VH2O2 sterilisation: The need for consistency

Richard Bancroft, science & technical director at STERIS Corporation, examines UK Guidance for vaporised hydrogen peroxide sterilisation, and asks why we do not have a consistent approach.

Steam sterilisation has long been the gold standard for the sterilisation of reusable medical devices. Increasingly, many reusable medical devices are heat-labile, hence needing to be sterilised by low temperature methods. The two predominant methods for low temperature sterilisation are vaporised hydrogen peroxide, which is abbreviated using the symbol VH2O2, and ethylene oxide, EO. EO was more common in hospitals several decades ago, however, with concerns about cycle time and toxicity, it is now predominantly used as an industrial sterilisation method.

Meanwhile over the last decade, VH2O2 has been rapidly adopted as the hospitals' method of choice for sterilisation of heat-labile medical devices, while also gaining increased use industrially. The advantages of VH2O2 for this application are quite significant; the process has excellent efficacy, cycle times can be as short as 16 minutes, no post-processing aeration is required, and there are none of the residual toxicity problems associated with other gaseous sterilisation methods such as EO.

The use of VH2O2 sterilisation, like any other sterilisation method, requires validation and subsequent routine monitoring and control. Each sterilisation method requires a different approach due to the varying critical process parameters of the method used. The methods of sterilisation process validation and control are generally addressed in international standards that are then in turn supported by regional guidance documents. These guidance documents allow more specificity in their requirements, allowing them to be aligned with local practices and regulatory requirements.

With VH2O2 sterilisation, no standards have been published specifically for the validation and routine control of these processes and so the generic sterilisation process standard, ISO 14937, *Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*, has been adopted for this purpose. This standard is designed to be applied to any sterilisation process where there is not a specific sterilisation modality standard published. Because of the prevalence of VH2O2 sterilisation, the International Organization for Standardization, ISO, has adopted a new work item that will result in publication a new standard that follows the general practice as dictated in ISO 14937, but with specific attention to VH2O2 sterilisation. This standard will be known as ISO 22441, *Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*. Work on this standard started slightly over one year ago and is intended to give the requirements for the sterilisation process (but not the equipment).

In addition to the ISO work addressing the VH2O2 process, the European Committee for Standardization, CEN, has begun work on an equipment standard for VH2O2 sterilisers, EN 17180, *Sterilizers for medical purposes – Low temperature vaporized hydrogen peroxide sterilizers – Requirements and testing*. This standard work, intended to provide a set of requirements for the steriliser itself to ensure that the steriliser can work to the minimum agreed requirements, is closely aligned to the ISO 22441 work.

Supporting both ISO 22441 and EN 17180 is a third work item within ISO to develop a biological indicator standard that will provide requirements for biological indicators specifically for use in VH2O2 sterilisation. This standard will be ISO 11138-6, *Sterilization of health care products – Biological indicators – Part 6: Biological indicators for hydrogen peroxide sterilization processes*. These three standards from CEN and ISO are likely to take about another two years to complete. Because of this, there is an urgent need for local guidance on the validation and routine control of VH2O2 sterilisers (see figure 1).

Health Technical Memorandum 01-01

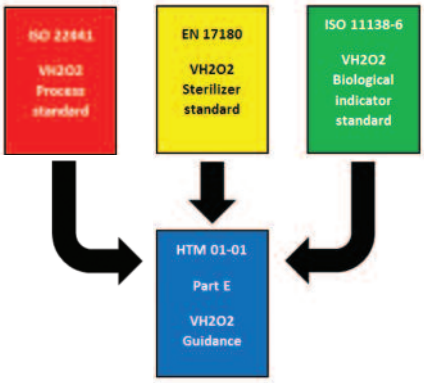

Figure 1 – Diagrammatic representation of the VH2O2 standards in relation to guidance

Part E: *Alternatives to steam for the sterilization of reusable medical devices, HTM 01-01 Part E*,[1] was published in England in 2016 and was intended to provide guidance on the operation of low temperature sterilisation methods within hospitals – essentially both EO and VH2O2 sterilisation. Unfortunately, the English HTM 01-01 Part E contained very little useful information about the validation and routine control of these processes. More recently, Scotland published its version of this guidance, *Scottish Health Technical Memorandum 01-01 Part E: Sterilization by Hydrogen Peroxide or Ethylene Oxide, SHTM 01-01 Part E*.[2] Although the Scottish version has a similar reference number and a slightly different title. But, the scope and content of the two documents are remarkably different (see table 1).

The Scottish document provides prescriptive guidance on the validation and routine monitoring of the VH2O2 process, whereas the English version gives only top-level guidance on what could arguably be applied to any sterilisation process, including steam, EO or VH2O2.

ISO and CEN standards are typically restricted in their scope by not defining periodicity requirements of tests, largely since local and national regulations may dictate varying requirements. So in certain aspects, local guidance documents can be more powerful than European or international standards, especially if the local guidance is written to underpin and support the requirements given in these standards.

The Scottish HTM 01-01 Part E has been drafted with consideration to the potential requirements that may be incorporated into the European and international standards work in this area. This approach has resulted in a complete set of guidance and requirements for the validation and routine control of VH2O2 sterilisation processes. The SHTM guidance has been written from a practical perspective, and gives a sensible balance between the cost of routine monitoring versus the knowledge of effectiveness of the sterilisation process.

One of the questions that could be asked is why does the Scottish HTM guidance differ so significantly from the English HTM? Perhaps one of the reasons is that more than two years separates the publication of these documents, giving the Scottish version the advantage of referencing CEN and ISO drafts that have commenced during this time. However, the fundamental difference between the two guidance documents is the level of detail that is evident in the Scottish version that is unfortunately not present in the English one.

It is disappointing that these divergent differences exist in the publication of guidance from the devolved administrations within the United Kingdom, leading each of the administrations to publish their own guidance based on what they consider necessary for their own country.

The benefit to us is that we now have a situation where we can review, compare and choose which guidance could be best adopted as a complete UK guidance. Surely best practice is best practice, wherever it originates from, and the relatively minor practice or legal differences that exist between the UK devolved administrations is insignificant in this context. However, there is no excuse for having regional guidance expressed in such vastly different ways. England, Scotland, Wales and Northern Ireland have a dialogue and understanding with each other, so for example, adoption of the Scottish document may be possible across the UK, and would greatly enhance the validation, control and monitoring of VH2O2 sterilisation.

A comparison of the structure of HTM 01-01 Part E and SHTM 10-01 Part E

HTM 01-01 Part E (England)	SHTM 01-01 Part E (Scotland)
Published March 2016	Published September 2018
19 pages	44 pages
Introduction - 10 pages (the introduction is largely identical to the other parts of the England HTM 01-01 series)	Introduction - 2 pages
Guidance for commissioners - 3 clauses	*not included*
Guidance for regulators - 7 clauses	*not included*
Role of non-steam sterilisation - 4 clauses	*not included*
Quality and safety standards for non-steam sterilisation - 5 clauses	*not included*
Guidance on safety risk assessment -	Guidance on safety risk assessment - 2 clauses 5 clauses
Surgical instrument and other device compatibility - 2 clauses	Medical device compatibility - 8 clauses
not included	Design and procurement - 98 clauses
not included	Validation - 48 clauses
not included	Periodic testing - 23 clauses
not included	Sterile product release - 6 clauses
not included	Maintenance - 1 clause

Table 1

References

1 Health Technical Memorandum 01-01 Part E: Alternatives to steam for the sterilisation of reusable medical devices, www.gov.uk/government/collections/ health-building-notes-core-elements
2 Scottish Health Technical Memorandum 01-01 Part E: Sterilisation by Hydrogen Peroxide or Ethylene Oxide, NHS NSS Health Facilities Scotland, version 1.0 September 2018