WFHSS Recommendation 01
Validation of Decontamination Processes

Aside from the requirement to have a quality system, validation of decontamination processes is also mentioned as an essential part of any applicable norm. The ISO-EN definition of validation states:

"*Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification".*

A complete initial apparatus validation including Installation Qualification ("Process of obtaining and documenting evidence that the equipment has been provided and installed in accordance with its specification"), Operational Qualification ("Process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with its standard operational procedures") and Performance Qualification ("Process of obtaining and documenting evidence that the equipment, is installed and operated in accordance with standard operational procedures, consistently performing in accordance with predetermined criteria and thereby yields product meeting its specification") ensures not only that a medical device reprocessor is functioning to the predetermined specifications but also ensures consistency for processes. Requalification ("repetition of part of validation for the purpose of confirming the continued acceptability, of a specified process") in combination with the necessary routine controls assures that the same certainty is maintained if the predetermined process parameters are met within the specified margins. Sterility then can be guaranteed.

Validation of these processes is a critical part of the quality system applied in the department.

This ensures that by monitoring and documenting the steps of the decontamination process, a good qualitative end product is consistently delivered. If all conditions are met, a periodic audit of the quality system, in combination with requalification, makes parametric release of the load possible. Parametric release for steam sterilization implies at least the control of all relevant physical parameters of a process, in combination with periodic vacuum leakage test and daily Bowie-Dick test.

Note: In the event of a non-conformance at any stage of the decontamination process, a risk assessment must be conducted ensuring control measures are identified, established and addressed immediately.

For the central sterilization department, this means a step towards quality release of medical devices reducing the number of procedures with little or no added value, which originate from the past and moreover can create a false sense of safety. Traditions are being replaced by objective physical measurements that are undeniable and that give certainty within the limits of technology. The direct measurement of physical parameters is far more accurate than conducting this through a chemical or biological detour.

Validation makes it possible to found “sterilization” scientific. This is essential if we want to establish decontamination as a discipline. By validation, decontamination may not just evolve into “industrialization” of its production but also to evidence based practice.

Besides validation, a regular calibration of measuring devices remains a prerequisite of good manufacturing practice.

The WFHSS strongly recommends initial and periodic validation of decontamination processes in combination with a regular audit of the quality system. When these principles are applied this will guarantee medical devices fit for purpose and therefore ensure patient safety.

WFHSS Education Working Group