RESPONSE TO HUMIDITY CONTROL EVENTS IN STERILE STORE & PERIOPERATIVE AREAS

Health Technical Advice. HTA-2019-001

Victorian Health and Human Services
BUILDING AUTHORITY

VICTORIA State Government

Contents

Preface

The purpose of this technical note is to provide guidance to healthcare practitioners on actions that should be taken in the event of humidity range excursions in sterile store and peri-operative areas.

Excursions of humidity outside of the controlled range for extended periods can cause significant impact to the health service organisation (HSO). The full implications of these events are often not realised until well after the humidity excursion. Impacts realised are not only financial, due to loss of stock that must be discarded but also additional work hours required by HSO staff to reprocess/rectify stock. There is also the flow on effect to surgical lists and elective wait times which add to the overall impact of the event. Additionally, the impact to staff morale and psychological impact along with service reputation is difficult to measure.

The proper handling, storage and transport of reusable medical devices and commercially manufactured sterile stock is essential to ensure that sterility is not compromised.

HSO are required to have written policies and procedures for the storage and handling and transportation of commercially obtained and reusable medical devices stock that is consistent with AS4187.

Introduction

Humidity can change quickly in spaces depending on temperature and moisture being introduced to the space from both internal and external sources. Taking the humidity in a space as an absolute value at any time is therefore a tricky thing to define. The issue is a hot topic globally in the healthcare community, and ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers) issued a paper in 2018 “Humidity Control Events in Perioperative Care Areas”[1] to clarify the responses required.

This paper draws directly from the principles set out in the white paper and adapts them to an Australian healthcare environment.

The relative humidity levels commonly accepted in healthcare facilities are:

Peri-operative areas – 40% to 60% (VHHSBA Engineering Guidelines for Healthcare Facilities)

Sterile storage areas – 35% to 70% (AS4187)

[1] *ASHRAE – Humidity Control Events in Perioperative Care Areas; ASHRAE Technical Committee 9.6, Healthcare Facilities*

Why is humidity important in healthcare?

We are unable to see water molecules. We are only able to see water when it is in its liquid or solid form. The water vapour in the air around us is continually switching states between liquid and vapour long before it reaches a saturation point. The higher the humidity the greater the frequency of water forming and immediately evaporating again. At point of saturation (100% RH) the water condenses and does not re-evaporate, the liquid and vapour states reach equilibrium, and we are able to see it as condensation. At lower humidity water is always condensing and evaporating, we are just unable to see it.

Figure 1 shows that at a RH of >60%, there is enough water condensing in the air and on surfaces to support growth at a microbial level under certain temperature conditions. The more humid the air becomes the wider the temperature band that can support biological growth. It is therefore important to recognise this and control the amount of water vapour in the air to ensure that surfaces and equipment that are required to be sterile are not exposed to elevated humidity conditions.

Experts have determined that prolonged exposure to saturation levels greater than 70%, would provide enough moisture to support microbial growth, and therefore a limit of 70% RH has been set in AS 4187[2] for storage of sterile stock.

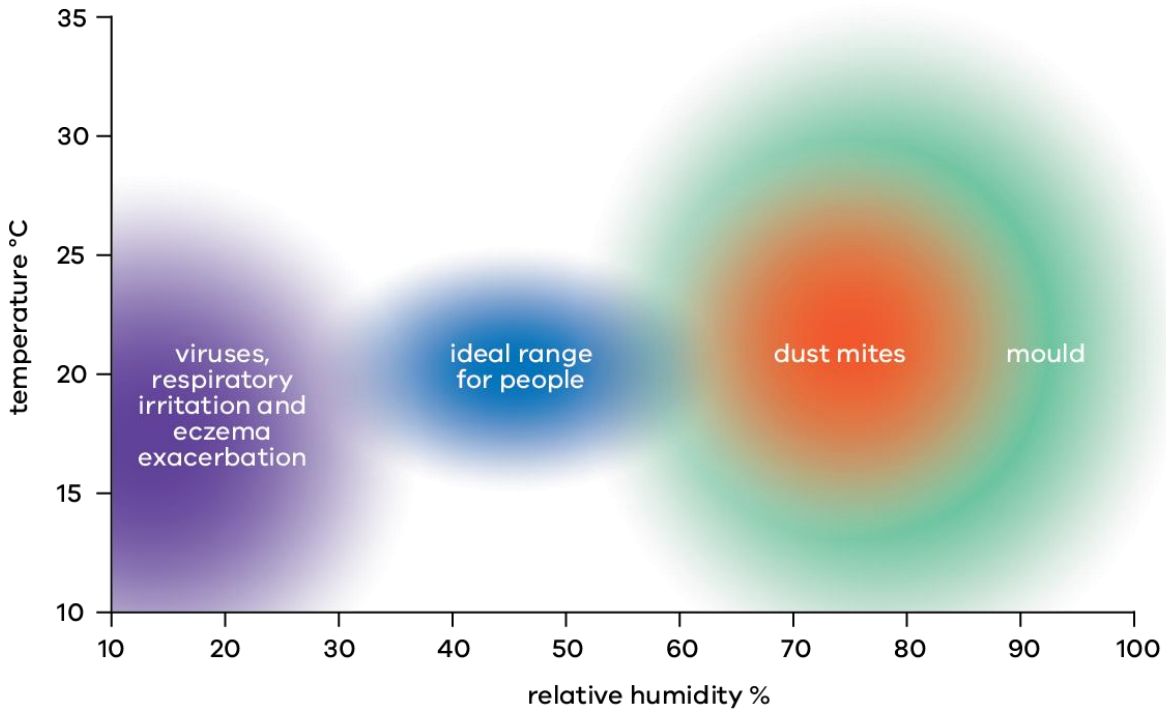

Figure 1 Humidity and its effects on our environment

It should also be noted that, in a healthcare scenario low humidity can also be a problem, water vapour is able to evaporate (escape) very easily and is not recaptured. This can lead to drying of moist tissue, discomfort, degradation of materials, AS 4187 recognises the lower limit as 35%.

[2] *AS/NZS 4187:2014 (incorporating Amendment Nos 1 and 2). Reprocessing of reusable medical devices in health service organizations.*

Protocol for establishing RH ranges in healthcare.

Humidity event review team (HER Team)

The healthcare facility should establish a humidity event review team (HER), to periodically review issues potentially relating to humidity control such as:

- changes to existing codes and standards
- infection control statistics
- facility indoor RH levels
- research trends

Note: Smaller health service organisations could consider having a permanent item on the perioperative or infection control committee meeting agenda for the periodic review of humidity control issues.

Ideally the team should comprise:

- hospital management
- infection control professional
- clinical professional
- hospital engineer

The 1st priority of the team would be to establish upper and lower RH limits for the spaces that they will review. Initially these limits may well be those established in the department guidelines.

Humidity Control Events

The HER team should be available to respond to humidity deviation events and assess the following impact to the facility:

- period and extent of the relative humidity deviation
- infection risk to patients
- level of clinical staff and patient comfort
- confidence of the facility engineering team's response for resolution

At the HER meeting the facility team should report on the relative humidity values in the rooms in question, and relevant information such as instrument calibration and duration of the humidity control event (e.g. the RH has been 65% in space Z for the last 8 hours).

Consideration by the HER Team

In the event of a humidity excursion event (low or high), the areas of risk that the team should consider are as follows:

- potential for mould and mildew in RH events
- integrity of the sterile stock in the spaces effected
- the equipment calibration
- transmission of airborne and droplet diseases
- potential survival rate for pathogens
- discomfort for the clinical teams
- decreased effectiveness of hand hygiene and surface cleaning because of surface re-contamination
- potential for the loss of healthy immune system functioning (respiratory, epithelium, skin etc) in vulnerable patients.

Responses to Humidity Control Events

Upper limit approached or exceeded in Sterile stores (35% to 70%)

If the upper limit is approached -5%RH (i.e. 65% of more) for over 2 hours, the facility engineer / maintenance team should take corrective action and inform the HER Team.

If the RH is more than 5%RH above the upper RH limit (i.e. 75% or more) for more than 8 hours, it is very likely that the mechanical system requires repair. HER team should consider the risk to the stock and advise on the appropriate course of action, see next section.

Lower Limit exceeded in Sterile stores (35% to 70%)

If the RH is up to 5%RH below the lower RH limit for over 6 hours, the facility engineer / maintenance team should take corrective action and adjust the mechanical system to bring the RH up. The HER Team should be informed if the RH is out of range for more than 12 hours, and the HER team should consider the risk to the stock and advise on the appropriate course of action, see next section.

Upper limit exceeded – Perioperative areas (40% to 60%)

If the RH is more than 5%RH above the upper RH limit (i.e. 65% or more) for over 2 hours, the facility engineer / maintenance team should take corrective action and inform the HER Team. If the RH is more than 10%RH above the upper RH limit (i.e. 70% or more) for more than 8 hours, it is very likely that the mechanical system requires repair. HER should consider halting operations until the situation is resolved.

If the upper limit is exceeded by 5%RH (65%) for over 6 hours the facility team should take corrective action and adjust the mechanical system to bring the RH down. The HER team should convene if the RH is out of range for more than 12 hours.

If the RH is up to 5%RH above the upper RH limit for more than 24 hours, the HER Team should consider halting operations for repairs. Traffic limiting, enhanced cleaning between cases, and perspiration controls may be added at the discretion of the HER Team.

Lower Limit exceeded – Perioperative areas (40% to 60%)

If the RH is up to 5%RH below the lower RH limit for over 6 hours, the facility engineer / maintenance team should take corrective action and adjust the mechanical system to bring the RH up. The HER Team should be informed if the RH is out of range for more than 12 hours. If the RH is up to 5%RH below the lower RH limit for more than 24 hours, the HER Team should consider halting operations for repairs.

Humidity Event Review Team Appropriate Actions

Sterile Stores – High Humidity Event

Visible effect of moisture (Action 1)

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

No visible effect of moisture (Action 2)

- If > 75% relative humidity is detected for +8hrs the packages should be assessed for moisture.

If not visibly damp, wet or damaged the consensus is that these packages may be used[3]. Where practical consideration should be given to relocating the stock from the affected area until the issue is resolved.

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 are stored in a limited access area, where the storage shelves are clean and the environment is maintained in accordance with standards. 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 aluminium 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

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.

Sterile Stores – Low Humidity Event

Sterile stores – low humidity (Action 3)

If humidity is < 30% for 12 hrs, some packaging materials are unable to withstand prolonged exposure to low humidity, the manufacturer or supplier should be contacted.

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[3] *Consensus Statement, Canadian Standards Association Meeting August 2007, Consensus Statement re: High Relative Humidity in Sterile Storage Areas*

Perioperative Area - High Humidity Event

Perioperative High Humidity (Action 4)

If the RH > 70% for +8hrs or > 65% for +24hrs, the HER team should consider halting operations until the situation is resolved.

Perioperative Area - Low Humidity Event

Perioperative Low Humidity (Action 5)

If the RH <30% for +24hrs, the HER team should consider halting operations until the situation is resolved.

References and Bibliography

ASHRAE – Humidity Control Events in Perioperative Care Areas; ASHRAE Technical Committee 9.6, Healthcare Facilities

AS/NZS 4187:2014 (incorporating Amendment Nos 1 and 2). Reprocessing of re-usable medical devices in health service organizations.

Consensus Statement, Canadian Standards Association Meeting August 2007, Consensus Statement re: High Relative Humidity in Sterile Storage Areas

Victorian Health & Human Services Building Authority – Engineering Guidelines for Healthcare Facilities (2019)

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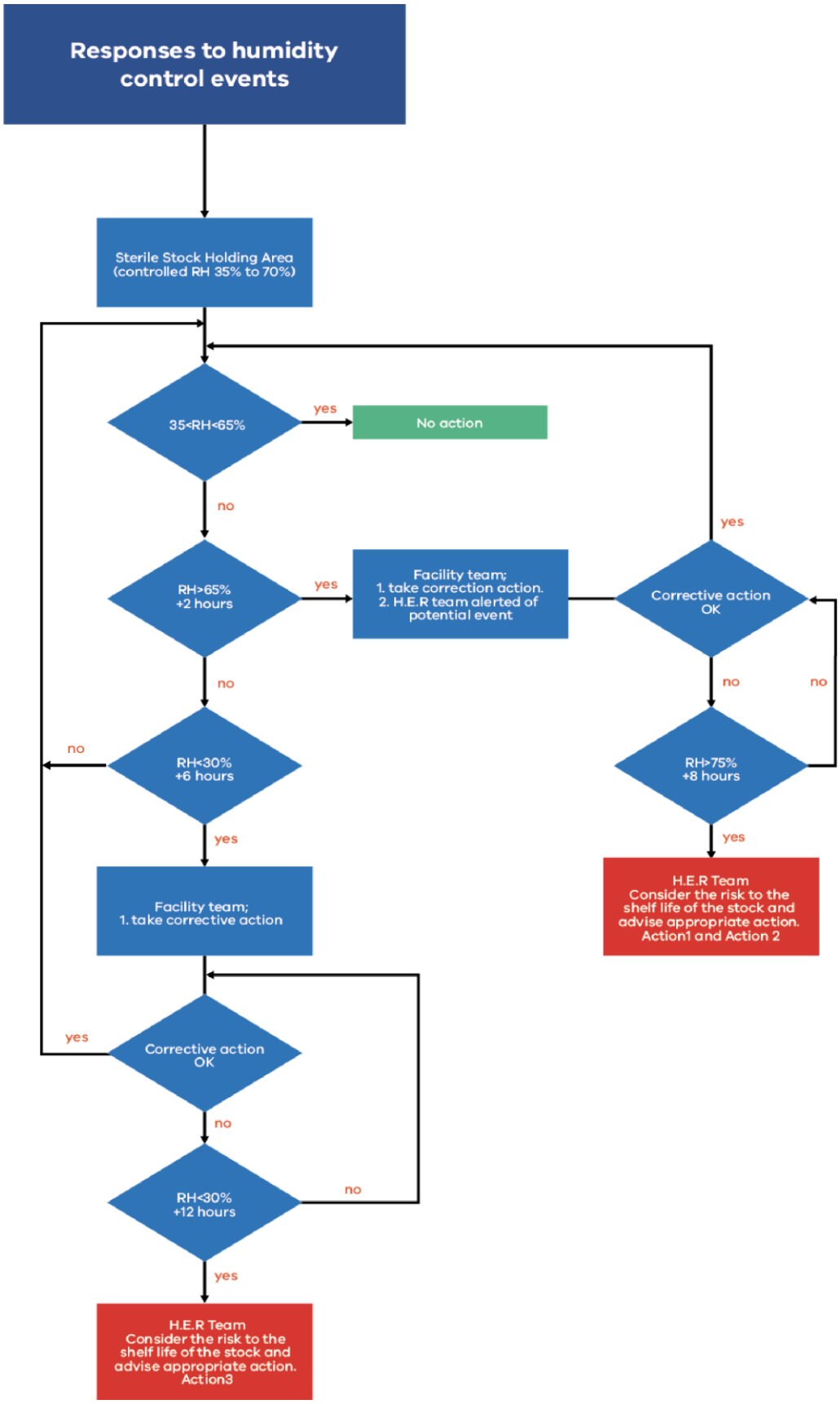
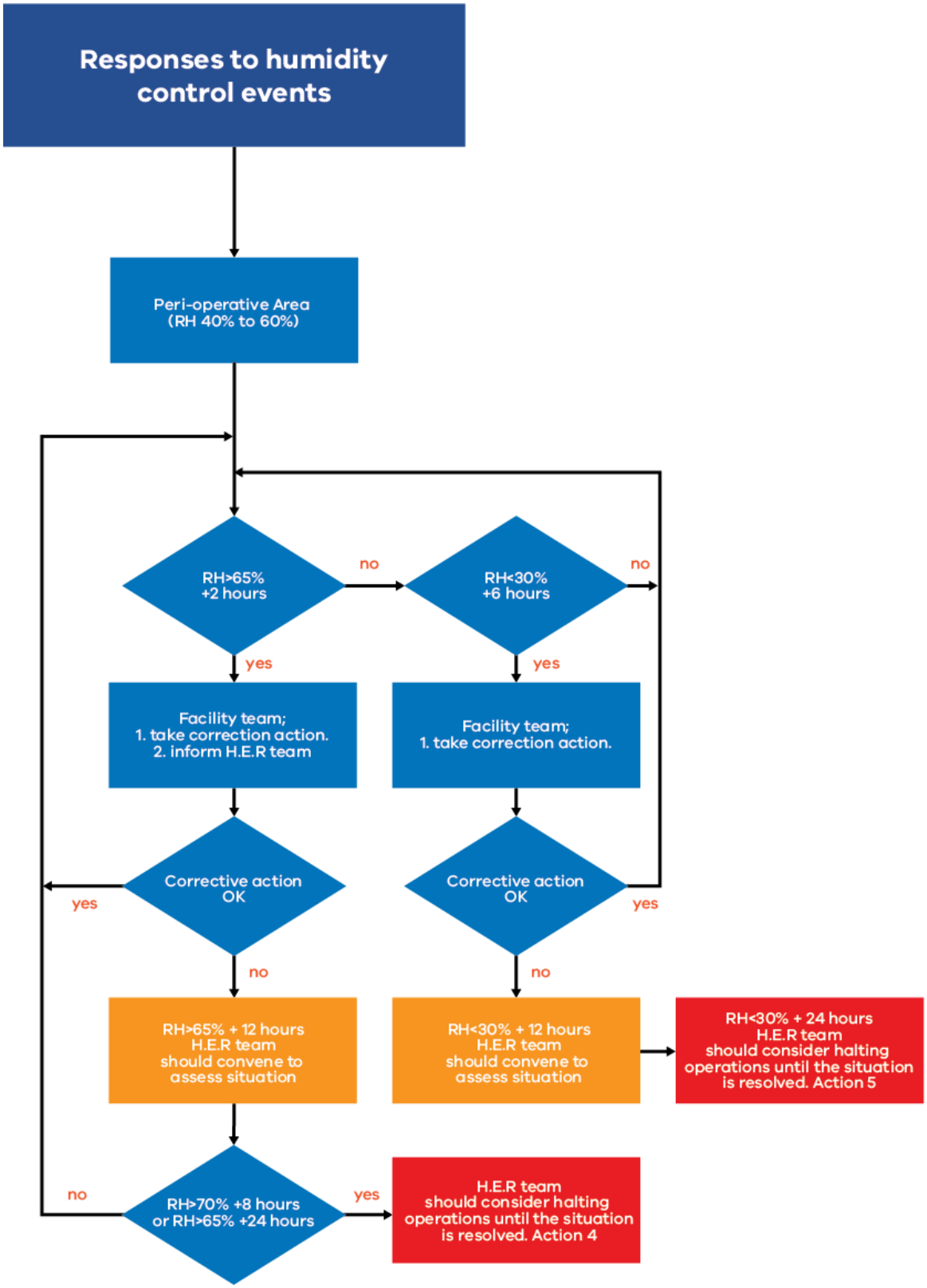
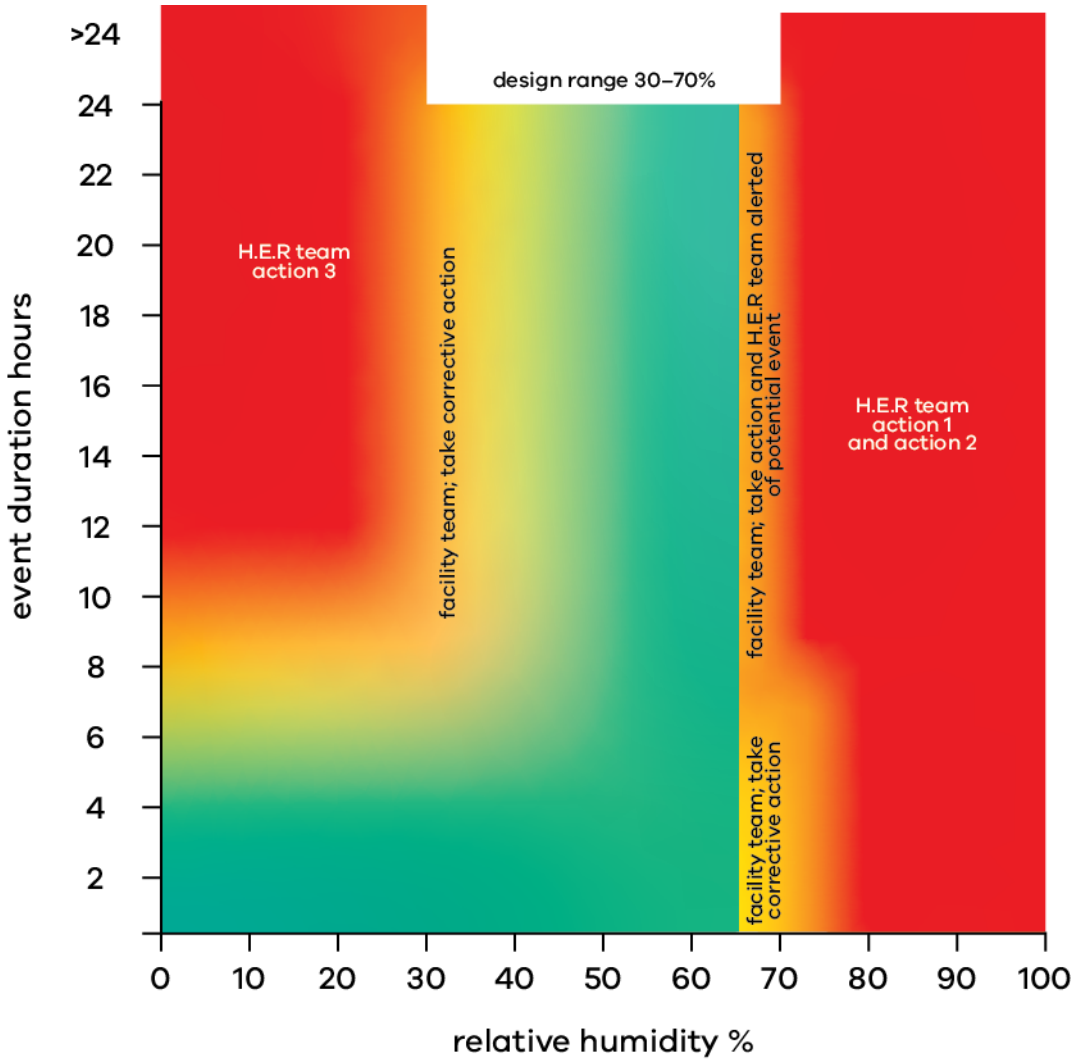
Action Flow Chart – Sterile Stores



Action Flow Chart – Perioperative Areas



Zone Charts – Sterile Stores



AS 4187 Sterile store

Action 1 – Visible 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 sterilised (or discarded if single-use medical devices).

Action 2 – No visible moisture

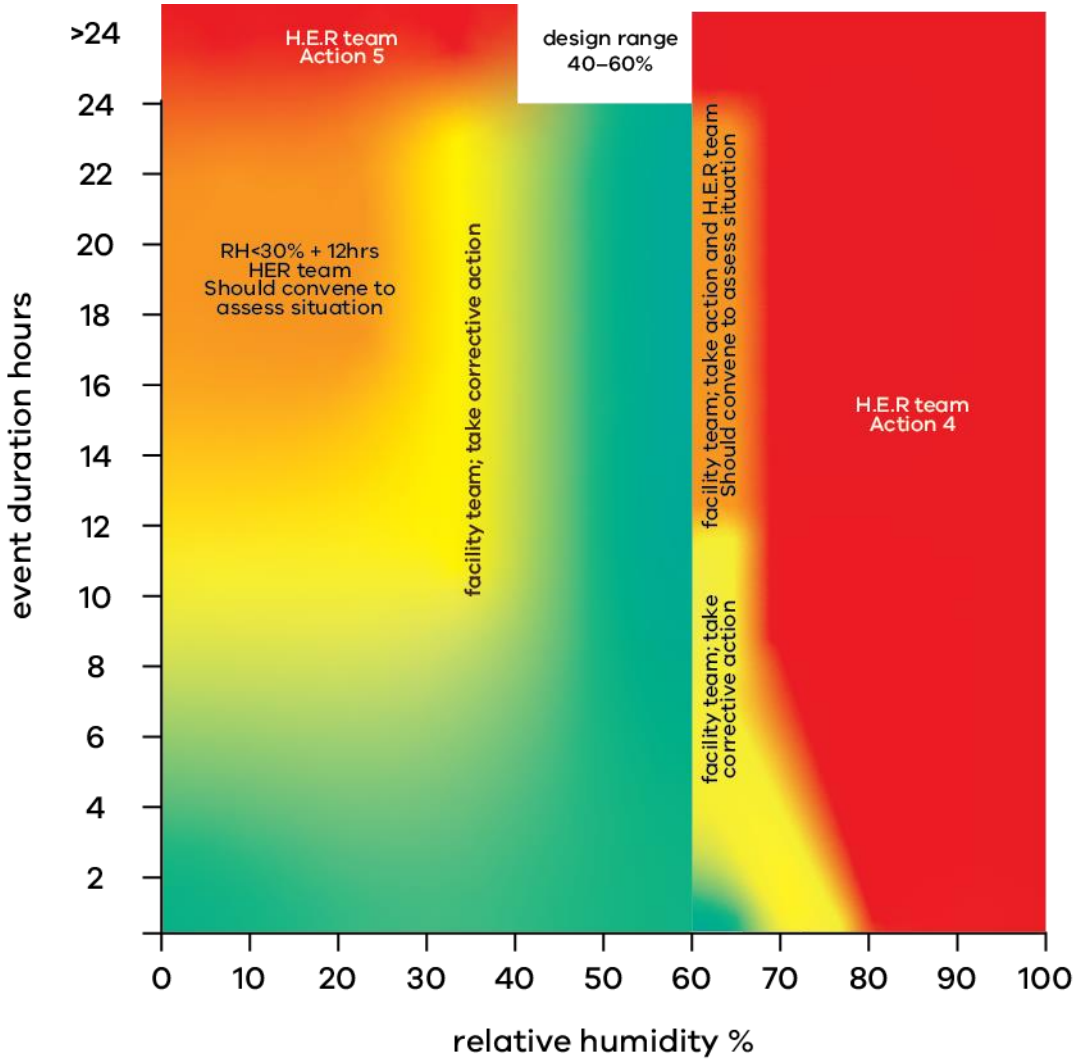
If not visibly wet or damaged the consensus is that these packages may be used (see technical note).

If the next humidity reading 24 hours 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:

Action 3 – Low humidity event

some packaging materials are unable to withstand prolonged exposure to low humidity, the manufacturer or supplier should be contacted.

Zone Charts – Perioperative Areas



Peri-operative areas

Action 4 – High Humidity event

If the RH > 70% for + 8hrs or > 65% for +24hr, the HER team should consider halting operations until the situation is resolved.

Action 5 – Low Humidity event

If the RH < 30% for + 24hrs, the HER team should consider halting operations until the situation is resolved.