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Accreditation 360
Preparation and Operational Impact

ASHRAE/ASHE Guideline 43 & AAMI ST 108 Update

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SMSHE
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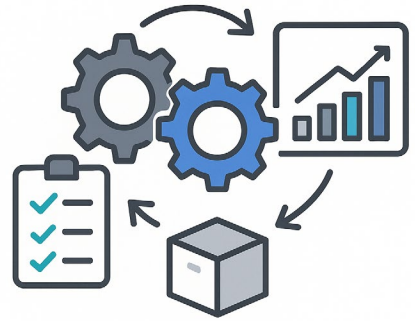
Impact on Normal Operations

- Minimal impact on operations
- Changes deal primarily with how the requirements are categorized
- Previous standards, as we knew them, go away and are replaced with:
  - PE Standards (Physical Environment)
  - Limited Elements of performance



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Report References: Representative items under each standard.

- PE.01.01.01: Building construction, Safety, use of state rules and regulations, Space allocation and design, condition of spaces, cleanliness, etc.
- PE.02.01.01: Procedures for routine storage, Hazardous Wastes,
- PE.03.01.01: Compliance with the provisions of the Life Safety Code, 2012, Fire drills, Airborne contaminants,
  - New Document Review List and Review Tool. Page 474 of SPG

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Report References: Representative items under each standard.

Continued

- PE.03.02.01: ILSM
- PE.04.01.01: Fire Protection, Emergency Power Systems, Medical Gas Systems, OR Evac Drills, Medical Equipment, Utilities
- E.04.01.05: Water Management

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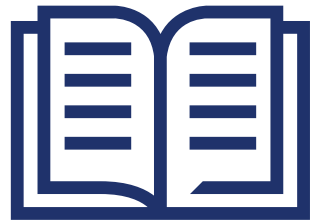
Preparation for Accreditation 360

- Obtain a copy of the Survey Process Guide
    - Best survey preparation tool
    - 626 pages, including all areas of the survey process
    - Physical Environment sections begin on page 222
    - The new Document List and Review Tool are pages 475-489
    - Evaluation Tools for Healthcare and Ambulatory Healthcare Occupancies, including all K-tags



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Preparation for Accreditation 360 *Continued*

- Review new PE Standards and EPs.
- Print and review all available crosswalks to better familiarize staff with the revisions.
- Review all supporting policies that may reference any of the old standards and EPs. Revise to reference the new revised standards and EPs.
- Any vendors that provide testing and maintenance services should be reviewed to ensure that documentation presented meets all the standards required relating to standard and EP reference.

Preparation for Accreditation 360 *Continued*

- Competency
  - Staff
  - Vendors

- Already being discussed during survey

- Competency must be criteria based and assessed based on the service or tasks being performed.

- Need for a specific certification or licensure must be identified as established requirements

- Competency assessment is a component of the position/job performance evaluation

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ASHRAE/ASHE GUIDELINE 43: Operations Guideline for Ventilation of Healthcare Facilities.

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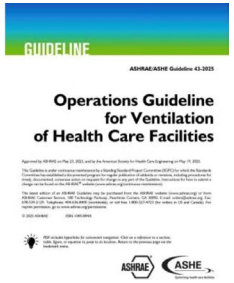
What is ASHRAE 43?

- A document that provides clear guidance for the implementation of an HVAC program by offering a framework for day-to-day ventilation operations. This type of program was not the intent or purpose of the original ASHRAE 170.

- Purpose of Guideline 43: This guideline provides recommendations for the operations of heating, ventilation, and air conditioning systems that provide environmental control and support in healthcare facilities.

- Scope: The scope includes the operation of healthcare facility HVAC systems and equipment, their normal and routine maintenance, major tasks of periodic maintenance, and energy conservation.



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Key Aspects of an implemented HVAC/Ventilation Management Plan based upon Guideline 43

- A clearly defined framework for plan implementation
- A written HVAC/Ventilation management plan is best practice. Although not required, it may well become an expectation by accreditation entities. This plan should provide and guide preventative maintenance, monitoring, and documentation, ensuring of a proactive and consistent response to unexpected ventilation issues.
- This new guideline will help reduce compliance risk by having a documented plan and processes to ensure consistent maintenance, monitoring and response.

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Creating an HVAC/Ventilation Management Program

- Identify internal stakeholders and form a committee
  - Utilize a multidisciplinary group of leaders across the organization, engineering, planning, design and construction, accreditation, infection prevention, nursing, pharmacy, lab, and perioperative services.
  - Include all locations

- Identify applicable code references
  - Currently CMS references the 2012 edition of NFPA 99, Healthcare Facilities Code, which references the 2008 edition of ASHRAE 170
  - Check state and other local requirements for any conflicting requirements

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Space and Systems Assessment

- Develop a comprehensive list of all spaces in the facility and systems serving all spaces identified.

- Note the room usage, room name, and the room name on the life safety is consistent. Note room HVAC requirements such as pressure requirements, level of risk, frequency of pressure testing, or other relevant monitoring. Note any construction completed to determine the correct version(s) of ASHRAE 170 applicable. It is best to begin with critical spaces and then to the non-critical spaces.

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Plan Development

- Facilities should create a schedule for measuring and monitoring:
  - Pressurization
  - Humidity
  - Air exchange rate
  - Any other additional factors determined by risk assessment and standards

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Plan Development *Continued*

- Response plan identifying steps to be taken in the event measurements fall outside acceptable ranges. This could be based upon:
    - Length of the length of the excursion
    - Severity of the excursion
    - This would include a requested excursion such as a requested temperature adjustment or a planned excursion event. These could be issues related to patient comfort, medical conditions, or a surgeon’s request.

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Education

- Possibly dedicate one of the early committee meetings to educate committee members on ventilation related definitions, such as room pressurization, temperature and humidity, and the purpose of air exchanges

- Consider creating ventilation maps for pressure, temperature, and humidity and assigning colors to spaces based on the element of risk rating and use of arrows to show the direction of air flow.

- Possibly install identifiers on the outside of the rooms

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HVAC/Ventilation Plan Policy

- The plan should be supported by and defined by policy that can be referenced by staff in the organization.

- Review any existing policies that have ventilation requirements and modify them to reference the new HVAC/Ventilation Plan, rather than indicating requirements in a separate policy.

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Maintain The Plan

- Update the room list as change requests are submitted and approved
- As part of routine rounding, each space should be evaluated to ensure that activities in the room or the room signage have not changed.

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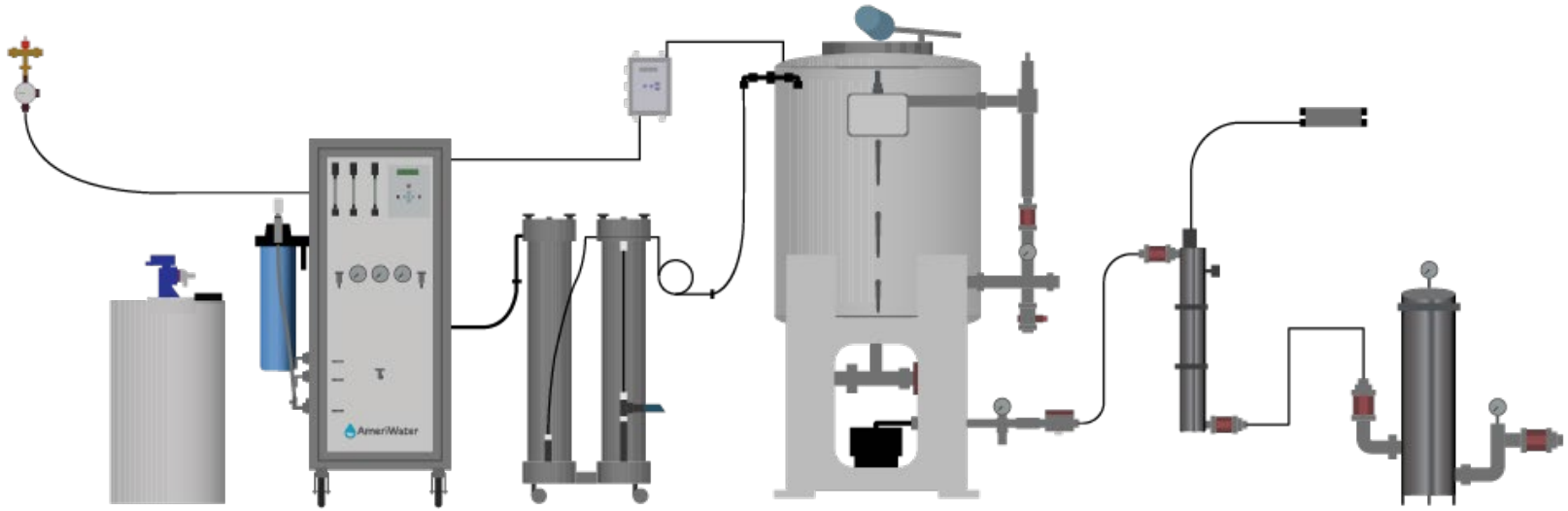
AAMI ST108: An Update



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What is AAMI ST108?

- This standard, created by the Association for the Advancement of Medical Instrumentation (AAMI) defines specific water quality requirements for the cleaning, disinfection, and sterilization of reusable medical devices. It replaced the less stringent AAMI TIR34.

- AAMI ST108 provides specific details and measurable criteria needed to satisfy the broader water management and patient safety requirements set by The Joint Commission.

American National Standard

ANSI/AAMI ST108:2023

Water for the processing of medical devices

AAMI

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Is AAMI ST108 compliance required by The Joint Commission?

- CMS QSO-17-30: Rev. 7/6/2018 is the CMS memo that identifies and spells out the requirements of the Water Management Plan. (Currently The Joint Commission Standard EC.02.05.02) The requirements for the cleaning, disinfection, and sterilization of reusable medical devices must be included in the Water Management Plan.

- The Accreditation 360, Joint Commission Infection Control standard, IC.04.01.01 EP 3, under note 3 states. “The hospital determines which evidence-based guidelines, expert recommendations, best practices, or a combination thereof it adopts in its policies and procedures.

    - Accreditation 360, Joint Commission Infection Control standard, IC.04.01.01 EP 4 identifies the requirements for the cleaning, disinfection, and sterilization of reusable medical devices.

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Is AAMI ST108 compliance required by The Joint Commission? *continued*

- The Joint Commission requires that an organization must demonstrate that its water management program- including the water used for reprocessing medical devices- meets the standards outlined in AAMI ST108. Although not specifically stating compliance with the ST108 standard, this effectively establishes compliance.

- Data relating to the risks associated with a non-compliant water management program:
  - CMS reports that 1/3 of hospitals have reprocessing deficiencies
  - The Joint Commission reports that the cleaning of medical equipment consistently ranks in the top 10 compliance issues
  - Deficiencies identified relating to hi level disinfection and reprocessing can, and often does, result in a “high risk” finding during survey and can be scored under the Infection Control and Leadership standards.

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Why is ST108 Important and driving change?

- Patient Safety
  - It helps prevent healthcare-associated Infections (HAIs) by ensuring devices are free of contaminants
  - HAIs affect 5-10% of hospitalized patients, with approximately 1.7 million HAIs per year, resulting in 99,000 deaths.

- Device Integrity
  - Prevents damage, corrosion, and biofilm build-up on medical instruments

Operational Effectiveness
  - Ensures proper function of cleaning chemicals and sterilization processes by providing high-quality water.

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What to expect with the AAMI ST108 Standard

- Building requirements: Unlike prior guidelines, ST108 provides mandatory requirements for sterile processing departments. (SPDs)

- Water Categories: The standard categorizes water into three types:
  - Utility water: Used for general tasks
  - Critical water: Specially treated to remove microorganisms and contaminants, used for final rinses and high-level disinfection
  - Steam: Vaporized water for steam sterilization, requiring specific purity standards.

- Provides guidance for when and where to use water of each category

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What to expect with the AAMI ST108 Standard *continued*

- Provides information on how to ensure water continues to meet those quality requirements, at a minimum.
- Sets performance criteria or water treatment/delivery system & monitoring program

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Preparation

- Establish a multidisciplinary Water Management Committee
- Define roles and responsibilities of committee members
- Review the water management program
- Perform ongoing surveillance when any exposures occur due to waterborne pathogens carried by instruments
- Review water monitoring test results
- Facilitate/perform risk assessments relating to water quality impacting the medical device processing
- Bring concerns/issues to the Infection Prevention & Control Committee and escalate as needed.

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In Summary

- Although AAMI ST108 is not, by name, a specific requirement, based upon CMS requirements for water management and the Joint Commission expectations for a quality program and based upon the aspects and requirements of AAMI ST108, this would be considered a “Best Practice” and at some time will be defined with the Joint Commission standards for water management.

- Review your organizations Water Management Program to ensure that all required components are clearly defined and evident. Work closely with the Infection Control department in the implementation of a solid and effective water management program.

- Assess your organizations water management program annually for any equipment or operational changes and revise the program as appropriate.

Questions