Recommendations by the Quality Task Group (78)

Management of Loan Instruments (Part 1)

The vast majority of an institution's reusable medical devices are owned by the authority responsible for operation of the institution (called the «operator» in the following). These are decontaminated using validated processes. However, healthcare institutions are also increasingly using medical devices loaned to the operators. These «loan instruments/loan systems» must also be decontaminated before and after use, while also using validated processes. That makes high organizational demands on all participants, so as to ensure that the safety and health of patients, users and third parties are not endangered.
With this recommendation the Quality Task Group gives tips to all parties concerned on management of loan instruments. First, the organizational measures needed are described from the perspective of the decontamination department. Part 2 will give a detailed account of the procedures used for management of loan instruments.
Part 1 of the recommendation now describes the procedures and responsibilities that must be organized at the operator's premises, if necessary with the involvement of external reprocessors, as well as at the lender's premises.
These include for example:

Procedure	Individual steps/measures to be organized
Ordering	– Designate person to take charge of ordering loan instruments and set out ordering procedure in writing – Clarify cost absorption within the organisation and set out in writing – Identify and describe scope of information needed • Operating manual (manufacturer's decontamination instructions as per DIN EN ISO 17664) ❑ Further details (form and scope) must be agreed between the lender and reprocessor • If necessary, lender to provide briefing/instruction in OR • Details of envisaged procedure, for example: ❑ Instruments and implants needed ❑ Information on patient (height, weight, procedure on right or left side, etc.) ❑ For reinterventions, details of implants to be removed
Setting deadlines	– Make a note of date(s) of use to facilitate planning – Clarify whether single or multiple use is intended – Specify shortest advance interval needed to assure proper decontamination • for first use • for repeated use • how to contact various parties when reprocessing (borrower, lender, to deal with any reprocessing queries arising) – Set collection date
Incoming/outgoing supplies	– Specify delivery point – Information (scope, type of devices, priority,) on delivery and collection to/from operator /reprocessor, and define information chain – Designate competent personnel to take charge of loan instruments delivered to operator/reprocessor – Nominate a member of operator's and reprocessor's staff to deal with subsequent queries relating to loan instruments – Specify collection point and collection time
Internal transport	– Specify internal transport procedure for loan instruments
Training/briefing	– Clarify need for, and organize, briefing of users and reprocessors – Document briefing
Storage place	– Designate storage sites for loan instruments, packaging materials and transport packaging at operator's premises

Procedure	Individual steps/measures to be organized
Inspection of incoming and outgoing supplies	– Assign competencies for inspection of incoming and outgoing supplies – Specify scope of inspection of incoming supplies on delivery and of outgoing supplies before collection to ensure • delivery content is complete and functional • cleanliness of loaned instruments • check respective documents (delivery note, operating manual, and if applicable evidence of decontamination, etc.) – Specify measures to be taken if discrepancies noted on inspection – Record inspection of incoming and outgoing supplies – Specify collection procedure after use – Return all documents supplied • Evidence of decontamination • Record outgoing supplies
Planning resources in the decontamination department	– Allocate manpower/resources within department to decontaminate loaned instruments
Risk assessment, classify before initial use	– Conduct risk assessment – Assign instrument to risk class – Set out decontamination steps in writing
Validation	– Check whether the loaned instruments are covered by the scope of the reference loads/worst case loads defined by process validation. – Document assessment – If necessary, execute performance qualification/requalification if warranted for special reasons – If necessary, refuse decontamination request
Decontamination/ reprocessing	– Loaned instruments are subject to the same decontamination requirements as the institution's own medical devices – If necessary, enter relevant data into the batch documentation system/instrument management programme (master data entry) • If necessary, generate photographic documentation – Assure traceability

Furthermore, when defining terms for management of loan instruments, the following parties, at least, must also be consulted:

– the internal or external decontamination department (expert personnel)
– the department using the respective instrument(s) (e. g. user, assistant personnel)
– infection control team (infection control nurse or specialist)
– business management department (in particular purchasing personnel)
– medical technology department (competent medical technology specialist)
– transport service (competent staff member)
– legal department/contractual agreements
– quality management

Management of loan instruments must be set down in writing as part of the operator's and reprocessor's quality management system, while paying special attention to the external interfaces. Set out in writing agreements with the lender and these should be comprehensible for all departments concerned.

Part 2 of this recommendation on «Management of Loan Instruments» shall be published in one of the forthcoming issues of *Central Service*. ■