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NEW: Q105 Validation Bundle
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Introducing our new look!
We are delighted to announce the launch of the new Isopharm brand identity. Our goal was to create an identity that would support continued growth, whilst retaining the unique ethos that has brought over 14 years of success. With our new logo we have developed a new colour palette and imagery, guidelines which means that you’ll notice changes in all of our new catalogues, packaging, stationery and signage.

We’re also busy working on our new website which will launch in September... here’s a sneaky preview of what’s in store!

We hope you like it!

 magically has been changed

Proteins

The Decontamination Support Centre, Taylors Court, Rotherham S62 6NU

Isopharm Limited
The Decontamination Support Centre, Taylors Court, Rotherham S62 6NU
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Fax: +44 (0)1709 52 52 56
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Website: www.isopharm.co.uk

ISSUE 14

BEST PRACTICE
Guiding you to compliance

www.isopharm.co.uk/dental

How do changes to HTM 01-05 affect your dental practice?

In April 2013 the Department of Health issued a revised version of HTM 01-05. Within the document there are a number of changes from the original that was published and issued to dental practices in 2009. The revised guidelines have yet again divided the dental community, with some believing that the Department of Health have made a significant U-turn in terms of the guidance, whereas others have welcomed the revisions.

This issue of best practice has been written to show you what the changes are and how they may or may not affect your dental practice. Whatever your thoughts on HTM 01-05, it is here to stay. Since 2009 it has become apparent that the majority of dental practices have embraced the guidance and are working hard to achieve not only the Essential Requirements but also the Best Practice expectations. We should also not forget the main aim of the document: To progressively raise the quality of decontamination work in primary care dental practices.

Isopharm have dissected the new document and taken the relevant paragraphs of text that are shown in column one, and in column two we articulate the differences from the original 2009 HTM 01-05. We also comment on the effect Isopharm believes this may or may not have on your practice.

There are some very significant changes, along with what would appear to be only textual changes, however, quite a number of the minor changes haven’t had much press, although the re-wording of certain paragraphs can have a significant impact on your practices decontamination processes.

Becky Blackmore
Dental Business Development Manager
becky.blackmore@isopharm.co.uk

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Changes to HTM 01-05
2013 Edition

Executive summary: 2013 Edition of Health Technical Memorandum (HTM) 01-05

This 2013 edition of Health Technical Memorandum 01-05 (HTM 01-05) reflects the consensus on patient safety in the area of storage of dental instruments. Consequently, this review of the guidance on storage items (in particular, see paragraphs 2.4k, 2.4l, and 2.4-2.4l) has been carried out in advance of the planned revision of HTM 01-05.

It is recognised that potentially infectious recontamination of sterilised dental instruments is event-related rather than time-dependent. Within dental practices, there is a rapid turnaround of the most regularly used dental instruments. The 2009 edition was not helpful in the management of these frequently used instruments.

The rationale for this change is that these dental instruments are used in contaminated body areas. Any environmental contamination that takes place would have a minimal impact on patient safety compared with contamination with another patient’s blood or body fluid, which would be a significant hazard to patients. Thus, the emphasis is on ensuring effective decontamination and preventing contamination with another patient’s blood and body fluid rather than on preventing environmental contamination of sterilized instruments.

The guidance document has also been updated to reflect the changes to the NHS infrastructure following the Health and Social Care Act 2012.

1.4

The guidance provided here follows the essential principles given in the Health and Social Care Act 2008: Code of Practice on the prevention and control of healthcare associated infections and related guidance (the Code of Practice). This requires that effective prevention and control of healthcare-associated infection be embedded in everyday practice. For this reason, the guidance is written with emphasis on practical and readily implemented measures. Appendix B of the Code of Practice refers specifically to the requirements for dental practices.

Slight textual alterations only, with the added mention of Appendix B of the code of practice that applies to dental practices specifically.

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<table>
<thead>
<tr>
<th>Code</th>
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<td>Inspection Lamp</td>
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<td>Alpron &amp; Biofilm Removal System Starter Kit</td>
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Sign up for Best Practice
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**HTM 01-05 Disinfectable Keyboard**

A full size HTM 01-05 compliant keyboard with UK Layout. Medical Grade, water-resistant and disinfectable with tactile feedback keys.

**Washable keyboard**

Fully submersible. Provides protection from dirt, germs and spills with sealed inner components and a rigid body featuring drainage holes.

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High grade, moisture resistant silicone. This thin cover maintains a clear view of the keyboard without sacrificing normal typing use.

**Sterilisable Mouse Mat**

Can be cleaned, disinfected, or sterilised in autoclave.

**HTM 01-05 Disinfectable Mouse**

HTM 01-05 compliant mouse. Medical Grade, water-resistant and disinfectable. Available in standard or petit versions.

**Manual Cleaning Thermometer**

Digital thermometer for monitoring the water temperature when manually cleaning instruments in compliance with HTM 01-05.

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Wall mounted glove and apron dispenser. Three compartments for different sizes of gloves or a mix of gloves, overshoes, masks etc. Large oval apertures allow easy access to each compartment. The lower horizontal slot is designed to take rolls of aprons. H440cm L36cm D145cm.

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Medical Grade, water-resistant keyboard with UK Layout.

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**MOUSP 001 HTM 01-05 Disinfectable Mouse – Petit – White**

**THEMC 001 Manual Cleaning Thermometer**

**POSTDECONA2 594 x 420mm**

**POSTDECONA2 594 x 420mm**
Changes to HTM 01-05
2013 Edition

What the changes mean and how they affect your practice?

2.4(k)(ii)
Wrapped instruments may be stored up to 1 year (see paragraph 4.25-4.29).
Pre-sterilization wrapped if type B or S; Post-sterilization wrapped if type N.

2.4(k)(ii)
Unwrapped instruments in the clinical area: maximum storage 1 day. Instruments should be protected from contamination, for example in mini-racks placed in cupboards or in covered drawer inserts. Instruments should not be stored on open work-surfaces, particularly in clinical areas. It is important that practices have well developed protocols and procedures in place to prevent contamination of these instruments by ensuring that those required for a particular patient are removed from their protected environment before treatment commences. This eliminates the need to open cupboard doors or drawers during patient treatment. If an instrument does not need to be retrieved from a cupboard or drawer during treatment, the practice should have protocols in place to prevent contamination and to ensure that staff hands are clean and that gloves are donned before handling unwrapped sterilized instruments. Regard all instruments set out for each patient as contaminated after the treatment whether or not they have been used. Instruments that are kept unwrapped should be reprocessed at the end of the working day, regardless of whether they have been used. Alternatively, instruments can be reprocessed at the beginning of the next working day.

2.4(k)(iii)
Unwrapped instruments in a non-clinical area: maximum storage 1 week. Non-clinical area in this context is designated as a clinical area not in current use or in a clean area of a separate decontamination room. Instruments should still be stored as follows: Dry, and Protected from contamination, for example in mini-racks placed in cupboards, or in covered drawer inserts. Instruments should not be placed on open work surfaces.

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The major change to the 2013 edition of HTM 01-05 is related to the storage of instruments: REGARDLESS of the type of sterilizer you use within your practice a wrapped/pouched instrument can now be stored for up to 1 year without the need for reprocessing. So the 21/60 day guidance previously advised is no longer required. Pouched instruments can be stored for up to one year.

The advice relating to unwrapped instruments stored in the clinical area has been worded differently and further guidance on protocols and procedures for this type of storage is given: The 2009 document said that unwrapped instruments in the surgery had to be used within that treatment session, now whilst some people took that to be one full day, others interpreted it as a morning or afternoon session.

2013 edition now states Maximum storage 1 day. K(ii) suggests that instruments stored open in surgeries (in mini racks or covered drawer inserts) are out ready for the patient requiring treatment so as to prevent the need to open drawers during patient treatments and it goes on to talk about how to adequately retrieve instruments from a drawer should this be required. This is not something new for HTM 01-05, the requirement has always been there for practices to follow the procedures as now set out in 2013 and it’s likely that all dental practices were following these procedures before HTM 01-05 was released in 2009 however advise on protocols and procedures has been documented.

A new entry to the 2013 edition is a protocol for storing unwrapped instruments in a non-clinical area. This doesn’t mean that you can now store instruments in a cupboard on reception, but it does mean that instruments, on kkidd trays, mini racks in cupboards etc. can be kept in a non-clinical area for example an unused surgery or the clean area of a separate decontamination room. These instruments can be stored for a period of 1 week maximum.

Instruments required for particular patients or sessions should be taken into the surgery but must remain in the kidded trays etc. until they are used. If you are taking a full day's worth of instruments into a surgery, these should be returned to the non-clinical area to store for the rest of the week. A rigid protocol should be in place and monitoring of these instruments to ensure that they do not remain stored for longer than the 1 week period specified.

For daily HTM 01-05 steam penetration testing of your B Type vacuum sterilizer. Please note that not all vacuum machines can process a B Type Helix device, contact ISL for more information.

For daily HTM 01-05 steam penetration testing of your Statham vacuum sterilizer.

For daily HTM 01-05 steam penetration testing of your Eschmann Little Sister 5 and Quickvac vacuum sterilizer.

For daily HTM 01-05 steam penetration testing of your SteriPak Bowie Dick Test Packs.

For daily HTM 01-05 steam penetration testing of your Helix device, contact ISL for more information.

For daily HTM 01-05 steam penetration testing of your Statham vacuum sterilizer.

For HTM 01-05 Daily Steam Penetration Testing, Pack of 20 tests.

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### Changes to HTM 01-05 2013 Edition

<table>
<thead>
<tr>
<th>What the changes mean and how they affect your practice?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appendix 1: Hand-hygiene policy</strong></td>
</tr>
<tr>
<td>- Carry out hand-hygiene between each patient treatment, and before donning and after removal of gloves.</td>
</tr>
<tr>
<td>- Hand washing should take place at least at the beginning and end of every session, and if hands are visibly soiled.</td>
</tr>
<tr>
<td>- If hands become sticky with the build up of hand rub residue, they must be washed as normal using a proper hand hygiene technique.</td>
</tr>
</tbody>
</table>

### What the changes mean and how they affect your practice?

- Develop a quality system approach so that the storage of wrapped instruments does not exceed one year.
- In the 2009 version of HTM 01-05 there was much confusion around whether a ‘bowl’ was suitable to be used as the second sink in the wash/rinse process. The guidance was meant to be interpreted as 2 sinks and 2 sinks only.
- In the 2013 revised edition of HTM 01-05 it now states that one sink and a removable bowl is acceptable, HOWEVER it goes on to say that it is still the least preferred method (see Adjacent).
- The bowl should be used for rinsing instruments ONLY and not for washing and never used as a hand wash sink.
- This alteration may appear to be text only, however realistically if could have an impact on the procedures you follow within your practice! 2013 version now recommends ‘A separate sterilized instrument tray should be used FOR EACH PATIENT’ and then goes on to talk about single use trays. In the 2009 document it only recommended that a ‘clean sterilized’ tray be used for the transportation of sterilized instruments to the treatment room.
- This may be a textual change for clarity as some dental practices say that it is still the least preferred method (see Adjacent).

### What the changes mean and how they affect your practice?

- 2.12 talks about instruments being kept moist using potable water (Potable meaning safe for human consumption) where as the previous version it stated that either immersion in potable or Reverse osmosis (RO) water might be considered. RO water is still recommended for other processes throughout the document.

### Original Appendix 1: Waste disposal

- "Waste disposal" has been removed.

### Appendix 1: Examples of logbook pages

*These personnel should have qualifications/training/registration defined in CFPP 01-01 Part A.

### Textual change only, CFPP 01-01 Part A was previously defined in HTM 01-01 Part A.

---

**HTM 01-05 Ultrasonic Cleaner Logbook**

- Decontamination Validation: Simply complete and comply.
- Provides 12 months of validation record keeping for a single Ultrasonic Cleaner.
- Code: LOGWUX01
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**HTM 01-05 Disinfector Logbook**

- Provides 12 months of validation record keeping for an instrument disinfector.
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- Provides 12 months of validation record keeping for a single Benchtop Steriliser (all cycle types).
- Code: LOGBSX01
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---

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- Available in Green, Silver, Yellow, White or Blue.

**Dry Cleaning Cloths – Lint FREE**

- Pack of 300 lint free dry cleaning cloths.
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---

**HTM 01-05 Decontamination**

- In the 2009 version of HTM 01-05 it now states that one sink and a removable bowl is acceptable, HOWEVER it goes on to say that it is still the least preferred method (see Adjacent).
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Changes to HTM 01-05
2013 Edition

What the changes mean and how they affect your practice?

2.18 Where endodontic reamers and files are designated reusable, they should be treated as single patient use or single use – regardless of the manufacturer’s designation – to reduce the risk of prion transmission. Practices must have effective procedures in place to exclude errors in identifying the instrument(s) and associating them with the correct patient.

2.19 Care needs to be exercised in the cleaning of re-usable endodontic reamers and files. Where automated washer-disinfectors are used, the risk of cross-contamination to other instruments would be very low, in view of the dilution factors. These instruments do not need to be processed on a separate cycle. However, owing to the variability in dilution during manual washing, the files/reamers should be washed separately from other instruments.

2.21 At a minimum, practices should audit their decontamination processes every six months, with an appropriate review dependant on the correct patient. The original paragraph in the 2009 HTM 01-05 was subject to change in March 2010 as evidence had been provided to the DoH stating that endo files and reamers COULD be reused but ONLY on the same patient (Chief Dental Officer’s update March 2010). The DoH accepts a proposed relaxation in this area, but only in so far as endodontic files and reamers may be re-used on the same patient. This is conditional upon the instruments being marketed as re-usable and the dental practice’s registered manager being satisfied that the tracing and audit procedures used are such as to exclude error in identifying the instrument(s) and associating them with the correct patient. As a key part of this assurance, particular care will be needed in respect of storage, and the advice given in paragraphs 4.27-4.31 of the guidance should be rigorously applied. Care needs to be exercised in the cleaning of these instruments. Where automated washer-disinfectors are used, the risk of cross-contamination to other instruments would be very low, in view of the dilution factors. Therefore, these instruments do not need to be dealt with on a separate run. However, owing to the variability in dilution during manual washing, the HTM guidance needs to be carefully applied so that when manual washing is used the files/reamers should be washed separately from other instruments. Regardless of the washing system employed, the instruments can be sterilized as usual and do not require a separate run. The KEY Point here is that you MUST have effective measures in place to ensure that re-used endo files/reamers are associated with the CORRECT patient. If you cannot be 100% certain that a file or reamer is being re-used on the correct patient then you must dispose of it as you could compromise patient care.

Previously every 3 months now only required every 6 months. We believe it is possible because practices weren’t managing to make the required improvements within the 3 month period so a 6 monthly audit seems timelier. The Infection Prevention Society provides the most widely used and recognised audit document, previously available as a paper copy and more recently an online document. The new IPS audit tool was made available via the IPS website as a download to allow for the 2013 revisions

Taken from the IPS website

Changes include:

- A modified question set to reflect the changes in the HTM mainly around storage times
- HTM 0105 has been reviewed and the tool will reflect these changes
- Revision of software analysis to identify non-compliance with Best Practice if separate decontamination room and washer disinfectors are not available.

What the changes mean and how they affect your practice?

15: Additional information on test procedures
(in addition to those provided in the Standards)

15.1 Most test procedures are defined in the referenced Standards shown in the testing protocol in Chapters 12–14. Unless these tests are to be performed by suitably-qualified and certificated practice staff (see Choice Framework for local Policy and Procedures 01-01 Part A for further guidance on training and certification), it will not be necessary for the practice to possess copies of these Standards. It will, however, be necessary that any contracted test performance include reference to the requirements of these Standards.

17: Steam and water quality

Endotoxin and water hardness level recommendations removed and confirmation with the washer disinfectant manufacturer should be sought.

17.9 Practices should check with the detergent manufacturer that level of hardness is compatible with the detergent used and for its use in a washer-disinfector.

17.11 The detergent should be chosen for its cleaning efficacy and its compatibility with the water quality.

Previously the test read ‘compatibility with the water quality and parameters of its use.’

19: Hot and cold water systems and dental unit water lines

Interestingly, the statement in the 2009 HTM 01-05 said that ‘ competent persons who are members of the Legionella Control Association are able to produce written schemes to the required standard’ It has now been replaced with the adjacent text. Isopharm would strongly recommend that members of the Legionella Control Association be consulted.

19.38 Advice on the use of biocides should be sought from the person advising the practice on Legionella.
Changes to HTM 01-05 2013 Edition

What the changes mean and how they affect your practice?

6.58 It is no longer good practice to refill spray bottles used to apply cleaning or disinfecting solutions. Bacteria can contaminate the bottles and become adapted to these solutions and grow in the spray mechanisms. Such bottles, whether supplied pre-filled or empty, should be single use.

10: Procurement of decontamination equipment and instruments

10.17 Ultrasonic cleaners may be designed to operate at a single frequency across a frequency range, and with a controlling system to adjust the frequency in response to the loading conditions.

11: Decontamination equipment: general guidance on maintenance and testing

11.0 As primary care trusts have been replaced with the national commissioning board it is not feasible to send the validation reports to the Authorising Engineer (Decontamination). In instances an AE(D) just needs to have sight of the validation reports annually for sign off purposes and it is unless that dental practices will be retaining the services of an AE(D) however should a practice require an AE(D) a full list can be found at www.iheem.org.uk/decontamination. It would be worthwhile checking with your engineers to see if they are sending annual validation reports to an AE(D) to avoid duplication and additional expense.

3: Cleaning instruments

3.13 The fitting and plumbing of washer-disinfectors must comply with the requirements of the Water Supply (Water Fittings) Regulations 1999. Further details can be found on the WRAS website. www.wras.co.uk

3.14 Rinse – Advice should be taken from manufacturers with respect to the compatibility of the hardness or quality of the water supply with the equipment and detergents used.

Section removed stating ‘Water Quality’ and referring back to Manufacturers.

12.0 Installation, validation, maintenance and testing of sterilizers

13.0 Installation, validation, maintenance and testing of washer-disinfectors

14.0 Installation, validation, maintenance and testing of ultrasonic cleaners

12.2, 13.2, 14.2 Manufacturers’ guidance on validation should be followed.

13.0 Installation, validation, maintenance and testing of washer-disinfectors

14.0 Installation, validation, maintenance and testing of ultrasonic cleaners.

Test Soils

For manufacturer’s periodic testing of your ultrasonic washer or ultrasonic washer/drier: Strips are machine specific, visit our website to find out which Test Soil you need to use.

Load Check

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<th>Load Check</th>
<th>Wash Check</th>
<th>PCD &amp; CEI</th>
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<tr>
<td>Starter Pack</td>
<td>£40 +VAT</td>
<td>£56 +VAT</td>
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Automatic Water Treatment

- Available in portable and static models
- Suitable for sterilizers and washer-disinfectors
- Removes iron and calcium
- Smart system indicates when refills are required

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<tr>
<td>2x 500ml AWT Starter Pack</td>
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3Ezyme Multi Enzyme Detergent

- Effective on a range of organic and inorganic substances
- Non-flammable and non-toxic
- Ideal for ultrasonic cleaning

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<td>6x 500ml AWT Starter Pack</td>
<td>£54.95 +VAT</td>
<td>£84.50 +VAT</td>
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## Changes to HTM 01-05 2013 Edition

### What the changes mean and how they affect your practice?

#### 3.29
The ultrasonic cleaner should be tested according to the manufacturer’s instructions or, in the absence of these, quarterly (see Section 3, Chapter 14).

Previously Quarterly testing was required. Manufacturers recommendations should now be used but the quarterly schedule as set out in HTM 01-05 should be followed if there are no manufacturers instructions.

#### 4. Sterilization

4.3 Records are required for every sterilization cycle.

If you have a data logger, sterilisation cycles will be automatically captured, likewise if you have a printer then all the printouts should be retained, if you have neither of these then the most beneficial way to record this data would be to manually record the parameters of each cycle, however, someone who checks each sterilisation process is usually unachievable therefore a pragmatic approach would be to use class 6 TST strips which will only change colour if the temperature and time element of the sterilisation cycle are met. If you have a fault log in your machine logbook you would record any failures of cycles, therefore complying with the ‘absence of a failure light’ because you would have a Class 6 TST strip for each cycle (which should be retained) and if you haven’t recorded anything in your failure log that would be evidence enough to prove that the cycles have been successful.

4.7 Practices can seek the advice on the decontamination of handpieces from the handpiece manufacturer. Dental handpieces are constructed with a number of features that are difficult to clean and sterilize.

Again, not a major change to what was previously written but advice is now given that the manufacturer advice should be sought to determine how they should be decontaminated.

4.16 A record of the temperature and pressure achieved at the daily test, to ensure this is satisfactory before the autoclave is used for sterilizing instruments.

Slightly less information than in the previous edition, although it still implies the same, a daily test (called the automatic control test) should be carried out to ensure that the temperature and pressure of the autoclave are within the validated parameters. Once that information has been ascertained then the autoclave can be used to sterilize instruments.

4.19 The manufacturer’s advice should be sought on whether the daily tests can be carried out while instruments are being reprocessed.

There are instances now where manufacturers would advise that a daily test (steam penetration for example) could be carried out with instruments rather than on a separate cycle. Unless manufacturers say that this is an approved method of testing then it is advised that the test still be carried out independently of instruments.

4.21 Any instruments processed in an unsuccessful cycle should not be used.

An addition for clarity, instruments that have been decontaminated using a process that has failed SHOULD NOT BE USED until they have been reprocessed.

4.22(a) These instruments are suitable for storage for up to 12 months in their original packaging as long as their packaging is intact.

Textual amendment to incorporate the new storage guidelines.

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## Changes to HTM 01-05 2013 Edition

### What the changes mean and how they affect your practice?

#### 4.22(b)
Immediately after removal from the sterilizer, instruments should be aseptically wrapped using suitable sealed view packs. This could be achieved by the use of forceps, clean gloves or any other appropriate process. In addition, the entire tray may be placed within a sealed pack for storage purposes. In both of these instances, storage for up to 12 months is recommended.

An additional paragraph, relating to the ‘clean’ area of the decontamination room when removing unwrapped instruments from a sterilizer.

The decontamination room should be subject to cleaning after every use.

Contaminated instruments must never be placed on the work surface in the clean area of the decontamination room and vice versa.

#### 6.0 General hygiene principles

6.35 Uniforms and workwear should be washed at the hottest temperature suitable for the fabric to reduce any potential microbial contamination (see the Department of Health’s (2010) ‘Uniforms and workwear: guidance on uniform and workwear policies for NHS employers’).

Referring back to manufacturers guidance, this time in terms of the temperature that uniforms should be washed at. Previously temperatures were provided, however now it’s at the hottest temperature suitable for the material.

6.47 Flooding in clinical care and decontamination areas should be impervious and easily cleanable. Carpets, even if washable, should not be used. Any joins should be welded or sealed. Flooring should be coved to the wall to prevent accumulation of dirt where the floor meets the wall.

This is not listed under one of the ‘essential quality requirements’ however the condition of flooding in a practice can have a huge impact on how clean a surgery/practice can be kept. If your practice does not have coved edged flooring then the practical approach is to ensure that, as it requires replacing it should be done so WITH coving. It may be possible to have your existing flooring amended but a suitable contractor should be sought to determine.

6.57 The use of disinfectant or detergent will reduce contamination on surfaces. If there is obvious blood contamination, the presence of protein will compromise the efficacy of alcohol-based wipes.

The DoH is providing advice regarding the use of alcohol wipes, best practice in the opinion of Isopharm would be that practices should consider the benefits of using alcohol wipes and the risks associated with them and determine if the best option for the practice is to cease using alcohol wipes.

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**We are happy to take calls on 0800 840 0105 for support or advice.**

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