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**Advice from IHEEM Decontamination Technical Platform/IHEEM Registered Authorising Engineer (Decontamination) Group.**

**July 2024**

**Re: HTM 01-01 and HTM 01-06 Decontamination of Medical Devices –**

**Protein Residuals on Reusable Medical Devices**

The UK Department of Health’s Advisory Committee on Dangerous Pathogens’ TSE sub-group (ACDP-TSE) recommendations for reduction in protein levels on reusable surgical instruments was issued in May 2015; the IHEEM Decontamination Technical Platform (Authorising Engineer (Decontamination) group) support this position of reducing protein levels on reusable surgical instruments and flexible endoscopes to a level as low as possible.

The guidance issued by Department of Health in HTM 01-01 and 01-06 in England repeat this ACDP position. Additionally, in HTM 01-01 only, it specifies that ‘assessment of residual protein by ninhydrin reagent is insensitive and that proteins are poorly desorbed from instruments by swabbing; protein levels on an instrument should be measured directly on the surface rather than by swabbing or elution.’

The use of ‘in-situ’ protein detection fluorescent technologies supports the safe processing of reusable medical devices, and have application in situations where the design of the instrument is small enough to fit into the detection area of commercially available protein detection devices, and where those devices do not have internal lumens, non-line of sight areas or incompatible surface materials such as some plastics.

There are many devices, however, where such ‘in-situ’ technologies are unable to assess protein residuals due to size, design and material of construction, and this is not limited to devices such as endoscopes (endoscope decontamination is covered in HTM 01-06).

The concerns expressed over lack of sensitivity of swabbing methods principally relate to detection based on ninhydrin reagent and do not relate to all current swab technologies; some of these validated technologies may be suitable for monitoring protein levels on instruments whose design does not allow use of in-situ protein detection techniques.

The Authorising Engineer (Decontamination) group recommend the use of other methods for residual protein detection as supportive technologies, provided that these methods are validated as being capable of detection of less than or equal to 5µg of protein on reusable medical devices; for higher-risk neurosurgical devices, these methods must be capable of detection below 5 µg of protein. This is also supported by BS EN ISO 15883-5:2021, where protein levels are required to be below 6.4 µg/cm2.

A combination of these different methods of fluorescent and validated systems provides the most balanced way forward obtaining a complete residual protein picture for the full range of devices processed through decontamination facilities, resulting in demonstration of cleaner surgical instruments and subsequently safer surgical procedures for patients.