Recommendation of the Quality Task Group (124)

# Is validation of processes in storage cabinets with controlled storage conditions legally mandated?

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## Introduction

Controlled environment storage cabinets for reprocessed, thermolabile (heat-sensitive) endoscopes are not classified normatively as medical devices (see EN 16442 [1], Introduction, NOTE 4). That viewpoint is generally not shared by the manufacturers of the cabinets and therefore the **STORAGE CABINETS** are often classified as medical devices (class I).

This is not the only reason why the issue of process validation in drying and storage cabinets for thermolabile endoscopes is being raised increasingly more often. There are divergent views on this, causing uncertainty among many economic operators, in particular when the cabinets are used exclusively for the storage and not for drying endoscopes.

**STORAGE CABINETS** are often classified by manufacturers as medical devices (Class I).

## Background

Storage cabinets (with or without controlled storage conditions) serve to preserve the **STATE OF A REPROCESSED ENDOSCOPE** until it is next used for a patient. As such, they constitute an area with high hygiene demands that must also be subject to the infection control/hygiene monitoring measures applicable in healthcare institutions. That requirement is aptly described in EN 16442:

**4 Performance requirements**
**4.1 General**

4.1.1 Storage cabinets are designed to provide a controlled environment for storage of endoscopes (with and without channels). The controlled environment provided by the storage cabinet shall ensure that during storage there is no deterioration of the microbiological quality of the endoscope. An optional drying function is provided to supplement, if necessary, any drying provided as part of the automated or manual reprocessing cycle.

Extract from EN 16442

The **STATE OF A REPRODUCED ENDOSCOPE** is maintained in storage cabinets until the next use.

## Legal requirements

Pursuant to the KRINKO-BfArM Recommendation [2], **DRYING PROCESSES** are part of the overall reprocessing process. Annex 8 "Hygiene requirements for reprocessing flexible endoscopes…" lists the individual process steps in Table 1:

**DRYING PROCESSES** are part of the reprocessing.

**Table 1: Overview of the various reprocessing processes for endoscopes***

| | Manual, or if necessary, with automated support | Automated |
|---|---|---|
| Precleaning | Immediately after endoscopic examination in the endoscopy suite: wipe off the outer endoscope sheath and flush out the channels | |
| Clean the endoscope channels with a brush | Clean thoroughly, manually, in the reprocessing unit (use a suitable, disinfected brush for each channel!) | |
| Rinse | Manually in the reprocessing unit | in AER** |
| Disinfection | Immerse free of air bubbles | in AER |
| Final rinse | Flush out with disinfectant solution | in AER |
| Drying | In the reprocessing unit | in AER |

* Extract from the KRINKO-BfArM Recommendation, Annex 8, ** automated endoscope reprocessor

As well as in the KRINKO-BfArM Recommendation, the drying processes are also considered to be part of the overall reprocessing process in the Guideline for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Heat-Sensitive Endoscopes) [3]. That view can also be inferred from EN ISO 15883-4 [4], which recommends that these steps also be included in the type test for the washer-disinfector.

We therefore believe that, based on Section 8 of the German Medical Device Operator Regulation (MPBetreibV) [5], **VALIDATION OF THE DRYING PROCESSES** should be carried out.

**VALIDATION OF DRYING PROCESSES** must be carried out.

**Section 8 Reprocessing medical devices**

(1) Reprocessing of medical devices intended for use in aseptic or sterile conditions must be carried out in accordance with the manufacturer's instructions using suitable validated processes in such a way that the success of these processes is verifiably guaranteed and the safety and health of patients, users or third parties is not endangered. This shall also apply to medical devices which are disinfected or sterilised prior to their first use.

(2) Proper reprocessing pursuant to Para. 1 (1) shall be presumed if the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices on hygiene requirements for reprocessing medical devices is observed. The reference shall be published by the Federal Ministry of Health in the Federal Gazette.

Extract from the Medical Device Operator Regulation (MPBetreibV)

That still leaves the question of whether processes in controlled environment storage cabinets for reprocessed, thermolabile endoscopes must also be validated if they are used exclusively for storage of reprocessed and already dried endoscopes. This question is not easy to answer and must therefore be considered from different angles.

## Storage cabinet with controlled storage conditions

Pursuant to the KRINKO-BfArM Recommendation, "Hygiene requirements for reprocessing medical devices" **STORAGE** is not part of the overall reprocessing process.

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**1 Basic information**

Reprocessing usually includes the following individual steps:
a) Proper preparation...
b) Cleaning, if necessary intermediate rinsing, disinfection, rinsing and drying,
c) Inspection for cleanliness and integrity,
d) Maintenance and repair,
e) Functional testing and, as required,
(f) Labelling as well as
g) Packaging
h) and sterilization.
Reprocessing ends with documented release of the medical device for use.

Extract from the KRINKO-BfArM Recommendation

However, Section 3 Transport and Storage draws attention to the storage requirements.

In addition, many other sources (39 references) point to the **PARAMOUNT IMPORTANCE** of, and requirements for, storage. There is therefore a need for hygiene measures (e.g. infection control policy, routine tests).

The KRINKO-BfArM recommendation refers to the **PARAMOUNT IMPORTANCE** and requirements for storage..

**3 Transport and storage**

Transport and storage must not adversely affect the properties of the reprocessed medical device. (...).
Aseptic (semi-critical) medical devices must be stored in such a way that recontamination during storage is avoided

Extract from the KRINKO-BfArM Recommendation

EN 16442 describes requirements for controlled environment storage cabinets for reprocessed flexible endoscopes, including verification of compliance with the hygiene requirements. Hence, an obvious step would be to verify or validate compliance with the requirements on that basis.

In addition to validation and routine requalification of the process, the hygienic condition should be monitored in routine tests (e.g. microbiology testing). Apart from technical malfunctioning, external influences can also lead to contamination of storage cabinets (e.g. contamination when loading and/or unloading, see also: EN 16442, Section 4.2.2).

**EN 16442** is not a harmonized standard but is cited by most manufacturers as the observed standard for storage cabinets and can therefore be seen to represent the general state of the art. Accordingly, storage cabinets should meet the requirements of that standard and be benchmarked against it.

**EN 16442** can be seen as the generally recognised state of the art.

In this respect, the Medical Device Operator Regulation (MPBetreibV) too stipulates that the generally recognized rules of technology be applied.

**Section 3 Duties of an economic operator**

(1) The economic operator shall perform the duties incumbent on them under this Regulation in order to ensure the safe and proper use of the medical devices used on patients in their healthcare institution.

**Section 4 General requirements**

(1) Medical devices may only be operated and used in accordance with their intended purpose and in compliance with the provisions of this Regulation and the generally recognised rules of technology.

Extract from the Medical Device Operator Regulation (MPBetreibV)

A controlled environment storage cabinet for reprocessed, thermolabile endoscopes is technically equipped to provide optimum (e.g. aseptic, particle-free) storage conditions for reprocessed endoscopes. It therefore constitutes an ongoing or continuous process whose **EFFECTIVENESS** must also be tested in accordance with the state of the art. This applies in principle for reprocessing flexible endoscopes (KRINKO-BfArM Recommendation, Annex 8, Para. 3.7) and especially for cystoscopes and bronchoscopes.

The **EFFECTIVENESS** of a storage cabinet with regulated environmental conditions must be tested according to the state of the art.

**Annex 6:**

With regard to reprocessing flexible cystoscopes and bronchoscopes
(...). If reprocessing does not take place immediately before use, dry storage that excludes recontamination must also be ensured.

Extract from KRINKO-BfArM Recommendation

**Conclusion:**

In storage cabinets two processes generally come into play: the storage and the drying process. Unlike in a packaging system (sterile barrier system), the

microbiological quality of the endoscope is not assured through a manual process (closure of a sterile barrier system) but rather by means of a technical appliance with a continuous ongoing process. EN 16442 describes the requirements for the equipment, for testing the effectiveness of processes and also gives details of the acceptance criteria. Therefore, the tests (methods) described in that standard can also be used for validation (process of confirming by providing objective evidence that the requirements for a specific intended use or application have been met).

Drying performance tests are also described in EN 16442 and are virtually identical to those test methods set out in other standards (e.g. EN ISO 15883-4). Unlike EN ISO 15883-4, EN 16442 limits the maximum time allotted for the drying process to 3 h.

Just like EN 16442, the standards of the EN ISO 15883 series are standards that describe device requirements and „tests for compliance“. They form the basis for the validation of processes at the economic operator's premises. Therefore, EN 16442 can equally be applied as the basis for process validation at the economic operator's site. So far, there is no **GUIDELINE** for validation of processes in a storage cabinet.

A **GUIDELINE** for the validation of processes in the storage cabinet does not currently exist.

## References:


1 EN 16442:2015: Controlled environment storage cabinet for processed thermolabile endoscopes.

2 Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM). Bundesgesundheitsblatt 2012, 55: 1244-1310.

3 Leitlinie von DGKH, DEGEA, DGSV, DGVS und AKI zur Validierung maschineller Reinigungs-Desinfektionsprozesse zur Aufbereitung thermolabiler Endoskope (2011) [Guideline compiled by the DGKH, DEGEA, DGSV, DGVS and AKI for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Heat-Sensitive Endoscopes].

4 EN ISO 15883-4:2019: Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

5 Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung – MPBetreibV) [German Medical Device Operator Regulation].