Recommendations by the Quality Task Group (38) Checklist for Preparation of Visits by the Competent Inspection Authorities

The Quality Task Group has compiled a checklist to help operators prepare for talks with the regional government authorities or the health authorities. We would like in particular to thank Mr. Nikou Ghassemieh for his help in taking charge of discussions with the Robert Koch Institute (RKI) and with the responsible parties at the health offices and at DIAM. We are aware that in Germany regional governments (Bundesländer) are responsible for audits and inspection. However, the RKI and the German Society of Sterile Supply (DGSV e. V.) would welcome the idea of using standard documentation for this purpose so that operators could systematically check to what extent they already meet, or are about to meet, the legally stipulated requirements.

The checklist is designed to reflect the various sections of the recommendation drafted by the Commission for Hospital Hygiene and Infection Prevention at the RKI: "Hygiene requirements for processing medical devices".

Checklist in Preparation of Inspection of a Central Sterile Supply Department

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
(CSSD), while bearing in mind the Recommendation by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) "Hygiene requirements for processing MDs" as well as Annex 4.4.1 "Hygiene requirements for functional and structural design of sterilisation units"				
I General				
Is there a Central Sterile Supply Department (CSSD)?				
Does this establishment have a quality management system? Has it been certified?				
Is decentralised processing carried out (additionally)?				
If there is decentralised processing, in which areas, which rooms:				
Disinfection (D):				
Cleaning (C):				
Packing (P):				
By whom?				
Sterilisation (S):				
How?				
By whom?				
Storage where?				
Is processing also carried out for other areas or for third parties?				
If yes, for whom? (enclose description and agreement)				
If yes, which medical devices (MDs)?				
Are there Infection Control Plans for all departments?				
When drawn up?				
Are there Cleaning and Disinfection Plans for all departments, with assigned competencies?				
Is the requisite protective gear available in all departments? (Gloves, aprons, goggles, etc.)				
Are operating instructions for hazardous substances displayed?				
Are MDs processed externally?				
Which?				
By whom?				
Has the processor been certified?				
Are surgical drapes being processed?				
Are there additional rooms for handling surgical drapes, and working areas for sorting, checking and packing laundry? Laminated materials?				

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
II Competence / Preconditions for Processing / Training in the CSSD				**1.1**
How are competencies assigned for processing within the hospital?				
Are competencies assigned and documented for all processing steps (QM)?				
Is the CSSD manager / sterilisation manager a qualified Technical Sterilisation Assistant?				
Specialist Course 1, 2 or 3?				
How many employees are there in the CSSD?				
How many are qualified?				
What is the qualification level of staff?				
Is there a Training Plan for staff?				
Are all staff regularly briefed and is this documented?				
Are medical devices classified as per the RKI Recommendation?				1.2.1.
In the case of medical devices that may be reprocessed only for a limited number of times (as specified by the manufacturer in the operating manual), has it been set out in writing whether and with which method each MD, or as applicable product group (as app, the test models, criteria for forming product groups or choice of test models must be documented) may be reprocessed?				
Have critical processing steps been defined during risk assessment?				
Have potential hazards been defined?				
Have risk minimisation measures been defined?				
Are standard operating procedures and work instructions available?				
Has proof been furnished of the suitability (product compatibility) and the effectiveness of the selected process on the basis of product/product-group-specific tests and validation (as per Section 4 MPBetreibV, Sterilisation and automated cleaning and disinfection processes are validable) (manufacturer's instructions)?				1.2
Are Critical Group C (as per RKI recommendations) MDs processed?				1.1
If yes, which? _____				
Has the quality management system for Critical C MDs been certified by a body accredited by the competent authority (pursuant to Section 20(1) MPG)?				
If no, which? _____				
Is processing conducted by a third party? If yes, is the establishment in possession of a quality management system / certificate ?				
III Structural and Technical Facilities (as per RKI Recommendation, Annex 4.4.1), including Health and Safety Measures				
General:				
Layout of premises?				
Is there an area with a window?				
Length of transportation pathways and duration?				
Are there ventilation (air conditioning)systems?				
Ventilation system (that complies with occupational safety regulations)?				
- unclean area?				
- clean area (LAF ceiling of 1 m x 1.50 m above packing station or terminal filter)?				
- Storage room?				
How many computer terminals are there?				
Staff transfer areas (2 room)?				
Are the unclean and clean areas spatially separated?				
Is there a recreation room?				

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Does the area before sterilisation have: **A) Unclean working area** 1) Is there a room for incoming materials? 2) Is there, if applicable, a separate recreation room? 3) Is there an area for disinfecting and cleaning transport containers? 4) Is there an area for disinfecting MDs? 5) Is there an area for cleaning MDs? 6) Are there washer-disinfectors (WDs) available? 7) Are there different loading trolleys for the WDs? If yes, which ? . . . . . (please specify in Remarks column) 8) Is/are the WD(s) a 2-door, load-through machine? If not, what type of WD? _____ 9) Is there an ultrasound machine? 10) Is there a connection for demineralised water? 11) Is there a pressurised water pistol? 12) Is there a connection for medical compressed air? 13) Is there an area for servicing and maintenance tasks? 14) Are there automatic dosing facilities for instrument disinfectants? 15) Are there automatic dosing facilities for surface disinfectants? 16) Are the dosing devices regularly serviced and inspected? – Detergents, etc. ? 17) Are there computers and scanners for recording and documenting working procedural steps?				
B) Clean working are 1) Is there a service room? 2) Is there an area for servicing, sorting and packing? 3) Is there a connection for medical compressed air? 4) Is there a workstation with a magnifying glass or microscope? 5) Are there computers and scanners for recording and documenting working procedural steps as per assigned competencies? 6) Is there suitable lighting – spec. requirements (as per regulations for precision work?				
Sterilisers' area: **Are the following available in the area after sterilisation:** 1) Sterile supplies' store 2) Area or hatch for handing out materials 3) Staff changing rooms? 4) Staff transfer area between unclean and clean sides				
Is anaesthetic equipment also processed in the CSSD? If not, where? Are working and wall surfaces as well as floors free of gaps, and easy to wash/disinfect? Are cables concealed or in closed channels? Are there separate exhausts for equipment with high thermal loads (e.g. vapour exhausts)? Is there an Infection Control Plan (Cleaning and Disinfection Plan)?				
IV Processing **1 Processing Unused Medical Devices** ***(if there is questionable or definite contamination, process as used MDs)*** Are supplies unpacked to check technical/functional safety? Are medical devices repacked?				**2.1**

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Is the sterilisation process as specified by the manufacturer being used? How is labelling done? Is processing documented? Is the release for use being documented? Are medical devices fully processed after their expiry date?				
2a) Processing Used Medical Devices Preparation (pretreatment, collection, precleaning, if nec., dismantling, transport) Are coarse soils removed immediately after use (pretreatment) (e. g. by wiping surfaces, rinsing channels)? Where? By whom? Which? How? Have the pretreatment agents and methods been tailored to the ensuing processing step (e. g.: avoidance of fixing procedures such as use of heat or aldehydes)? Are jointed instruments stored in an opened state? Are supplies dry when transported to the CSSD? If supplies are transported wet, specify the disinfectant, concentration and exposure time: Is protein fixation ruled out? Who prepares the solution? Are dosage aids available? How are MDs transported to the CSSD? How is timely transport to the CSSD assured? Are contaminated MDs transported to the CSSD in securely sealed containers? How often are supplies collected? How are arrangements for the weekend? Are there suitable containers for transport and intermediate storage, as needed, to rule out chemical, mechanical and physical damage to MDs (e. g. through kinking, crystallisation of residual liquids)? Are certain MDs cleaned and disinfected at a decentralised location? If yes, how? Where? By whom? Where are these MDs sterilised, if necessary? If decentralised location, who is responsible for release?				2.2
2b) Cleaning / Disinfection, Rinsing and Drying – Using Ultrasonic bath Are there written standard operating procedures for **manual** cleaning and disinfection procedures, listing agents/processes with proven efficacy and suitability for respective MD? Are the manufacturer's instructions available as per EN ISO 17664 and they taken into account? Is protective gear available (gloves, aprons, goggles, etc). TRBA 250? (Technical Regulations for Operating Safety) Regulations drafted by the statutory accident insurance companies (e. g.TRBA 250)? Have staff been briefed? Hazardous Substances Register? Are there immersion baths for manual cleaning and disinfection? Which detergent is used? Concentration: _____ Exposure time: _____ How often is the cleaning solution changed? Which disinfectant is used? Concentration: _____ Exposure time: _____				**2.2.1**

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Has the disinfectant been approved by the German Society of Hygiene and Microbiology (DGHM)? Is there an Expert Opinion attesting to virucidal activity? Is there an Expert Opinion attesting to virucidal activity against hepatitis B virus (HBV)? Is protein fixation ruled out? For how long can the same disinfectant solution be used? Is the disinfectant solution renewed daily? Is there a water pistol for purging internal lumens? What is the quality of the water used to rinse disinfected instruments? Are MDs dried with non-linting cloths?				
Are there written standard operating procedures for **automated** cleaning and disinfection procedures, listing agents/processes with proven efficacy and suitability for respective MD? Are the manufacturer's instructions available as per EN ISO 17664 and are they taken into account? Have the WD processes been validated? Is there a validation protocol? Who conducted validation? With which programmes and reference loads? Have the respective tests for the WDs been specified and set out in writing (the test parameters are listed in the validation protocol), e.g. b) daily routine tests c) batch-related routine tests d) Monitoring/testing of process parameters using measurement technology methods e) periodic tests of cleaning with cleaning indicators? f) periodic tests of disinfection with thermologgers? g) which programmes are used for cleaning and disinfection? – Vario programme with thermal disinfection? – Vario programme with chemicothermal disinfection? – For which MDs? – BGA programme (“Epidemic programme”)? If others, which? _____ Do the detergents/disinfectants have access to all external and internal surfaces? (jointed instruments opened, modular instruments dismantled, valves/cocks opened) Is cleaning conducted, if possible, above pH 10 (pronounced efficacy in respect of dissolution of protein and fat residues, but can adversely affect materials)? Are MDs amenable to thermal disinfection actually thermally disinfected?				
Ultrasonic cleaning Is an ultrasonic procedure used for processing? Are there written standard operating procedures for ultrasonic procedures, listing agents/processes with proven efficacy and suitability for respective MD? Are the manufacturer's instructions available as per EN ISO 17664 and are they taken into account? Is cleaning conducted in the ultrasonic bath? Name of detergent: _____ Concentration _____ Is cleaning and disinfection conducted in the ultrasonic bath? Name of detergent: _____ Concentration _____ Exposure time _____ Has the disinfectant been approved by the German Society of Hygiene and Microbiology (DGHM)? Are the agents employed suitable for use in an ultrasonic bath? Is protein fixation ruled out?				

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
How are the ultrasonic bath functional capabilities checked? Are there standard operating procedures for daily start-up of ultrasonic equipment? Do the MDs lend themselves to ultrasonic cleaning (caution: adhesive joinings, soft or air-filled MDs)? Is the air removed from lumened MDs? Is the ultrasonic bath properly loaded and are all items immersed in the liquid (incorrect operation, e. g. spray shadowing)? What is the operating temperature of the ultrasonic bath? Is the ultrasonic bath renewed if visibly contaminated or at least each working day (avoidance of microbial growth, impaired cleaning performance and of cross-contamination)?				
Disinfection Is disinfection conducted in the CSSD? Is it conducted manually or in the ultrasonic bath? Is it conducted in the WD? With DGHM-approved disinfectants. See manual and ultrasonic processing Which disinfection processes are used (s. ISO 17664)? Thermal? What temperatures are used for processing? Are there manufacturer's instructions available for processing? Chemical? Are there manufacturer's instructions available for processing? Chemothermal? What temperatures are used for processing? Are there manufacturer's instructions available for processing? Are the disinfection procedures used endowed with proven bactericidal efficacy? Are the disinfection procedures used endowed with proven fungicidal efficacy? Are the disinfection procedures used endowed with virucidal efficacy? (AB spectrum of action)? Is there a DGHM-approved agent for manual disinfection? Name of the disinfectant? Concentration and exposure time? Has the disinfectant efficacy been certified for disinfection in washer-disinfectors in an Expert Opinion issued by the manufacturer? Name of the agent? Concentration and exposure time? Have procedural measures been taken to ensure that precleaning does not cause fixation of residues on the MD (blood, secretions, tissue residues)? Is the Operating Manual observed, in particular the exposure time?				
Rinsing, Final Rinse and Drying Is formation of reaction products and residues due to intensive reversible flow during rinsing ruled out (effect a function of time, temperature and water volume)? Is suitably tested water used for rinsing (at least, demineralised water)? How often is the water quality checked? Is medical compressed air used for drying? Is recontamination of disinfected MDs ruled out? Are the dosing devices regularly serviced and inspected? Last time serviced:				

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Microbiological testing: Is the WD subjected to microbiological testing? If yes, what is the outcome? Machine: Date: Results:				
2c) Inspecting Cleanliness and Integrity of Surfaces Are there standard operating procedures for inspecting cleanliness and integrity of surfaces? Are all parts of medical devices – inspected for cleanliness and integrity (visually also for any residual contamination)? – additional chemical or physical check? If the cleaning outcome cannot be assessed through visual inspection, e. g. long, narrow lumens, hollow cavities, B+C Critical“ MDs, is a successful cleaning outcome assured by taking procedural steps ? (e. g. by validated automated processes? Are test instruments and equipment available? Which, e. g. magnifying lamp?				
2d) Maintenance and Repairs / Checking Technical/Functional Safety Are there standard operating procedures for maintenance and repairs? Are there standard operating procedures for checking technical/functional safety? Is contamination with dangerous substances (e. g. toxic care agents) or particles (e. g. talc) ruled out (if necessary, check with magnifying glass)? Have measures been taken to ensure that care agents do not compromise sterilisation results (e. g. medical white oils, if necessary get name of care agent manufacturer)? Is there the necessary equipment for functional tests (pipe flowmeters, compressed air, drive systems, etc.) ? Are the manufacturer's instructions observed? Is technical/functional testing conducted before sterilisation? Is the scope and nature of the MD defined in standard operating procedures? Is protective gear available (gloves, aprons, goggles, etc). TRBA 250? (Technical Regulations for Operating Safety) Briefing? Hazardous Substances Register?				**2.2.2**
2e) Packing (mechanical protective packaging, sterile packaging, if necessary repacking) Are there standard operating procedures for packing? Are packing procedures regularly validated as per ISO 11607 Part 2? (IQ, OQ and PQ) What sterilisation processes are used? Steam sterilisation? EO sterilisation? FO sterilisation? Plasma sterilisation? Is suitable packaging used for steam? Is suitable packaging used for EO? Is suitable packaging used for FO? Is suitable packaging used for plasma? Is the sterile packaging tailored to the sterilisation process to be used (providing for sterilisation)?				2.2.3

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Does the packaging lend itself to preservation of the functional capabilities of the MD to be sterilised? (e.g. mechanical protection of delicate components) Does packing take account of respective needs? Are packing lists used? Is the sterilisation date or batch number printed on the sterile packaging? Is the packaging tailored to the envisaged storage and transport (e. g. protection against mechanical stress and recontamination)? Are unwrapped supplies sterilised (e.g. using ‘flash’ sterilisation)? Is there a rotary sealing machine? Is the rotary sealing machine able to monitor the critical parameters (temperature and contact pressure) and interrupt the process in the event of any deviation from these? Is the sealing machine regularly inspected ((full service from manufacturer? Daily inspection of sealing seam (using welded seam and visual inspection using suitable test? Is the packer’s name recorded?				2.2.3
2f) Sterilisatio What type of sterilisation is used / number of sterilisers / Name: 1. Hot-air sterilisation (dry heat): 2. Steam sterilisation (moist heat): – 134°C / 5 minutes – 134°C / 18 minutes – 121°C /20 minutes 3. Ethylene oxide gas sterilisation (if available, for more information see Annex 1): 4. Low temperature steam formaldehyde sterilisation (LTFS) (if available, for more information see Annex 2): 5. Plasma sterilisation Is a sterilisation process with proven suitability and effectiveness for the MD being used (preferred process: thermal sterilization with saturated steam 121 °C or 134 °C)? Have the processes been validated? Has the sterilant access to all external and internal surfaces? (valves/cocks opened, lumens cleaned) Is the steam steriliser regularly serviced by authorised personnel as per EN 554? Date it was last serviced: Is the technical condition of sterile containers (single-use paper filter, filter cloths, valves for conveyance of steam and air, seals) regularly inspected? Are the requisite tests needed in various situations set out in writing (the parameters to be checked can be consulted in the validation protocol), e. g. a) commissioning test (installation test) b) daily routine checks c) batch-related routine tests d) monitoring/testing of process parameters with measurement technology methods e)periodic tests? f) test equipment? Is protective gear available (gloves, aprons, goggles, etc). TRBA 250? (Technical Regulations for Operating Safety) Is the Accident Prevention Regulation (UVV TRBA 250) available? Briefing? Hazardous Substances Register?				**2.2.4** 2.2.4

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
Gas sterilisation, legally regulated by the Hazardous Substances Regulation ((GefStofV of 01/10,1986, Section 15 „Gassing“, supplemented by Techn. Regulations for Hazardous Substances (TRGS 513), Annex 1: Ethylene oxide gas sterilisation (penetrating disinfection, temperature 45–50 °C, humidity approx. 90 %)				
Has approval been granted by the competent authority (Trade Supervisory Inspectorate)?				
Is the sterilisation process fully automated (since 1995 only fully automated EO sterilisers may be operated in hospitals)?				
Are sufficient qualified staff available (proof of qualifications)?				
Are there operating instructions for staff?				
Accident Prevention Regulation (UVV)				
Documented briefing?				
Does documented briefing take placeannually?				
Have measures been taken to rule out danger to the environment by exhaust gas generated during operation of exhaust air cleaning systems (catalytic combustion of exhaust gas)				
Washing out EO in a 1–5 % H2SO4 solution (gas wet-washing procedures):				
Is there measurement equipment for detecting EO in the ambient air and in the sterile supplies?				
Is the steriliser serviced as per TRGS 513 at least once annually?				
By whom?				
Is there a list of the MDs to be sterilised?				
Are there written manufacturer's instructions giving information on EO sterilisation?				
Annex 2: Low-Temperature Steam-Formaldehyde Sterilisation (LTFS) Negative-Pressure Processes at 60–70 °C				
Has approval been granted by the competent authority (Trade Supervisory Inspectorate)?				
Is the sterilisation process fully automated (since 1995 only fully automated formaldehyde sterilisers may be operated in hospitals)				
Are sufficient qualified staff available (proof of qualifications)?				
Are there operating instructions for staff?				
Does documented briefing take place annually?				
Have measures been taken to rule out danger to the environment by exhaust gas generated during operation of exhaust air cleaning systems (not validable)?				
Desorption of formaldehyde by repeatedly rinsing with steam:				
Is there measurement equipment for detecting FO in the ambient air and in the sterile supplies?				
Is the steriliser serviced as per TRGS 513 at least once annually?				
Is there a list of the medical devices to be sterilised?				
Are there written manufacturer's instructions giving information on FO sterilisation?				
Annex 3: LTP Sterilisation (Plasma Sterilisation):				
Is the pretreated item rinsed with demineralised water? Manually? _____				
Which MDs are processed with this procedure?				
Is suitable packaging material used?				
2g) Labelling				**2.2.5**
Are the requirements for labelling as per the RKI recommendations observed?				
Is the MDs itself clearly and permanently labelled?				
MD designation affixed to MD, packaging, if not readily visible?				
Time and type of sterilisation process used (batch designation, sterilisation date)?				
Expiry date, up till which safe use is demonstrably possible?				
Are there safety and warning notices (e. g. “Critical C“ MD group, manufacturer's name and, if applicable, batch and serial numbers)?				

No. Requirement	yes	no	Remarks	Reference to RKI Recommendation
If processed by third party, are the name/address of processor clearly visible? If a limited number of reprocessing cycles has been imposed by the manufacturer, are the number of times and type of reprocessing already conducted clearly shown?				
V Documentation / Servicing / Release for Use Are the persons authorised to release supplies named in writing (level of qualification)? What is the qualification level of these persons? Is there a standard operating procedure specifying how the decision for release is taken, is this documented? Is there a standard operating procedure specifying procedures in the event of deviation from correct process sequence? Is there an agreement between the process parameters obtained during processing and those specified in the validation protocol? Are routine tests conducted and documented? Daily – for sterilisation (e. g. Bowie & Dick test): Batch-related routine tests and batch documentation (e.g. chemical indicators, process indicators such as pressure, temperature and time): Periodic semi-annually microbiological tests or after 400 batches (biological indicators): Is the packaging inspected for integrity and dryness? Is the labelling inspected? Are the measured values recorded for the process parameters during processing documented? Programme control (Acknowledgement signal): Temperature-time recorded as diagram: Temperature-time recorded as printout of process data: If the release decision documented while giving the name of the person responsible for release as well as the batch? Is there a record that the processing procedure used was conducted as per the standard operating procedures, while observing the parameters set out in the validation protocol? Have the individual steps been recorded and archived (Section 9 [2]) Medical Devices Operating Ordinance (MP BetreibV); are data also saved on data storage media?				**2.2.6 und 2.2.7**
VI Transport and Storage Has a storage period been set out in writing for sterile supplies? Are processed supplies left to cool down for the specified time before being transported? Have measures been taken to ensure that the properties of processed MDs are not adversely affected by transport and storage? Are the instructions of the MD and packing materials' manufacturer observed (cool, dark, protected against dust, dry, free of vermin, adequate distance from floor/wall? Are there mechanisms to ensure containers are securely closed and show any tampering seals, adhesive strips)? Are the expiry dates of supplies checked on time? By whom?				**3**
VII Processing MDs in the Light of vCJD/ CJD Are the respective recommendations implemented? Are there standard operating procedures for handling potential vCJD–contaminated MDs? Are there standard operating procedures as regards how long an MD must be preserved until a diagnosis is made? Are staff familiar with the contents of the RKI Recommendation for vCJD/CJD?				