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Luftfugtighed og opbevaring

Elsebeth Tvenstrup Jensen, SSI – FSTA 25. april 2024

Agenda

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- Hvor ligger grænserne og hvorfor?
- Overskridelse – kan kort tids overskridelse accepteres?

Udgangspunkt

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- DK (NIR Genbehandling af steriliserbart medicinsk udstyr, 2019)
  - Luftfugtighed <70 % rH
  - Temperatur max. 24 °C
  - Ingen større temperatursvingninger jf. dugpunktsberegning
  - Ingen større trykvariationer

- CDC
  - The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%).

Emballagemateriale/-systemer til sterilvarer - inderste (primære) lag

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- Man skal kunne evakuere luft fra pakken
- Luften skal kunne diffundere ud igen
- Emballagen skal være impermeabel for mikroorganismer
- Man skal kunne dampsterilisere (autoklavering/sundhedssektoren)
- Man skal kunne sterilisere med ethylenoxid (industrien)

Generelle krav til emballage

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4 Requirements

NOTE. Guidance on the interpretation of these requirements is given in annex A.

4.1 General

4.1.1 The conditions under which the packaging material and/or system is produced, stored, transporte and handled shall be established, controlled and documented, if applicable, in order to ensure that:

– the conditions are compatible with the use for which the packaging material and/or system is designed; and

– the performance characteristics of the packaging material and/or system is maintained.

As a minimum, the following shall be considered for a packaging materials and/or systems:

– temperature range;

– pressure range;

– humidity range;

– maximum rate of change of the above, where necessary;

– exposure to sunlight or UV light;

– cleanliness;

– bioburden.

NOTE. The bioburden of the packaging material and/or system should be considered when determining the sterilization process parameters.

Producenten af emballagemateriale/-system skal som minimum overveje følgende:

- Temperatur-interval
- Tryk-interval
- Luftfugtighed-interval
- Evt. max. ændringshastighed for ovenstående
- Udsættelse for sollys eller UV-lys
- Renhed
- Bioburden (hvor kontamineret er materialet)

Uddrag af DS/EN 868-1:1997 (dog ikke gældende)

Faktorer af betydning for fortsat sterilitet

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NOTE 2. The maintenance of sterility by a packaging material and/or system is judged by the ability of the packaging to prevent the ingress of micro-organisms. Many factors affect the extent of such ingress. These include, but are not limited to:

- the level of micro-organisms in the environment;
- the sizes of particles on which the micro-organisms occur;
- environmental conditions of temperature, humidity and pressure and the rate of change of these conditions;
- flow rates through the layers of packaging material;
- pore size and other filtration parameters of the packaging material.

Uddrag af DS/EN 868-1:1997 (dog ikke gældende)

Emballagematerialets/-systemets fortsatte sterilitet vurderes på, om indtrængning af mikroorganismer kan undgås.
Her har bl.a. følgende faktorer betydning:

- Mikroorganismer i omgivelserne
- Partikelstørrelse (som bærer mikroorganismerne)
- Omgivelsernes temperatur, luftfugtighed og lufttryk samt hastigheden, hvormed de ændres
- Flow-hastighed gennem emballagelagene
- Emballagematerialets porestørrelse og andre filtreringsparametre

Fysiske rammer – krav til opbevaring

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6.5 Fysiske rammer – krav til opbevaring

a) Produkter bør opbevares i et formålsegnet, separat lokale.
b) Området må ikke anvendes til almindelig passage eller som transportvej.
NOTE 1 – Der henvises til ANSI/AAMI ST79:2006, 3.2.3 og 3.3.7.1 [7]; AS/NZS 4187, 2.5 [8]; GMP, 3.7 [6].
NOTE 2 – Et formålsegnet, separat lokale af den i a) nævnte type betegnes ofte som et depot.
c) Adgangsforholdene skal være passende, og adgangsregler til opbevaringslokalet skal fastsættes.
NOTE 3 – For inspiration henvises til ANSI/AAMI ST79:2006, 3.2.4 [7]; AS/NZS 4187, 9.2.2 [8] samt GMP, 2.11, 3.5 og 5.16 [6].
d) Luftfugtigheden i opbevaringslokalet skal ligge under 70 % rH.
NOTE 4 – Fugtigt miljø kan medføre kondensdannelse og øger dermed risikoen for gennemtrængning af mikroorganismer ved diffusionsbare emballageformer. Der er endog rapporteret dødsfald på grund af kontaminering med *Aspergillus fumigatus* [11].
e) Temperaturen i lokalet bør maks. være 24 °C.
NOTE 5 – Vedrørende c) og d) ovenfor henvises til ANSI/AAMI ST79:2006, 3.3.6.5 og 3.3.6.6 [7]; AS/NZS 4187, 9.2.1 [8]; [9], 2.3.
f) Der må ikke forekomme større temperatursvingninger [80].
g) Der bør ikke forekomme større trykvariationer [80].
NOTE 6 – Efterhånden anføres det i flere og flere standarder, at holdbarhed ikke er tidsrelateret men hændelsesrelateret. Det betyder, at fastsættelse af udløbsdato bør ske på baggrund af en videnskabelig risikovurdering af barriereegenskaberne (filtereffektiviteten) sammenholdt med de aktuelle miljøforhold. Ved fastsættelse af renhedskrav ved hændelsesrelateret holdbarhed bør det mikrobiologiske krav leve op til ISO klasse 8 [80].

DS 2451-13:2010 kapitel 6.5

Svampeinfektion efter rygmarvsbedøvelse ved kejsersnit

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Aspergillus meningitis following spinal anaesthesia for caesarean section in Colombo, Sri Lanka

N. Rodrigo, K. N. T. Perera, R. Ranwala, S. Jayasinghe, A. Warnakulasuriya, S. Hapuarachchi
Colombo, Sri Lanka

SUMMARY. We report six cases of Aspergillus meningitis after spinal anaesthesia for caesarean section administered in June and July 2005. Three patients died before a fungal infection was confirmed at the first post-mortem examination in August. Thereafter anti-fungal therapy was successful in saving the lives of the other three patients. Some syringes and spinal needles supplied to the hospitals concerned were found to be contaminated with Aspergillus fumigatus. Investigators found that medical supply storage facilities were substandard following the influx of donations after the tsunami of December 2004.

- 6 tilfælde af meningitis med *Aspergillus fumigatus* (3 døde) efter rygmarvsbedøvelse
- Dyrkning påviste *Bacillus*-arter på 27 sprøjter og *Aspergillus fumigatus* på 13 sprøjter og 2 spinal-kanyler (fra lagrene på de pågældende hospitaler)
- Inspektion af lager viste uacceptable forhold

Samlet antal sprøjter og kanyler testet fremgår ikke af artiklen.
Alle de anvendte og testede emner var stadig pænt inden for udløbsdato.

Svampeinfektion efter rygmarvsbedøvelse ved kejsersnit, årsag til forurenet udstyr?

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They found that sterile disposable items of equipment, particularly syringes, were stored under conditions that did not conform to recommended standards of storage for medical equipment.
All contaminated syringes were obtained from stores at Colombo 6, which was an old building acquired for use after the tsunami of 2004. Inside the stores both the temperature (41C) and humidity (>75%) were found to be unacceptably high. Also some syringes had been obtained from sources that could not be traced due to inefficient store management.

- Lageret var en gammel bygning
- Temperatur 41°C
- Fugtighed > 75 %

Containere – lige så udsatte for ændringer?

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Measurement of the microbial barrier effectiveness of sterilization containers in terms of the log reduction value for prevention of nosocomial infections

Hartmut Dunkelberg, MD, and Friederike Fleitmann-Glende, MS
Goettingen, Germany

RESULTS

The 105 standard containers could be categorized as 11 containers with paper filters, 79 containers with reusable textile filters, and 15 containers with permanent plastic filters. Two, 300-cm^2 plates filled with Sabouraud agar could be placed in each of these containers. Figure 1 shows the cumulative distribution of containers with increase of CFU per 600 cm^2. Two out of 11 containers with paper filters and 9 out of 79 containers with textile filters remained without colony growth on the plates. The mean LRVs were >4.1 (sterile container with paper filter) and >3.9 (sterile container with textile filter).

Furthermore, the barrier effectiveness of 5 brand new standard containers with permanent plastic filters was compared with that of double-layer paper wrapping and nonwoven material. No nonsterile containers or nonsterile double-layer packages could be observed in any case. The mean LRV was >4.25.

Metode:
Containerne blev placeret i kammer og udsat for spray med mikroorganismer under forskellige trykforhold.
Tp. ikke angivet, rH kontrolleret (ingen kondensdannelse).
I containerne var placeret agarplader, som bagefter blev undersøgt for vækst.

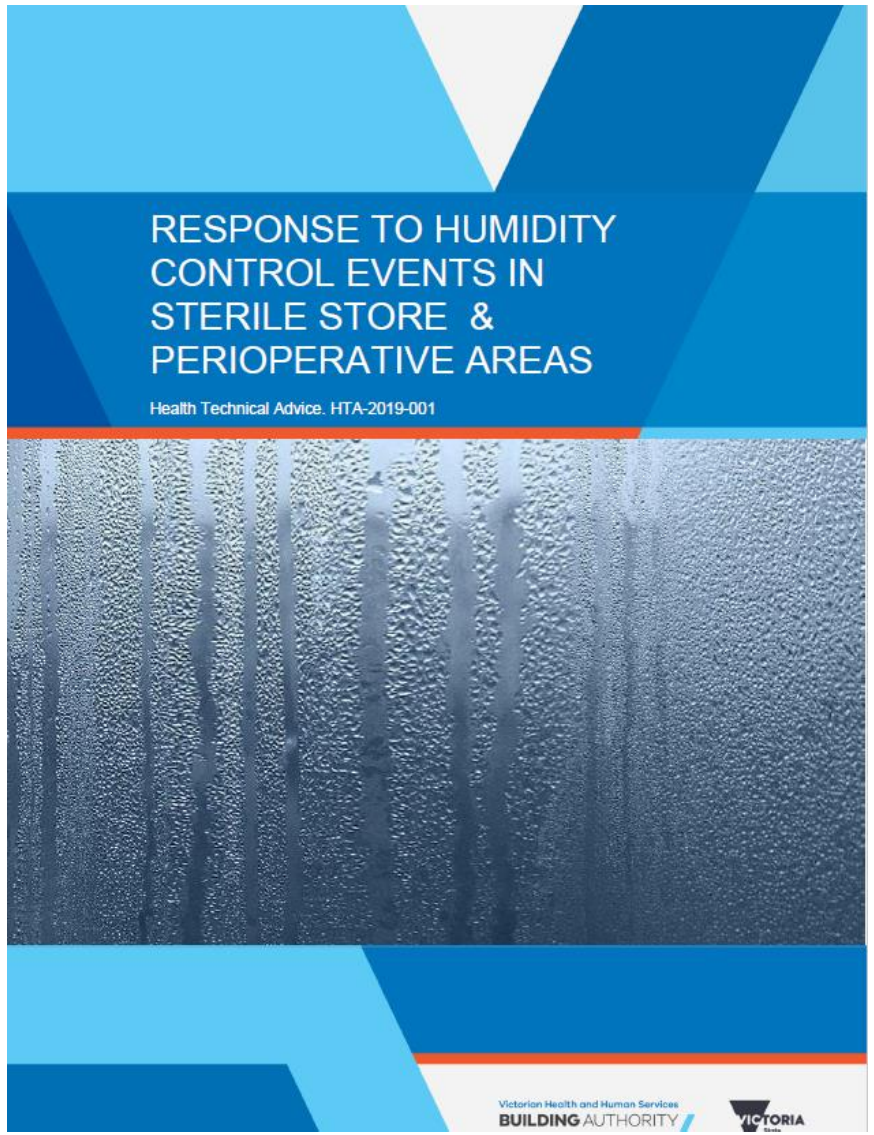
Ingen vækst efter udsættelse for mikroorganisme-spray i

- 2/11 containere med papirfilter
- 9/79 containere med tekstilfilter
- 14/15 containere med plastikfilter

Desuden blev 5 helt nye containere med plastikfilter sammenlignet m dobbelt papir/non-woven emballering: Alt indhold var sterilt efter udsættelse uanset emballeringstype.

Dunkelberg 2006

Sterildepot o.l. – Luftfugtighed > 70 % rH



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.

Sterildepot – hvornår og hvilken handling påkrævet?

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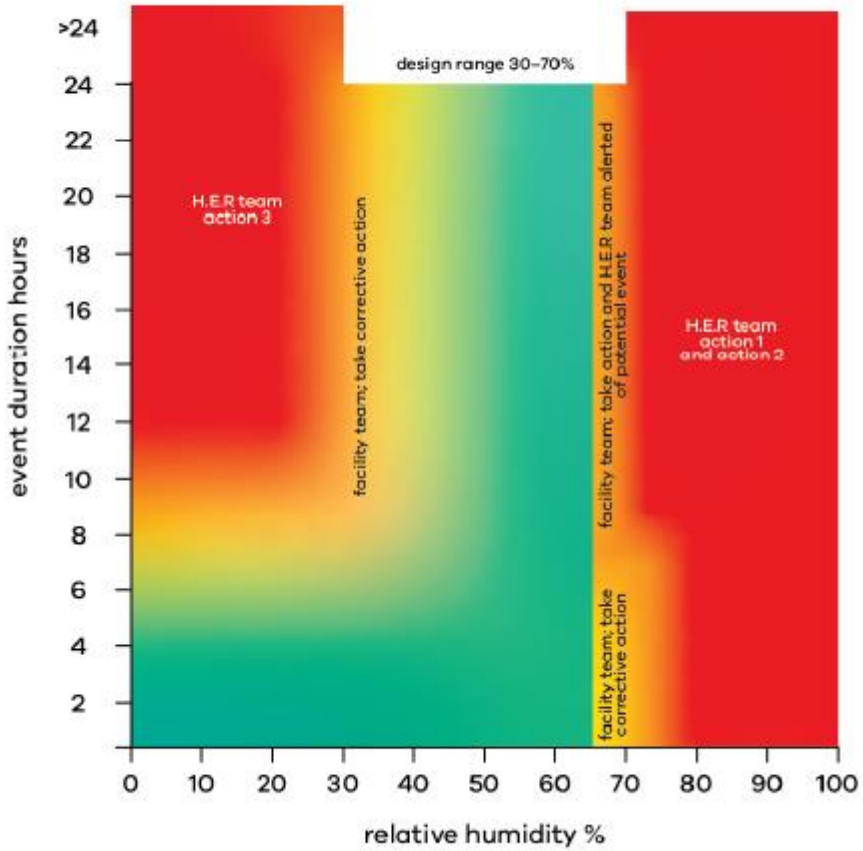
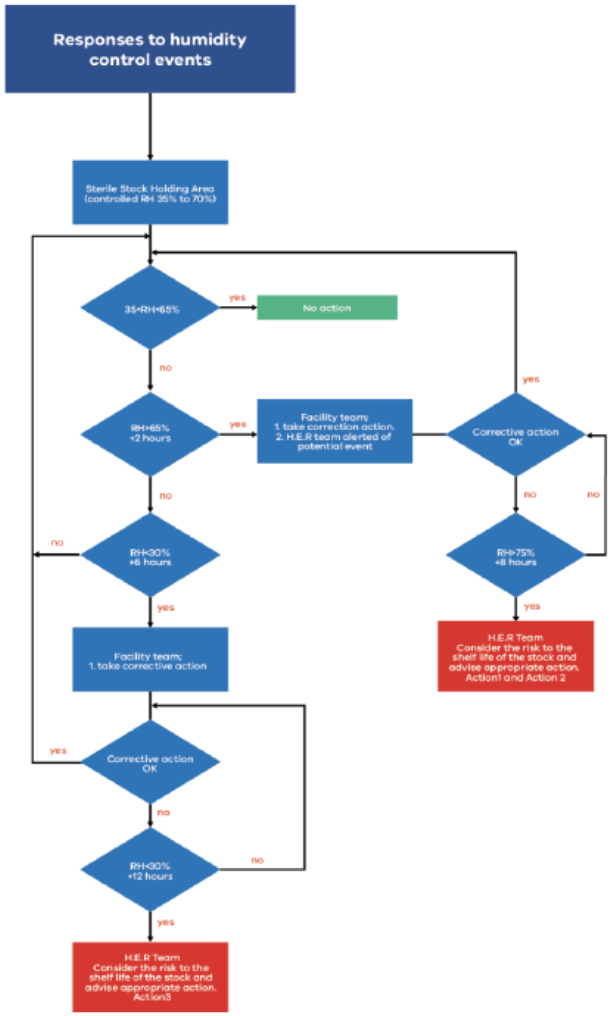
Zone Charts – Sterile Stores



Action Flow Chart – Sterile Stores



Operations-området – hvornår og hvilken handling påkrævet?

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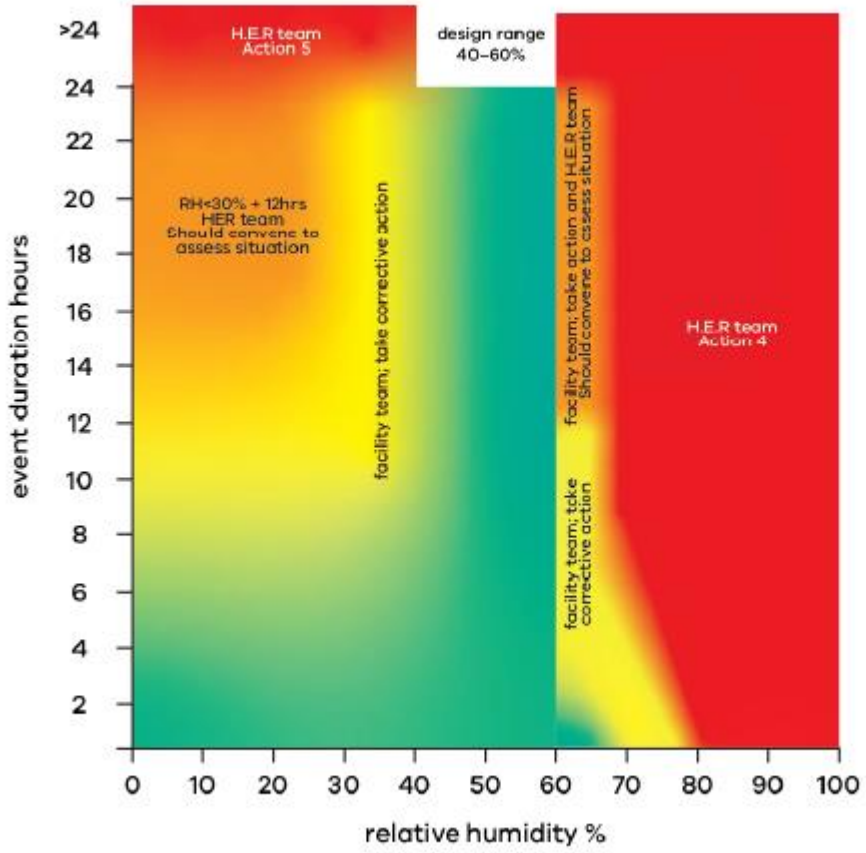
Zone Charts – Perioperative Areas



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.

Action Flow Chart – Perioperative Areas