The Derivation of United Kingdom Physical Steam Quality Test Limits

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ABSTRACT: The purpose of this short article is to provide the background and thinking behind the physical steam quality test methods and acceptance criteria found in HTM 2010 (1) and EN 285 (2). The article does not include information relating to the necessary chemical and microbiological quality aspects, details of which may be found in HTM 2031 (3). It will be seen that while the physical test methods are rudimentary, they have stood the test of time and provided the British National Health Service (NHS) with a quantitative means of assessing physical steam quality, which has satisfied the original objectives of improving process assurance and reducing costs. While the methods may not have received universal acceptance, there can be little doubt that poor quality steam will adversely affect the sterilization process when applied to porous/equipment cycles.

Background

Until HTM 2010 was published there had been no requirement for routine physical steam quality testing within the NHS. While HTM 10 (4) provided details of dryness value and non-condensable gas tests, these were to be employed as circumstances demanded. Prior to this, testing had been restricted to the subjective assessment of load dryness and the assessment of superheat as part of routine thermometric testing.

A limit of less than 5^{o} C of superheat at the start of the sterilizing hold period dropping to less than 2^{o} C after 1 minute applied throughout the NHS. These limits had been established in the mid 1960's by the Medical Research Council (MRC) using 126^{o} C porous load sterilizers and basing it's recommendations on parametric and biological studies. The need to establish values for the 134^{o} C cycle was noted in the report. At the start of the investigation, such a study was considered to be expensive and not justified. Engineering solutions were thought to be more appropriate, particularly as the problem was not limited to superheat.

Development

In the mid 1970's the British National Health Service was incurring significant costs as the result of failed porous load/equipment sterilization cycles. Failures were principally due to wet loads, the failure of chemical indicators on packaging and in the Bowie Dick test to properly change colour and air detectors causing cycles to automatically fail. In addition to the evident quality issues, this resulted in loads having to be re-packaged and re-sterilized at considerable expense.

K W Oates C.Eng., MIEE, Dip Microb. a Scientific Officer from the Scientific & Technical Branch of the Department of Health & Social Security was charged with the task of resolving these issues. Oldham District General Hospital was selected as being a representative site, where these problems were endemic.

Dryness Value

Having ruled out mechanical and control issues relating to the equipment, attention was turned to the steam supply. Using equipment available in the hospital laboratories and engineering workshop, a test was devised to monitor the dryness of steam. Because the methodology employed did not represent the true dryness fraction, the term dryness value was employed to indicate the approximate nature of the test. At the outset, the tests were restricted to the effects of wet steam and superheat. A simple relationship was soon established between wet loads and the dryness value. If the dryness value of the steam was below 0.9, wet textile loads could be experienced. If metal components were present in the load, problems could be experienced with dryness values below 0.95. The distribution system was changed to a ring main and additional steam traps fitted to improve steam dryness. By switching the steam traps in and out of the system, the dryness value could be modified and cause/effect established.

Non-condensable gases

Having resolved the issue of wet steam, failures still continued to occur with chemical indicators and air detectors. During the course of the tests, under certain loading conditions, dryness values in excess of 1.0 were experienced, indicating the presence of superheat, despite the mathematics of the effects of pressure drops indicating otherwise. A theory was developed that the exceptional readings were due the presence of other components in the steam, having different thermal characteristics. As a direct result, a test was devised to quantify the amount of non-condensable components in the steam. Steam was condensed in water at atmospheric pressure and non-condensable components collected in a burette. This simple test indicated a variable presence of non-condensable gases and cause/effect established between the levels encountered and chemical indicator/air detector failures. Additional air vents were fitted to the steam ring main and by switching both these and the steam traps, in and out of the system, the non-condensable gas levels could be modified at will.

In a similar fashion to the dryness value exercise, the non-condensable gas levels could be modified and it was found that at levels below 3.5 ml of gas per 100 ml of condensate collected, few, if any problems were encountered with the chemical indicators or air detector. It should be noted that all of the original work was conducted using processes having only sub-atmospheric air removal stages. Higher gas levels may be permissible when more effective air removal systems are used.

The outcome for this hospital was a dramatically improved level of assurance. These works were followed by an extended survey aimed at correlating the results of steam quality tests with process failures and confirmed the original findings.

It has been found that the limits applied to steam quality testing can easily be satisfied by well designed and maintained steam boilers/generators and distribution systems within the NHS, though problems may still exist with conventionally well designed systems

operating at extremes of demand. Further guidance may be found in HTM 2010 Part 2 (5).

Steam supply manifolds

Further works were undertaken to develop a steam manifold to improve steam quality at the point of use. This relied on reducing the steam velocity and allowing quantities of both moisture and non-condensable gases to be eliminated. This work was undertaken at St James Hospital, Balham. The results of the work provided evidence that a properly designed steam manifold could significantly improve steam quality. Details of the manifold may be found in HTM 2010 Part 2.

It is regrettable that during the relocation of the different agencies of the Department of Health, recorded data relating to the aforementioned work was mislaid.

Superheat test

In the mid 1990's the superheat test was developed in conjunction with Liverpool University for inclusion in EN 285. It provides a quick and simple test to identify whether steam supplied to a sterilizer will become superheated when expanded into the chamber. The test relies on the mathematics of pressure reduction, which can be seen by the use of a Mollier chart. The test assumes that if steam at 5 BarA having a certain dryness fraction is reduced to atmospheric pressure, with a superheat test value of less than 25^{o} C, then it will not generate excessive superheat in the chamber when reduced from 5 BarA to 3.2 BarA (the preferred sterilizing pressure in the NHS). Neither HTM 2010 nor EN 285 makes reference to either the supply pressure or the sterilization pressure, both of which may have an impact on the results. In both documents advice is provided the steam supply pressure drops should not exceed a ratio of 2:1.

Other research

The works referred to above resolved the immediate issues but all the causes of the superheat phenomena remained unclear. The phenomena could be due to pressure drops, velocity/kinetic energy effects, the presence of gases in the steam or a combination of these factors. In the mid 1980's further original research work was commissioned at the University of London to investigate the relationship between these factors. The results were inconclusive, due to the difficulties in producing steam with specific characteristics. For this reason, unless we are clear of the causes of the observed elevated temperature, we refer to the phenomena as overheat rather than superheat.

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convenor for working groups in ISO, IEC and CEN technical committees concerned with moist heat sterilization.

References

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