

Consensus Statement re: High Relative Humidity in Sterile Storage Areas

Prepared August 1, 2007, by an ad hoc committee of sterilization experts attending a Canadian Standards Association meeting

Introduction:

Current guidelines provide ranges for acceptable humidity levels in healthcare sterile storage areas of 30 – 60% relative humidity. The CSA Sterilization Standards Committee has recommended that the range for acceptable relative humidity for sterile storage should be 30-70% (unless contraindicated by device manufacturer). This range is to replace the current 30 – 60%, and is based on the recommended range in the American Standard; ANSI/AAMI ST79 “*Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities*”.

Note: The upper limit of 70% is only for dedicated sterile storage areas – all other areas (e.g. reprocessing depts.) have the upper limit for humidity as 60%.

The relative humidity is affected by the temperature^{1,2} however, since the problems associated in healthcare sterile storage are primarily related to excessive moisture, this consensus statement focuses only on how to deal with excess humidity issues.

Facilities that provide healthcare services have a responsibility to ensure that the air-handling system is designed to achieve the relative humidity range indicated. Relative humidity in sterile storage should be monitored, recorded and reviewed by the reprocessing personnel on an ongoing basis (daily monitoring preferred). Frequency of monitoring should be increased if problems are encountered. It is important that an independent humidity monitor be used in each sterile storage area and that it is calibrated regularly (as per manufacturer’s recommendations). Humidity monitors available from hardware and department stores may not be reliable for healthcare monitoring purposes.

The concern when relative humidity is > 70% relates to damage to the integrity of the package (e.g. “wicking” of microorganisms through the packaging) and moisture levels that will allow microbial growth (especially airborne fungi).

Exposure to > 70% relative humidity is an “event” and maintenance of sterility during storage is “event-related”. If packages are exposed to these conditions for long enough periods of time – sterility might be compromised. There is no published data to conclusively determine what the maximum allowable exposure time is for packages that are exposed to high humidity.

This ad hoc committee felt there should be some consensus guidance provided for users when high humidity is an issue. The following actions were proposed by the committee:

Action 1:

Immediately initiate corrective action including:

1. Notification to facility management dept of excess humidity reading in sterile storage and ensure they implement remedial action.

2. Convene a meeting with stakeholders and determine if transfer of packages to an alternative site with controlled humidity is feasible. Keep as little inventory as possible in the affected storage areas.

Action 2 (visible effect of moisture):

If packages are visibly wet or damaged (e.g. labels peeling due to moisture or visible moisture on the package), the packaged items shall not be used. The contents need to be repackaged and sterilized (or discarded if single-use medical devices).

Action 3 (no visible effect of moisture):

If > 70% relative humidity is detected:

1. the packages should be assessed for moisture
2. if not visibly wet or damaged the consensus of the ad hoc committee is that these packages may be used
3. if the next humidity reading 24 hrs later is still > 70%, then the site needs to perform a risk assessment to determine which items may be used, reprocessed or discarded. Consideration should be given to the following:

A. Storage environment:

To reduce the risk of accidental contamination it is critical that packaged items be stored in a limited access area, where the storage shelves are clean and environment maintained as per CSA standards (Z314.15, Z314.2, Z314.3).

Personnel with appropriate attire and frequent hand hygiene are an integral aspect of ensuring an appropriate storage environment. When relative humidity levels exceed 70% having a controlled storage environment helps reduce the risk of contamination.

B. Packaging:

Some packaging materials are more able to withstand the effects of high humidity than others. Generally, packages that have plastic covers or are sealed in aluminum foil pouches are relatively impermeable to moisture whereas the plastic-paper pouches and uncoated textile wraps are permeable to moisture. To obtain more details on the permeability of the specific packaging used on site, the manufacturer or supplier should be contacted.

C. Duration of exposure to high humidity

Generally speaking, the longer the exposure of the package to excess humidity the greater the risk of contamination. Routine/continuous monitoring is important to evaluate the duration of exposure to high humidity.

References:

1. CSA Z317.2 Special requirements for heating, ventilation, and air-conditioning (HVAC) systems in healthcare facilities.
2. CSA Z314.3 Effective sterilization in healthcare facilities by the steam process.
3. CSA Z314.2 Effective sterilization in healthcare facilities by the ethylene oxide process.