

Routine monitoring of the disinfection / washing process ISO 15883

WFHSS

Oman

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Peter Newson

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Objectives

Validation

Parametric release

Validation tools

Routine Monitoring

Conclusion

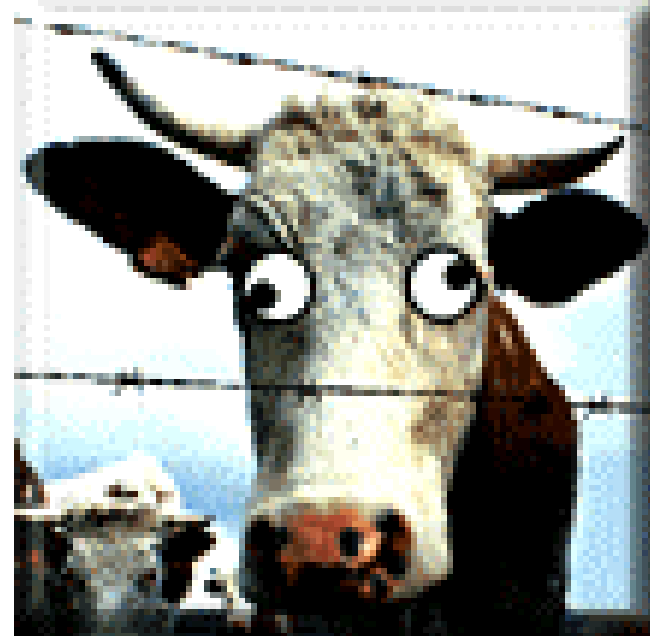
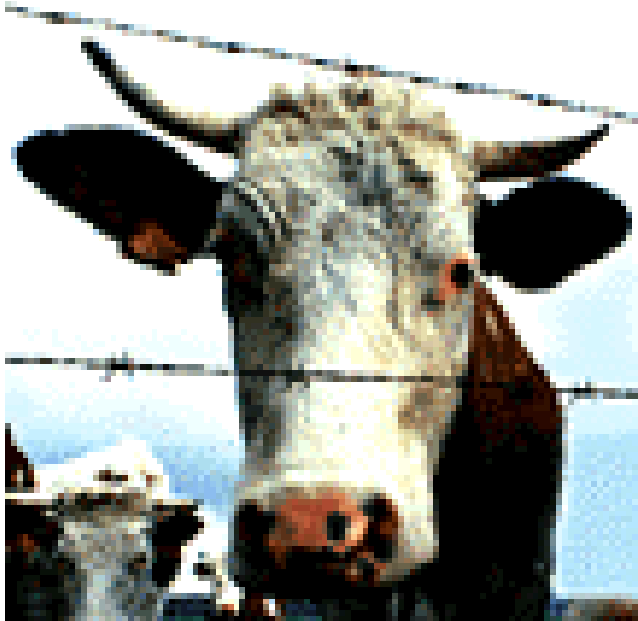


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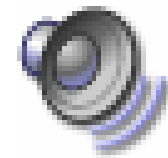
Public Service Announcement

How to identify if your cow has mad cows disease..



If your cow sound like this
then fire up the barbecue.

If your cow sounds like this
may we suggest the fish.



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ISO 15883

Regulates the validation of processing sequences in washer – disinfectors for medical devices as well as **revalidation** and **routine monitoring** of these processes.

IQ,OQ and PQ are now considered to provide only a portion of the monitoring required to ensure that **consistently effective** and **reproducible** processes are being conducted.



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Performance qualification

The process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, **consistently** performs in accordance with predetermined criteria and thereby yields product meeting it's specification

15883 Guidelines

The most important **positive** and **negative** parameters of influence include:

- mechanical effects
- chemical effects
- thermal effects
- blockage of detergent components

15883 Guidelines

The most important **positive** and **negative** parameters of influence include:

- Protein coagulation
- sufficiently long hold times for swelling, disintegration, hydrolysis (disinfection)
- avoidance of recontamination

Parametric Release

Pre-validation of all process variables

Water quantity per process step.

Temperature and holding time

Water pressure

Lumen patentcy

Verification after process that all parameters and variables were within pre-set defined limits

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ISO 15883 General requirements

Although those constitute an indispensable base for your validation and routine monitoring they do not suffice on their own **additional quantitative checks of the cleaning performance must be carried out on a regular basis.**

ISO 15883

Preference must also be given to the use of standardised, quantitatively assessable test models as they yield reproducible results.

Current national formulations - to a large extent - require the tests to be individually made by those conducting the tests

Soils

Commercially available soils have approached this goal.

Many laboratory soil formulations have been described in literature and have recently been consolidated in the ISO EN standard 15883 Part 5 (regarding test soils and methods for demonstrating cleaning efficacy of washer-disinfectors);

Described soil formulations.

Load Type Surgical Instruments

UK soil ('Edinburgh')

Blood, egg yolk, mucin

German soil

Blood, egg, semolina, butter, sugar, milk

ASTM soil

Protein with endospores.

Bowls/Dishes

Swedish soil - Coagulated blood

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Described Soil formulations

Bedpans

UK bedpan soil('Huckers') Flour, paste, eggs, ink, water

Flexible endoscopes

Biofilm soil - France - *P. aeruginosa* biofilm

German endoscope soil - Blood, *E. faecium*



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What's on the instrument?

Following surgical or investigational use soils found on instruments are complex mixtures of various components. Organic (or carbon-based) materials like proteins, carbohydrates, lipids and microorganisms. (e.g. blood, mucus)

Inorganic (or non-carbon based) materials including various minerals and salts. Soil may also include some specific components due to their presence in water used for reprocessing (e.g., calcium carbonate or scale) and device damage (e.g., iron oxide or rust).

Soil – Soil removal

Protein – less than 45°C

Polysaccerides

Lipids – require high temperatures for effective removal –
often in the presence of detergents

Therefore each stage of the washer disinfecter cycle is
equally important.



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Commercial soils

There are also a few commercially available soils which have been specifically developed and validated for use in cleaning efficacy tests. standardized, easy to prepare (by dilution in water when needed), reproducible, non-toxic and stable (as a dried formulation).

Commercial soils



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Soils

It should be noted that none of these soils are universally accepted and that it is intended that a single, best case test soil should be developed in the future.



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Frequency of testing?

Additional quantitative checks of the cleaning performance must be carried out on a **regular basis?**

Does that mean by load, daily, weekly or monthly?

Options - Cycle

Very few available – apart from the obvious visual inspection.

Commercially available
“ Load controls”

Load control

Offers consistent ongoing challenge to the process.

Representative test soil

Representative surface

Developed as a worse case

Easy & safe to use

Creates physical evidence of cleaning efficacy within the department.

However these are not actual instruments used in procedures

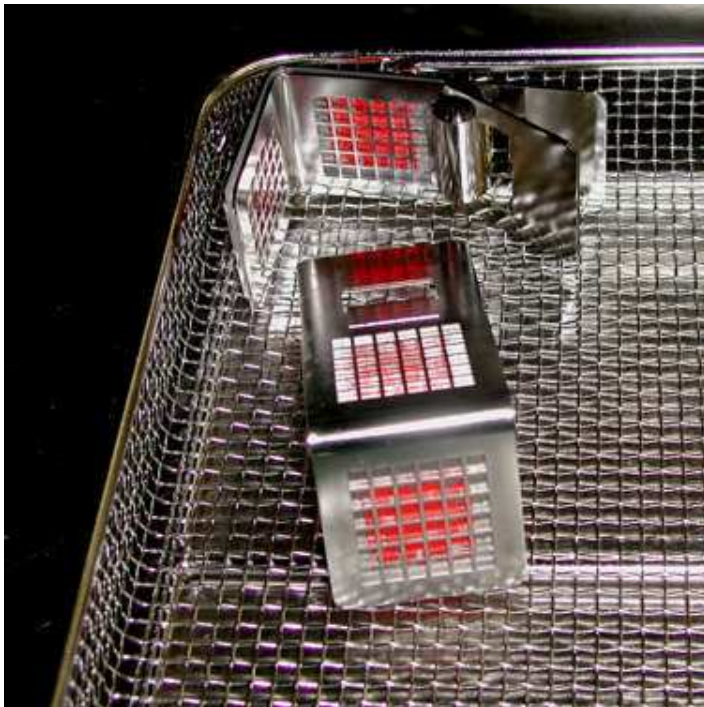
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Load control / Daily Soil removal efficacy tests



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Daily / weekly tests

Soil removal efficacy test – physically painted onto sample instruments.



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Daily / weekly testing

Physical soil removal efficacy test.

Protein detection testing methods

An example of this would be the Ninhydrin test



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Ninhydrin testing

Purple colour development on reaction with proteins peptides
and amino acids

Positive control with arginine

Incubation at 55 – 57 °C for >5 min / < 60 min

Physical evidence then recorded and saved.

Remember

- First and foremost you have to go back to your primary objective –
- **To provide as much evidence as possible that the correct cleaning / disinfection conditions were present in each and every basket or item processed.**

Conclusion

- Each facility is different
- Everyone of you is different
- You all have different budgetary constraints

Therefore

Above all else you have to be comfortable, and confident with the systems you have in place !

THANK YOU !!!



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