full face shields), in accordance with site-specific SOP, within classified areas of the APF.
    d. Listed chemicals, for the purposes of this chapter shall include:

        i. Eye Irritation Classification: The diluted pH of the products/mixtures within the classified areas of the APF shall not exceed ≤ 2 and ≥ 11.5 including buffering capacity (GHS Classification Category-1);
        ii. Eye Irritation Classification: The products/mixtures within the classified areas of the APF shall not be classified as corrosive to skin (GHS Classification Category-1), except where full-body PPE is required; and
        iii. The pre-diluted products shall be part of the risk assessment, not just the full-strength/unbuffered products.

e. All processing and cleaning activities using listed chemicals are performed per site specific SOP.
f. The APF Staff has a SOP and is trained for appropriate response to chemical exposure.

    i. Cleaning chemicals, which are listed, for the purposes of this chapter shall be pre-diluted to the extent practicable, prior to bringing them into APF facilities to reduce the risk of worker exposure to full strength chemicals.
    ii. Production process, to the extent practicable, shall be a closed-process, to reduce the risk of worker exposure to full strength chemicals.
    iii. The APF Staff's SOP shall include a requirement to don and wear eye/face PPE at all times within the classified areas APF during cleaning activities.
    iv. The APF Staff's SOP shall include initial and regularly scheduled training on the location, use and operation of the eyewash station(s). This training should also include practice runs where an "injured" person (usually blindfolded) is assisted in the flushing process, as well as in moving through the area to the nearest plumbed emergency eyewash/shower station.
    v. The training program should provide documented feedback opportunities for improvement. The program in its entirety shall be reviewed by all personnel on a regular basis.

g. The cleaning contractor has a SOP; and is trained for appropriate response to chemical exposure.

    i. Cleaning chemicals used in these areas shall be pre-diluted prior to bringing them into APF facilities to reduce the risk of worker exposure to full strength agents.
    ii. Cleaning shall be conducted by cleaning vendors and/or self-performed by APF staff who shall utilize pre-moistened mops and wipes. These shall be used to the extent practicable to reduce the risk of worker exposure to full strength agents, and large quantities of un-absorbed/un-adsorbed agents.
    iii. The cleaning contractor's SOP shall include a requirement to don and wear eye/face PPE at all times within the APF.
    iv. The cleaning contractor's SOP shall include initial and regularly scheduled training on the location, use and operation of the eyewash station(s). This training should also include practice runs where an "injured" person (usually blindfolded) is assisted in the flushing process, as well as in moving through the area to the nearest plumbed emergency eyewash/shower station.
    v. Training program should provide documented feedback opportunities for improvement. The program in its entirety shall be reviewed by all cleaning personnel on a regular basis.

Appendix 2: Emergency Eyewash Equipment Selection and Placement Options

The selection of the emergency eyewash equipment shall be reviewed by the ORS Division of Occupational Health and Safety (DOHS).

1. **Secondary Two-Bottle Eye/Facewash Station**

    a. Bottled eyewash stations do not meet the standard criteria for emergency eyewash as outlined in the ANSI standard. These are used to support eyewashes that do meet the standard; they do not replace them.
    b. Safety showers and eyewash stations (including secondary two-bottle systems) must be located on the same level as the hazard, and the path of travel shall be free from obstructions.
    c. Provide a cleanroom compatible, secondary two-bottle eyewash station with a minimum of two (2) bottles, 946 ml (32 oz.) or larger each, of flushing solution, ("potable water, preserved water, preserved buffered saline solution or other medically acceptable solution").
    d. Station shall be in a fixed location (i.e. not cart mounted) and maintained with unobstructed access.
    e. A fixed, high-visibility sign shall be affixed to designate the station, not less than 89 mm x 127mm (3.5" x 5"), compatible with the environment (cleanable, smooth, resistant to degradation from cleaning chemicals, etc.)

2. **Placement of Emergency Eye/Facewash Stations**

    a. Secondary Two-Bottle Eye/Facewash Station

        i. Shall be located not more than 10 seconds or 16.8 m (55 feet) travel distance from another Eye/Facewash Fixture; or a compliant, plumbed Laboratory Eye/Facewash fixture, on the same floor level capable of the release of a continuous flow of tepid flushing solution for a minimum of 15 minutes.
        ii. Shall be placed so as to be free of obstructions by a minimum of 6".
        iii. Shall be installed such that the distance to floor from the middle of the bottles is 813-1219 mm (32-48").

3. **Maintenance of Emergency Eyewash Stations**

    a. The area in front of the all emergency eyewash stations shall be free from obstructions.
    b. For sealed bottles and reservoirs, the expiration date of the flushing solution shall be logged into the APF's calibration and maintenance calendar, and the APF users shall order and install replacement bottles and reservoirs not less than 1-month prior to expiration.

c. Partially discharged sealed bottles and reservoirs shall be immediately replaced before the room is returned to operation.
d. Sealed bottles of emergency solution should be checked weekly to determine whether the fluid may be degraded or compromised and replaced before operations are initiated.
e. Fixtures and stations shall be regularly cleaned per APF-Specific cleaning SOP.
f. Fixtures and stations shall be regularly inspected and maintained for degradation of the unit, components, and sealant to adjacent architectural finishes. Visually degraded or damaged fixtures or components shall be immediately replaced.

4. **Inventory**

a. The APF shall maintain at least one replacement set of sealed bottles and reservoirs in controlled inventory to avoid prolonged downtime of the APF following an event.

5. **Inspection and Compliance**

a. Perform a daily inspection noting the presence of ready-to-use eyewash bottles, properly located.
b. Perform a comprehensive inspection of the facility to evaluate modified work space, assess new hazards introduced into the area, and to identify fixtures needing replacement or repair, not less than annually.
c. For plumbed and non-sealed reservoir fixtures, flush lines and test by activating weekly, including valve mechanism activation, flow metering, and flow pattern via test gauge. Other required inspections and testing shall be completed in conformance to ANSI Z-358-1, NIH instructions and other regulatory standards.

6. **Disposal**

a. Expired (meaning beyond the marked expiration date on the reservoir of eyewash/facewash flushing solution), and partially, or completely discharged sealed bottles and reservoirs shall be removed from the APF, emptied into a sink, and recycled or placed in regular waste stream, depending on the material.
b. Visually degraded or damaged bottles or fixtures shall be removed from the APF and recycled or placed in regular waste stream.