Process chemical residues

On the publication by H. Biering: Determination of tolerable process chemical residues after reprocessing thermolabile endoscopes (Central Service 3/2016: 160–164)

Letter to the Editor by Prof. Dr. H. Martiny, TechnischeHygiene, Weygerweg 20, 12249 Berlin, Germany

First, I would like to thank the IHO for addressing the topic of residues on medical devices. Priv.-Doz. Biering has given a clear and detailed description of the tests carried out (1). To make it easier to apply the test methodology, it would be helpful if some minor points could be added.

1. Since a variety of products based on different active substances were tested, which are generally used at different temperatures, I would like to know if it is also intended to perform the tests, apart from at 20 – 25 °C, at application temperatures of up to around 60 °C?

2. At what intervals were the repeat tests carried out and can one really assume that identical active substance concentrations were used (see the given active substance variationrange)?

3. Since we, too, have investigated this topic (2, 3), I am aware that with such tests wetting (unused?) synthetic materials is a major challenge, which is why we finally performed our tests directly during the EWD (endoscope washer-disinfector) process. In the study design chosen by the IHO the PCDs were placed for 15 s on blotting paper: How much of the liquid was still present at the end? And after this the PCDs were air-dried for one hour: in which way have the PCDs been stored during this period?

4. The test material chosen, with reference to an endoscope, was the "root brace rubber" of an endoscope. While discussing this matter with colleagues the question arose as to which part of the endoscope was meant by that. Was it the root brace rubber or the "distal end"? An explanation of this would be very helpful since, after all, only the distal end comes into contact with the patient.

5. Based on the results obtained the reference material proposed for future tests was polyurethane, "since this material is used to produce endoscopes" as well as "and the values obtained were on a par with those extracted from distal end pieces of endoscopes". If one takes a look at the extracted amounts in Table 2, that conclusion does not appear to be supported since when comparing all 12 extraction tests performed, the highest amount was determined once for the "root brace rubber", six times for silicone rubber but only five times for polyurethane. To gain a better understanding of that, it would be important to know whether the material polyurethane is identical to the outer surface of an endoscope or to that of the endoscope channels.

6. For product A based on glutaraldehyde the author had considered that long extraction times were not beneficial since this led to strong absorption or penetration into the polymer material. However, that behavioural mechanism was not observed for product B, also based on glutaraldehyde. The reasons for that should be clarified in further studies since glutaraldehyde, in particular, is known for its good material compatibility, which among other things explains its high application relevance. ■

References

1. Biering H: Determination of tolerable process chemical residues after reprocessing thermolabile endoscopes. ZentrSteril 2016; 24(3):160–164.
2. Emmrich M, Bloß R, Martiny H: Glutaraldehyde (GA) Residues in Flexible Endoscopes. Part I: Development of an Analytical Method for Detection of GA Residues. ZentrSteril 2014; 22(1): 46–49.
3. Emmrich M, Bloß R, Martiny H: Glutaraldehyde (GA) Residues in Flexible Endoscopes. Part II: Analytical Method and Factors for Detection of GA Residues. ZentrSteril 2014; 22(2): 84–87.

Author's reply

Many thanks for the suggestions, remarks and questions put forward in Prof. Martiny's reader's letter on the publication "Determination of tolerable process chemical residues after reprocessing thermolabile endoscopes".

To clarify these issues it is advisable here to call to mind two of the goals pursued by the Expert Working Group of Process Chemicals Manufacturers within the Industrial Association for Hygiene and Surface Protection (IHO):

– Development of a consistent, stepwise test programme to assess the biocompatibility of process chemical residues on the surfaces of reprocessed medical instruments, on the basis of which tolerable residual amounts can be determined – the results have been published (1).
– Formulation of a uniform methodology to determine the tolerable residual amount of products to be specified by the manufacturers of process chemicals for validation of reprocessing processes for thermolabile (heat-sensitive) endo-

scopes – the results have been published in (2) and are the issues raised by Prof. Martiny in her reader's letter.

Based on the findings published by the Working Group (1, 2) it is intended that the manufacturers of process chemicals will carry out the following procedural steps for each of the products used to reprocess thermolabile endoscopes:

- Determination of a tolerable residual amount of the respective product based on the test programme described (1).
- Investigation of the adsorption and extraction profiles of the process chemicals with respect to the endoscope and/or PCD as described in (2) under the respective process conditions.
- Development and provision of an analytical method for determination of the tolerable residual amount at the time of validation on the user's site.

The issues raised by Prof. Martiny in her reader's letter are now addressed in detail below:

1.As mentioned above, the manufacturers of process chemicals will carry out appropriate tests for each product used under the respective process conditions.

2.The experiments reported on in the published article were carried out in six laboratories with specialist knowledge of the respective product . Using a standard operating procedure, one product each was tested by each of four laboratories and two products each by each of two laboratories. Preliminary testing of the endoscope distal ends/cuffs was performed several weeks earlier (Table 1) than the tests comparing the results for endoscope distal end pieces with PCDs made of various types of synthetic materials (Table 2). For all tests the concentration given in the section "Materials and Methods" was used for each product.

3.In the course of the experiments we had to determine whether the process chemical residue amounts on the surfaces of PCDs could be detected with adequate accuracy. That was demonstrated by the analytical methods employed. Taking account of the reduced wetting of "unused" synthetic surfaces it is thought that accordingly on "used" surfaces greater residual amounts can be measured. The amount of liquid remaining after allowing the PCDs to drip off was not determined. The PCDs were not stored under specific conditions (ambient humidity, temperature) but rather under the normal laboratory conditions at room temperature (20 °C to 25 °C).

4.The cuffs of the distal end of thermolabile endoscopes were used for testing.

5.The Working Group's decision to use polyurethane as material for future uniform PCDs was based essentially on the following points:

- In the majority of thermolabile endoscopes the outer sheath is made of polyurethane.
- The product constituents deemed by the experts to be of importance (glutaraldehyde, peracetic acid, non-ionic surfactants), which were also used as analyte, as seen in Table 2 yielded higher extracted residual amounts for an extraction time of 1 h for polyurethane PCDs compared with the distal end pieces and silicone rubber PCDs (except for Product B).
- The higher residual amount of Product G on silicone rubber compared with polyurethane was attributable to the special effects between alkylamine and the test material.

The characteristics of the polyurethane composition used to produce endoscopes are unknown and may also differ from one endoscope manufacturer to another. Hence, the only assumption that can be made is that there is adequate concordance between the proposed PCDs and the materials of which the endoscope sheaths are composed.

6.Products A and B are based on the same active substance, glutaraldehyde, but have different compositions. In particular, the excipients can impact the adsorption and/or penetration profiles, which serve to explain the different results obtained for the two products on using long extraction times. That was not studied in greater detail for the publication.

As mentioned at the outset, the adsorption and extraction profiles of each product should be tested by the manufacturers of process chemicals under the conditions prevailing at the respective site of use. Based on these findings, it will then be possible to issue concrete recommendations for determination of the residual amounts of each product at the time of validation of reprocessing processes for thermolabile endoscopes. ■

Priv.-Doz. Dr. H. Biering

References

1. Biering H: Assessment of the biocompatibility of process chemicals used for decontamination of medical instruments. ZentrSteril 2013(1): 34–37.
2. Biering H: Determination of tolerable process chemical residues after reprocessing thermolabile endoscopes. ZentrSteril 2016; 24(3):160–164.

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