CSA Standard Z317.2-10

IAS/CTC Interpretation and Comments Regarding Airborne Isolation Room Filter Systems

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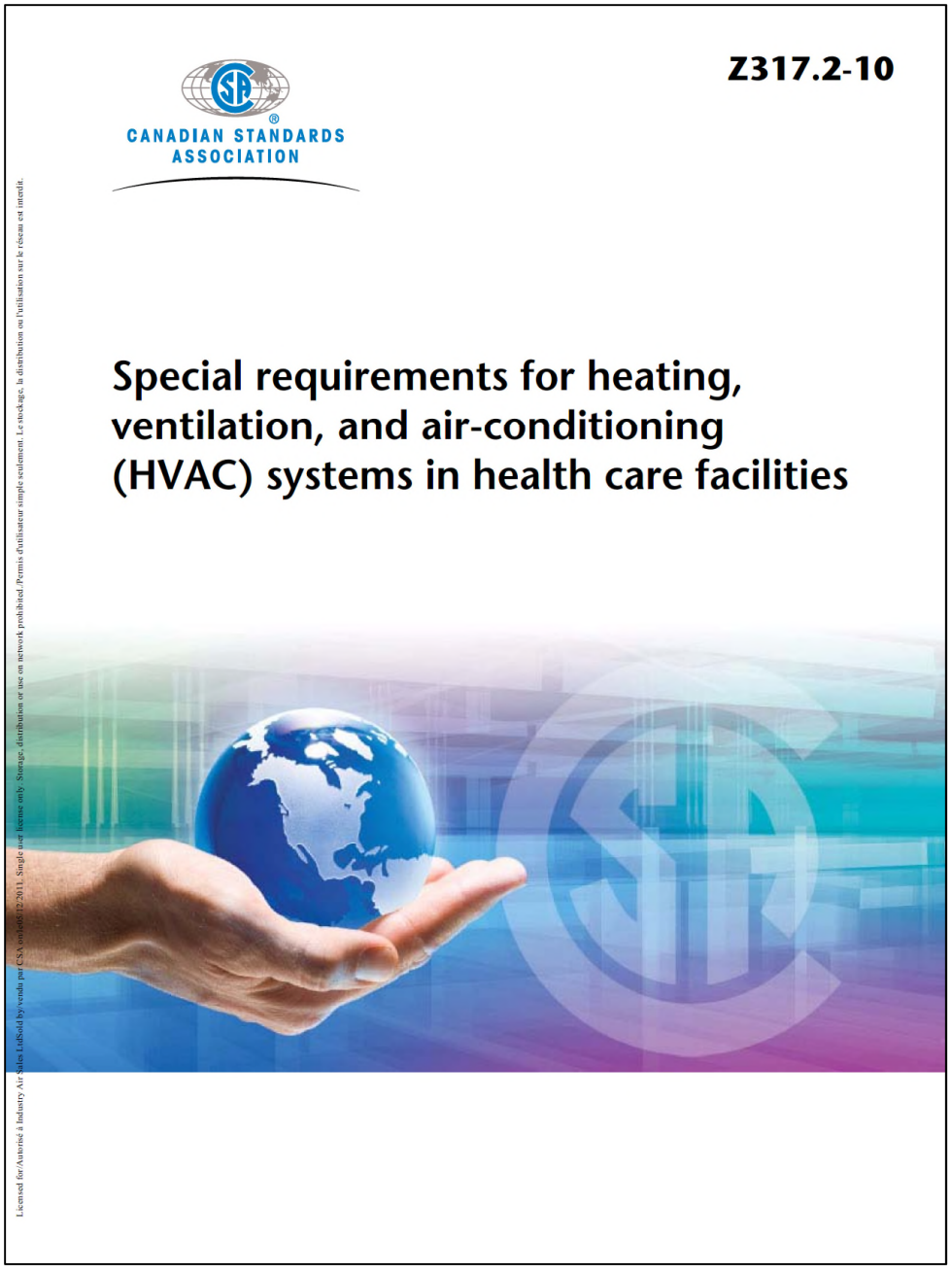

Introduction: The purpose of this bulletin is to present sections of the CSA Z317.2-10 Standard that concern the design of Bag-in/Bag-Out (BIBO) Filter Systems employed on **Airborne Isolation Room (AIR) Exhaust Air**, and to provide our interpretation with regard to equipment design considerations. CSA sections will be presented within boxes and then our interpretation will follow in standard body type (Calibri 12-font). Our intent is to assist consulting engineers, design-build contractors/engineers and project managers with practical information that can be applied to this important equipment.

6.1.8 Maintenance

HVAC systems for Type I areas shall be designed such that they can be shut down for maintenance and emergency repair without jeopardizing the relative pressurization of adjoining areas.

6.1.8 Interpretation: Bag-In/Bag-Out (BIBO) Filter Systems employed on Airborne Isolation Room (AIR) Exhaust should have fully redundant or N+1 Redundant filter systems and fully-redundant fans to permit filter change-out in complete isolation. In other words, to permit filter change-out without loss of negative pressure to the room being served by maintaining filter Pressure Drop and airflow thru the use of redundant filter systems and fans.

6.5.5 Air-handling unit redundancy

6.5.5.1 Class A-1

6.5.5.1.1

Class A-1 HCFs shall have parallel air-handling units for any areas that accommodate the following critical functions:

(a) animal research (including labs and holding areas);
(b) critical care (e.g., intensive care, coronary care, cardiac care, pediatric critical care, surgical intensive care, neuroscience critical care, etc.);
(c) interventional or invasive imaging (e.g., DI suites such as angiography and cardiac catheterization, interventional MRI suites, etc.);
(d) special laboratory testing;
(e) emergency resuscitation and trauma care;
(f) major emergency assessment;
(g) maternal newborn Caesarean delivery;
(h) surgery, operating rooms;
(i) surgery, sterile core;
(j) post-anaesthetic care or recovery;
(k) protective isolation rooms;
(l) IT server rooms; and
(m) storage of sterile materials and supplies.

Consideration should be given to providing fully redundant air-handling units to all areas of Class A-1 HCFs (including those not specified in this Clause).

6.5.5.1.1 (j) Interpretation: Airborne Isolation Rooms (AIR) in Class A-1 HCF's must have redundant filter systems and fans on the exhaust airstream to ensure negative-pressure is maintained at all times. For the BIBO filter system, redundancy can either be 100% or N+1 Redundancy. (We will explain the difference between these two types of redundancy in an Appendix to this paper.)

6.7.3

Air filters and associated systems shall be

(a) designed, installed, and located so as to avoid wetting from humidifiers, cooling coils, or other sources of moisture;
(b) composed of materials that do not pose carcinogenic or other health hazards;
(c) designed and installed for ease of access to allow for changing of filters;
(d) equipped with manometers or other pressure-drop monitoring devices;
(e) provided with gaskets or seals, either as an integral part of the filter or as part of the housing or filter-holding frame, to prevent leakage between filter segments, adjacent filter frames, and the surrounding filter plenum enclosure; and
(f) protected during construction by sealing of the associated ductwork to prevent intrusion of dirt, dust, and hazardous materials that could contaminate existing or new filters and associated system components.

6.7.3 (c,d,e) Interpretation: AIR BIBO filter systems should be installed in mechanical rooms whenever possible, to facilitate filter change-out into the bags. Avoid the installation of BIBO filter systems in ceiling spaces and out-of-doors where BIBO change-out and filter certification is extremely difficult to perform. We strongly recommend employing differential pressure gages c/w transmitters, these permit filter DP transmittal to the BMS for filter pressure alarm.

6.7.7

Air filtration on exhaust systems shall be

(a) located as close to the exhaust duct inlet as possible;
(b) in an accessible location to allow for a filter change;
(c) located on the inlet side of the fan; and
(d) provided with air-tight dampers upstream and downstream of filters as a means of isolating and decontaminating the filters prior to removal and replacement.

Procedures shall be established in accordance with Clause 8.1.5 to minimize risk during replacement of filters.

6.7.7 (b,c,d) Interpretation: We recommend locating the BIBO filter system(s) inside mechanical rooms whenever possible, and close to the floor to facilitate BIBO filter change-outs. Opposed bubble-tight dampers should be provided to isolate the filters from the airstream during change-out and to eliminate the possibility of contaminant migration. BIBO filter systems must be located upstream of fans and silencers.

6.10.5 Airborne isolation rooms

6.10.5.1

Airborne isolation rooms shall have

(a) inward directional airflow from adjacent spaces to the room;
(b) sufficient differential between supply and exhaust airflows to maintain a normal operating pressure gradient of 7.5 Pa, measured between the room and the corridor;
(c) directional airflow within the room such that clean supply air flows first to parts of the room where workers or visitors are likely to be present, and then flows across the infection source (i.e., patient area) to the exhaust;
(d) non-aspirating diffusers;
(e) low-level exhaust near the head of the patient bed;
(f) all air exhausted to the outdoors;
(g) HEPA filtration of exhaust in cases where exhaust air is not discharged clear of building openings or where a risk of recirculation exists (see Table 3);
(h) visual indication local to the room to indicate that the room pressure is being achieved;
(i) audible and visual alarms local to the room and at the nurses' station to indicate that the room pressure is not being maintained;
(j) room pressure, alarm system, and supply and exhaust system monitored by a central alarm and control system; and
(k) exhaust fans, alarms, and controls supplied by the essential electrical system.

Where HEPA filtration of exhaust is required, the system shall be arranged such that filters can be changed without disrupting service in the room. This shall be accomplished by having two sets of filters with isolation dampers for each system. Mechanical dampers should be located outside airborne isolation rooms so that they remain accessible for engineering maintenance.

6.10.5.1 (g,k) Interpretation: Exhaust air requires HEPA filtration "where a risk of recirculation exists". When required, HEPA filters must be installed in Bag-in/Bag-out (BIBO) systems. All BIBO systems must have integral bubble-tight dampers and built-in redundancy to permit isolation and change-out of filters without loss of negative pressure at the AIR. BIBO systems should be located in mechanical space outside the AIR to permit access at all times in case of urgent filter or fan service.

6.10.5.2

The following should be considered in the design of airborne isolation rooms:

(a) Exhaust systems should include standby fans with automatic activation to ensure that fan systems are always functional and to maintain negative pressurization in the event of a single fan failure or scheduled maintenance.

6.10.5.2 Interpretation: Fan interlock is required and fan redundancy is mandatory to ensure continuous exhaust from the Airborne Isolation Room(s). Bubble-tight dampers on both sides of all filter systems allows for isolation of each filter system for on-line change-out. This is accomplished by opening the dampers on the stand-by unit and then closing the bubble-tight dampers (BTD's) on the primary filter system to isolate it from the contaminated gas stream. Filters can then be changed-out by BIBO method or by decontamination method.

6.10.5.3 Portable or fixed HEPA filtration units

6.10.5.3.1

Portable or fixed HEPA filtration units may be used as a temporary measure to help older facilities achieve the minimum required number of air exchanges per hour.

Portable or fixed HEPA filtration units shall not be used as a permanent solution for a building installation as the HVAC system's airflow rates, distribution, and pressurization can be compromised.

6.10.5.3 Interpretation: Portable or Fixed HEPA filtration units are NOT a permanent solution and should only be used for temporary negative pressure. A properly engineered redundant BIBO filter/fan should be the permanent solution for AI rooms.

6.13.3 Dedicated exhaust

A dedicated exhaust is defined as an exhaust system serving only areas of identical use. Such systems are generally installed on the basis of one fan per machine, room, area, or type of equipment serviced.

Dedicated nonrecirculating exhaust systems shall be provided for the following equipment and areas:

(a) anaesthetic gas scavenging;
(b) animal facilities;
(c) autopsy suites;
(d) biohazard laminar flow hoods, fume hoods, fume cabinets, chemical storage cabinets, and biosafety hoods;
(e) cart and can washers;
(f) chemical storage;
(g) cooking facilities (see NFPA 96);
(h) ethylene oxide (see CSA Z314.9);
(i) radioisotope hoods;
(j) perchloric hoods;
(k) areas using hazardous gases;
(l) isolation rooms; and
(m) bronchoscopy procedure rooms.

A low-flow sensor and audible and visible alarm shall be provided for each system specified in Items (d), (i), and (j).

Areas of similar function may be combined on a common exhaust system, but radioisotope and perchloric hoods shall have separate exhaust systems.

6.13.3 (l) Interpretation: Airborne Isolation Rooms (AIR's) should have dedicated BIBO HEPA filter systems and dedicated fans. (In other words, 100% of the AIR room air must be exhausted through a dedicated air system.) AIR exhaust air filters and fans must always have built-in redundancy to ensure continuous negative pressure in the AIR and the AIR ante-room.

8.1.5 Filter and seal inspection and replacement

8.1.5.1 General

The condition of filters and seals in Type I and II areas shall be verified by visual inspection at least once a month. In cases where filters cannot be inspected visually, alternate provisions shall be made for inspection.

Note: *The purpose of visual inspection is to verify the presence of the filter or seal and to ensure proper installation and physical condition (e.g., to prevent leakage and dust overload). Visual observation is not an accurate method of determining filter performance.*

8.1.5.2 HEPA filters

Ventilation equipment with HEPA filters and seals shall undergo visual inspection at least once a month. HEPA filters shall be replaced when loaded (based on measurements of pressure drop across the filter bank); in no case shall HEPA filters remain in service for more than 36 months.

HEPA filters that are located downstream of a possible contaminant source (e.g., negative pressure isolation room, operating room) shall be housed in a "bag-in, bag-out" filter housing and replaced by mechanics who have been trained in such procedures.

8.1.5 Interpretation: Interpretation is not required, the clause clearly indicates that Bag-in/Bag-out (BIBO) filter systems c/w bubble-tight dampers must be employed on AIR exhaust. Service must be performed by an accredited contractor to ensure the safety of hospital staff, patients and visitors. Service technician must have NSF or NAFA certification and experience working on BIBO filter systems.

Table 4
Filter efficiency
(See Clauses 6.7.2 and 6.12.4.)

Room type	Minimum MERV rating (Filter #1)	Minimum MERV rating (Filter #2)	Minimum MERV rating (Filter #3)
Specialized operating rooms (transplants, orthopedics)	8	14	HEPA
General operating rooms	8	14	—
Wound intensive care units (burn units)	8	14	HEPA
Airborne isolation rooms (exhaust)*	8	—	HEPA

Table 4 Interpretation: Once again, this Table is clear about the Minimum efficiency for AIR BIBO filter systems: Primary filters must be minimum MERV8 (ASHRAE 52.2 Std.) and HEPA filters must be minimum 99.97% @ 0.3 microns (Acceptance Level "A", per IEST-RP-CC001.5). **For AIR Exhaust, IAS recommends using 99.99% @ 0.3 micron high-capacity HEPA filters that are scan tested at the factory to IEST Acceptance "C".**

Here's a summary of our interpretations of the CSA Z317 Standard, with respect to **Airborne Isolation Room (AIR)** exhaust:

1. AIR Exhaust must be HEPA filtered (in any application where re-entrainment is possible) and, when employed, HEPA filters must be housed in a side-access Bag-In/Bag-Out (BIBO) type housing. The BIBO filter system must have opposed bubble-tight dampers (BTD's) to permit isolation of the filter housing for change-out while the system remains online 24/7.
2. AIR BIBO HEPA filter systems must be either 100% (Fully) Redundant or N+1 Redundant to permit filter change-out while the system remains on-line 24/7. Likewise, AIR's require fully redundant fans or equal capacity to ensure adequate negative pressurization of the AIR in the event that one filter hits High-DP alarm or if one of the fans goes off-line for any reason. Fans should be interlocked to ensure that only one fan runs at a time and that the standby fan is automatically started-up if the primary fan goes off-line for any reason.
3. BIBO filter systems must have a two-stage filter system (at minimum): Primary filter must be MERV8 efficiency as minimum and the final stage filter must be 99.97% @ 0.3 micron HEPA filter as minimum efficiency.
4. BIBO filter systems must have a Differential-Pressure (DP) gage across each filter section, and it is preferred if a gage/transmitter is employed so that the filter DP alarm can be transmitted to the BMS.
5. The BIBO filter system must be located in a "service friendly" location due to the inherent difficulty of performing a filter change-out on a BIBO system. Ideal location is on a housekeeping pad (or base/skid) minimum 6" AFF within a mechanical room with minimum 48"x48" clearance on the filter door side of the system. Second choice is roof-top location on a stand minimum 24" above roof (in case of snow accumulation), and third choice is AIR Ante-room ceiling space with 36"x36" access hatch, positioned below the filter access door.
6. BIBO filter service must be performed by accredited and thoroughly trained and experienced technicians. Accreditation by NAFA or NSF is recommended. PPE and procedures to industry and hospital Infection Control standards and SOP's.
7. Replacement Filters must be "equal-to or exceed" OEM performance specifications. IAS/CTC recommends the use of 99.99% @ 0.3 microns HEPA filters, Factory scan-tested to IEST Acceptance "C". All HEPA filters should be High-capacity type, with capacity of 2000CFM @1.45"wc (Initial Pressure Drop) maximum. Maximum service life of 36-months as indicated in section 8.1.5.2.