

# The new packaging guideline – practical implementation in a CSSD in Germany

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The Elisabeth Hospital in Essen (613 beds) operates three **washer-disinfectors** (WD), two sealing devices and two steam sterilisers (6 StU) (each identical in construction) in its central sterile supply department (CSSD). Containers (70 %), packaging wraps (10%) and pouches (20 %) are used to package medical products. Gusseted Pouches are used, and these are sealed mechanically using the sealing devices.

## Introduction

Validated preparation processes are required according to the European Medical Device Directive (MDD). Validation has become common practice for cleaning & disinfection and sterilisation processes. If one considers, however, that the packaging itself is the key reason why medical products remain sterile right up until use in the operating theatre, it becomes clear that the packaging process is a fundamental part of this instrument reprocessing chain. Only a reproducible, validated packaging process will ensure sterile medical products for clinical use. For this reason, the harmonised European EN ISO 11607 standard was published in 2006 which, in its second part, requires the validation of all packaging processes, regardless of whether they are automatic using sealing devices or manual, for instance during wrapping or when filling and closing a container.

## Validation of the sealing process (automatic process)

Sealable pouches and reels must essentially be closed with a sealing device. Accordingly, the process is carried out automatically, which is why the validation process is relatively easy to implement in practice. The German Society for Sterile Supply (DGSV e. V.) therefore joined forces with the TÜV organisations to publish guidelines on the validation of sealing

processes according to EN ISO 11607-2 in 2008. Checklists enable the validation process to be carried out. Essential requirements of course include sealing devices which monitor the critical process parameters temperature and contact pressure (the additional monitoring of speed/time is also recommended by the DGSV) and which alert the user in the event of any problems (Fig. 1). These devices must be confirmed by the manufacturer as being compliant with EN ISO 11607-2. Where older sealing devices are used, the manufacturer should be asked whether they already satisfy the standard's specifications. The packaging material must comply with the EN ISO 11607-1 standard. The manufacturer must provide a data sheet which lists the sealing temperatures (e. g. 170 to 200 °C).

Validation is carried out using checklists. Once the process has been validated, the sealing seams must be checked on a routine basis. The best way to do this is with either an ink test (Fig. 2) or a seal indicator (Fig. 3). We and many other hospitals have been carrying out validations of sealing processes for many years and, thanks to the automatic processes involved, everything has run without a hitch.

## Validation of manual packaging processes (wrapping and container)

**Standard operating procedures** are required for the mandatory validation of manual processes. But are these enough? In response to this question, the DGSV has revised the existing guidelines and, at the DGSV Conference in 2011, published the «Guideline for Validating Packaging Processes according to EN ISO 11607-2». The «Sealing» section has been supplemented with a few very helpful sample standard operating procedures (SOP). New checklists for validating the «wrapping» and «filling and closing containers» processes were also included. Since these proc-

esses are entirely manual compared to the sealing process, the validation procedure is slightly unfamiliar and significantly more labour-intensive. This was however already noted during the planning stage. The entire team within our department needed to be given in-depth instruction in the contents of the guideline, its requirements and information on the practical aspects of carrying out the validation. Training courses and instructions were given to all employees on the various packaging techniques.

The first major obstacle was how to determine the number of validations and how to draw up a validation schedule. Countless documents, data sheets, product specifications and declarations of conformity have to be requested from the manufacturers of the packaging systems and their accessories. Experience has shown that this worked very well in most cases (PDF files from manufacturers). A lot of time was spent filling out the validation plan checklists. The installation qualification (IQ) was comparatively easy, since all that needed to be ensured was that all of the standard operating procedures were available. The guidelines include sample standard operating procedures (SOP) that were compared with our existing SOPs. The guidelines even provided examples for training employees.

The operational qualification (OQ) required the comprehensive documentation of the entire container and its accessories. The most critical packaging configurations for the containers and sets packed in packaging wraps had to be defined. In this case, we followed the guideline's in-

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Fig. 1: Validatable heat sealer in action (here: hawo hm 3010 DC-V)



Fig. 2: Checking the quality criteria using the ink test (here: hawo InkTest)



Fig. 3: Checking the sealing seam with a seal indicator (here: hawo Seal Check)

structions and orientated our activities towards the heaviest and largest containers or sterilisation trays («worst-case scenarios»). Once these configurations had been defined, several employees who were unaware of the validation process and who were not under surveillance had to package 10 of these configurations in accordance with the standard instructions.

It became truly clear for the first time at this stage what effects the human factor has on the process. Differences in the quality of the finished packaging compared to the required quality criteria were found depending on the time of day and the employee responsible. It is essential that a constant level of performance is maintained in the department (e. g. through further training). Employees must always be deployed in accordance with their strengths. Only then can their performance be harnessed and documented.

The 10 «worst-case» packages were unpacked again and each step was documented with a photo. A corresponding series of photos was then incorporated into the «operational qualification» checklists. After a lot of work and training, there were no further obstacles to get in the way of the final stage – the performance qualification (PQ). A performance assessment must always be carried out after sterilisation. In accordance with the guideline, we removed a container or a sterilisation tray packaged in a packaging wrap (it should be noted that the largest and heaviest container or sterilisation tray is always removed) during three different sterilisation cycles. These were then unpacked step by step, with each step being photographed (8 – 10 photos/see Fig. 4) and compared with the required quality criteria. The results were entered into the «performance qualification» checklists; everything was brought

together in a validation report and the next repeat performance assessment was defined.

#### Summary

The «heat sealing of pouches and reels» validation generally runs smoothly, since it has been going on for a few years now and the process is pretty automatic. Things are significantly more difficult, however, with the validation of «folding and wrapping of sheets» and «filling and closing of reusable sterilization containers». Obviously, these processes are entirely manual activities. In these instances, humans and their varying performance levels on the day have a considerable influence. For practitioners, the implementation of the «Validation of packaging processes» guideline is undoubtedly a challenge, but one which has to be overcome. The DGSV guideline provides the resources required to do this. ■



Figs. 4.1 to 4.3: Typical images of photographic documentation (containers) taken during the functional and performance assessment