The steps involved in risk management are, *inter alia*, assessment of the identified risks, risk control , acceptance of the overall residual risk.

The medical device-related aspects under consideration that include both the testing of material properties and of function, require relevant product information that can usually obtained from the manufacturer of the medical device in question. Moreover, relevant, product-related standards must be included in each case.

The parameters of interest in terms of **material properties** that must be considered, if necessary, for risk control purposes in the context of reprocessing validation, can be, for instance:

- surface characteristics
- corrosion resistance
- embrittlement
- breaking, tensile strength
- stability of bonding/contact points
- joint lubrication
- material fatigue
- residues/absorption of process chemicals (such as cleaning, disinfecting and sterilising agents)
- integrity of housings, casings and components.

Considering the broad spectrum of medical devices, differentiated instructions for **functional testing** cannot be provided in full. As a rule, the function(s) ascribed to the device by its manufacturer should be included as test parameters into testing for validation and implementation of reprocessing. As stated above, product-relevant standards should be observed, here, too.

Moreover, the maximum number of reprocessing cycles and the useful life of the reprocessed products should be stipulated and justified based on stability testing.

The reasons for the decision that, based on the performed validation, product-specific reprocessing results in a product that not only reliably meets technical and functional requirements but also satisfies the requirements set out in section 4 subsection (1) of the Medical Devices Act (MPG) should be documented (risk analysis). The instructions according to Directive 93/42/EEC, Annex I, 13.6h) that the manufacturer must provide with respect to any known product risks in case of reuse should be considered and addressed separately.

Annex 3 Commissioning and operation of washers-disinfectors (WD) for the reprocessing of medical devices (check list)

Applicable Annex to the Recommendation from he Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Documentation of the **WD's suitability**

Characteristic	**Documentation by**	**Documentation in**
Type approval test (DIN EN ISO 15883), in-plant testing	Manufacturer (CE marking)	Instruction manual
Suitability for reprocessing of the concrete medical devices of category semi-critical A/B or critical A/B		
Required accessory equipment e.g. for medical devices of category semi-critical or critical (e.g. special connectors/nozzles, mobile units,...)		

Suitability of the installation site and operating materials documented by the operator

Characteristic	**Documentation by**	**Documentation in**
Installation room and installation type (e.g. front loading, front and rear-opening devices)	Operator in co-operation with service provider/service technician, validator, as appropriate	e.g. room data sheet, technical documents
ambient conditions (aim: discharge of thermal and chemical loads; e.g. fume extraction, ventilation		
electric supply		
water supply, waste water (aim: adequate water supply, smooth drainage)		
water quality (e.g. drinking water, deionized water)		
matching the process chemicals used to the processing method in the WD: Process temperatures ph-value, water hardness material compatibility	operator, following the instructions of the process chemicals' manufacturer	product fact sheets safety data sheets SOP/ working instructions
acceptance inspection: **installation qualification (IQ)** • checking order scope against scope of delivery	operator in co-operation with	validation report with

Characteristic	Documentation by	Documentation in
• proper installation • checking of connections, supply lines and media quality, compliance with installation plan instructions • empty chamber profile • test run with test load • check of engineered safety devices • handover of operating and maintenance instructions • instruction in operating the device and guidance on malfunctions • installation and handover record **Operational Qualification (OQ)** • operating conditions and operating materials during the test • positioning of sensors • disinfection conditions (suitability of the load carrier and load, temperature control function) • doors and locking mechanism • dosage of chemicals • water quality • check for freely draining pipework • check calibration of measuring instruments • correctness of the process cycle • reproducibility • fault indication	manufacturer (checklists included in the guidelines of by the **DGKH-DGSV-AKI, such as List 4/Installation Qualification, lists 5 and 6/Operational Qualification**	product data sheets, recorder printouts, photo documentation

Documentation of both the WD's performance and the instruction of the operation staff in the proper **operation of the WD**

Characteristic	Documentation by	Documentation in
operating instructions	manufacturer	operating instructions
Overview and risk classification of the MD to be reprocessed acc. to No. 1.2.1 of the Recommendations of the RKI and the BfArM	operator	operator document
description of the medical devices/configurations being used: description of all use-relevant loading configurations and identifying the MD that are the most difficult to clean and disinfect (stating the reasons why)	operator considering the manufacturer's instructions validator, as appropriate	operator document with photos
stating the maximum interval between the end of use and start of the cleaning process	operator	operator document

suitability of operation parameters **Performance Qualification (PQ)** • List of loading patterns matched to tested WD programmes • operating conditions and operating materials during test • **function** of the spraying system • as appropriate, logging of flushing pressure • positioning of sensors • effectiveness of cleaning[1] (test and real loading incl. chamber walls and load carriers) • description of disinfection conditions • disinfection effectiveness (incl. chamber walls, load carriers, boiler, tanks) • drying effectiveness • process residues • dosage of chemicals	operator considering manufacturer's instructions in co-operation with qualified validator	validation report with product data sheets, recorder printouts, photo documentation as appropriate evidence of equivalence
specifications for in-process controls: • if appropriate, selection of a suitable process challenge device: surface, fissure, lumen PCD • frequency of PCD use (in case of stable process flow, in case of complaints, in case of operational malfunction) • processes to validate the cleaning result, residual protein determination (specify sufficiently sensitive methodology)	operator referring to the validation report	operator document
regular instruction of operating staff	operator	training document (training content, participants, trainer)
servicing: maintenance, if necessary repair and repeat performance qualification for specific reasons	manufacturer or service provider, operator	instruction manual (chapter on maintenance and repair documentation)

[1] alternatively:
Evidence of efficiency for specific loads / configurations and device types furnished by a recognised test laboratory with evidence of equivalence of the concrete loads and specification of suitable PCD

Tests to be performed every working day

Characteristic	Documentation by	Documentation in
visual check (e.g. chamber, flushing arms, connectors, sealings, mesh trays)	operator in line with manufacturer's instructions	test record and check list
functional testing of movable parts		
filling level chemicals container, daily use rates		
if necessary additional tests, based on the validation results		

batch-related testing

Characteristic	documentation through	Documentation in
load consistent with configuration as validated	operator	batch record and release record
suitability of the programme applied		
documentation of the relevant process parameters. • dosage of chemicals • process cycle (time) • Process temperatures • where appropriate flushing pressure (flushing ensured)		
visual check of the **load items**: • cleanliness (if appropriate referring to a cleaning indicator, e.g. for critical B medical devices) • integrity • dryness, residual moisture		

clearance

Characteristic	Documentation by	Documentation in
authorisation list: • authorisation basis • list of authorised persons	operator	evidence of qualification, name list
release criteria (see also tests above)	operator	release record
approach and , if appropriate, reasons for release in case of deviations from the regular process flow	operator	release record

periodical testing and **approach in case of deviations** from the regular process flow and relevant framework conditions

Characteristic	**Documentation by**	**Documentation in**
determining the due dates of periodic tests (repeat performance assessment, see performance qualification) , if appropriate coordinated with maintenance when determining testing intervals, process stability history shall be taken into consideration	operator and validator considering manufacturer's instructions, if appropriate calling in the hygienist	validation report
scope of testing		

Annex 4 Commissioning and operation of small-scale sterilisers for the reprocessing of medical dev ices (check list)

Applicable Annex to the Recommendation from he Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Documentation of **steriliser suitability**

Characteristic	**documentation through**	**Documentation in**
type test (DIN EN 13060), factory test	manufacturer (CE marking)	instruction manual
process type specification: Type B: for packaged and unpackaged massive products, hollow-ware Type A and porous products Type N: for unpackaged massive products Type S: for products according to manufacturer's instructions		

Documentation of **suitability of the installation site and operating materials** kept by the operatorl **The suitability of the installation site and operating materials shall be documented by the operator**

Characteristic	**documentation through**	**documentation in**
installation room (room function, e.g. sterilisation room, processing room) , installation type (table-top device, fitted device) and ambient conditions (climate, wall clearance - to avoid overheating-)	operator in co-operation with service provider /service technician, if appropriate validator	e.g. room book, technical documents
electric supply		
water supply (water connection, tank without direct connection) and waste water management (sewage, waste steam/vapours)		
feed water quality DIN EN 13060, Annex C		
acceptance inspection: • **Installation Qualification (IQ)**:	operator in co-operation with	**directions for use and**

Characteristic	documentation through	documentation in
○ **scope of the order checked against scope of delivery** ○ proper installation ○ vacuum test, empty chamber test ○ test run with test load ○ check of engineered safety devices ○ handover of operating and maintenance instructions ○ instruction in operating the device and guidance on malfunctions ○ installation and handover record • **Operational Qualification (OQ)** ○ process evaluation system (DIN EN 13060, Annex B) ○ process flow test with defined load (most difficult to sterilise medical devices and packages) ○ test of air removal and steam penetration by means of suitable PCD (hollow device) ○ test of the error detection system as specified by the manufacturer ○ documentation of the results in a qualification report ○ data and test results provided by the manufacturer must be taken into consideration	manufacturer	**maintenance** installation and handover certificate, validation report with recorder printouts and photo documentation
sterile goods packaging: • packaging in line with DIN EN 868-2 and following parts as well as DIN EN ISO 11607-1 • heat sealers: ○ critical process parameters are temperature and contact pressure ○ sealing seam width must be at least 6 mm ○ minimum distance between sealing seam and MD must be 3 cm ○ operating instructions / directions for use must be available ○ suitability of the method as stated by the manufacturer of the heat sealer or sterile barrier system ○ routine checks comprise ➢ ink test or seal check ➢ sealing seam strength / peel strength ➢ critical parameters	operator in co-operation with manufacturer	operator document operating instructions / directions for use, instruction manual

documentation of steriliser performance and instruction of operating staff in the proper **operation of the steriliser**

Characteristic	**documentation through**	**Documentation in**
operating instructions (see installation and handover record)	manufacturer	operating instructions
risk classification of the MD to be sterilised in line with RKI-BfArM recommendation (if appropriate, pooled into product groups)	operator	operator document
description of the medical devices/configurations being used: description of all loading configurations incl. the "most challenging" load(s) (stating appropriate reasons)	operator considering the manufacturer's instructions	operator document with photos as appropriate evidence of equivalence
suitability of operation parameters **Performance Qualification (PQ)**[2] • determination and documentation of test loads incl. proof of equivalence • evidence of test load sterilisation as stipulated in DIN EN ISO 17665-1 and DIN SPEC 58929 o if appropriate, testing of partial cycles, if parametric testing is not sufficient • measurement of pressure and temperature profile at the critical points within the load through an independent calibrated measurement system (e.g. logger) • microbiological testing in places that do not allow physical measurement	operator in co-operation with qualified validator	validation report with product data sheets, recorder printouts, photo documentation
specifications for in-process controls: • evidence of effective sterilisation parameters by means of batch record and/or process evaluation system (DIN EN 13060, Annex B)	operator referring to the validation report	operator document

[1] Alternatively: Evidence of effectiveness for specific loads / configurations and device types furnished by a certified test laboratory with evidence of equivalence of the concrete loads and specification of suitable PCD

Characteristic	documentation through	Documentation in
• selection of PCD in case of hollow device sterilisation (see also (DIN EN 13060, Annex A) • for the selection of chemical indicators see below "specific guidance on the use of chemical indicators"		
regular instruction of operating staff	operator	training document (training content, participants, trainer)
servicing: maintenance, if necessary repair and repeat performance qualification for specific reasons	manufacturer or service provider, operator	instruction manual (chapter on maintenance and repair documentation)

Tests to be performed each working day

Characteristic	documentation through	Documentation in
visual checks of • chamber and sealings • feed water container, feed water • cooling water, if appropriate	operator in line with manufacturer's instructions	test record and check list
functional testing • vacuum test, if appropriate • steam penetration test with suitable PCD, if appropriate • logger (e.g. printer)		

batch-related testing

Characteristic	documentation through	Documentation in
load consistent with configuration as validated	operator	batch record and release record
Checking for complete and proper process cycle • checking and documentation of the treatment indicator result (cl. 1) • checking and documentation of process parameters (readings of process parameters, if appropriate process evaluation system) • checking and documentation of the process indicator result o critical A: without PCD (cl. 5) o critical B: with PCD, e.g. helix test (cl.2)		
visual check of the packaging: • dryness • integrity • sealing seam integrity • complete labelling		

release

Characteristic	documentation through	Documentation in
authorisation list: • authorisation basis • list of authorised persons	operator	evidence of qualifications, name list
release criteria	operator	release record
approach and , if appropriate, reasons for release in case of deviations from the regular process flow	operator	release record

periodical testing and **procedure in case of deviations** from the regular process flow and relevant framework conditions

Characteristic	**documentation through**	**Documentation in**
determining the **due** dates of periodic tests (repeat performance assessment, see performance qualification) , if appropriate coordinated with maintenance	operator and validator considering manufacturer's instructions, if appropriate calling in the hygienist	validation report
scope of testing		

Appendix to Annex 4

Guidance on the use of biological and chemical indicators

Sterile medical devices (MD) cannot be visually distinguished from non-sterile devices. Neither physical measurements, nor biological or chemical indicators can, on their own, prove that the devices subjected to the sterilisation process have been successfully sterilised or are sterile. Therefore, sterilisation procedures must be validated (see 1.3; Annex 1). However, successful validation alone does not ensure that sterilisation requirements are actually met during routine operation, too. In addition to changes in loading patterns, packaging or the goods used, other factors that the operator may not notice or not identify as problematic due to ignorance, may also affect the process. Therefore, suitable routine monitoring must be carried out (see DIN EN ISO 14937 chapter 10), to ensure that the validated procedure will be applied consistently . In doing so, the manufacturer's instructions for use (e.g. fitness for purpose, positioning and interpretation) of the systems selected must be observed to avoid misleading results. The results of biological and chemical indicators must be documented without delay. Indicators need not be retained.

For steam sterilisation procedures, too, sterilisation conditions can change during routine operation (see DIN EN ISO 17665-1 chapters 10 and 11). Temperature and pressure patterns over time can be monitored and documented with relative ease through the measuring instruments that are installed in the steriliser. In the context of release, achievement of the physical parameters **established** and documented during validation must be confirmed, among other things.

Biological and/or chemical indicators complement physical measurements.

Specific guidance on the use of biological indicators

The requirement for sterilisers to be checked by means of bioindicators every half year or after 400 batches derives from an older chapter, "Inspection", of the meanwhile completely withdrawn DIN 58946-6 on the operation of large-scale steam sterilisers. The applicable successor standard DIN EN ISO 17665-1 (related guidance DIN EN ISO 17665-2), that incorporates a broader scope of application, including small scale sterilisers, no longer contains this specific requirement. For performance assessment, this standard says that also microbiological methods , whereby the biological indicators must be affixed to the medical device or the medical device is directly inoculated with the biological indicators, are eligible for complementing physical measurements. The informative annexes C and D to this standard stress that, for microbiological testing, the points in the medical device be selected that are hardest to reach by the sterilant under the required conditions Like standard DIN EN 285 for large-scale steam sterilisers, DIN EN 13060 for small steam sterilisers does not address requirements for validation and routine monitoring.

Biological indicators are not suited for assessing the retention time that must be ensured because, in most sterilisation cycles, it exceeds the time it takes to inactivate the bioindicators. This requires physical measurements. Both the heating phase it takes to reach the retention time and the subsequent cooling phase at temperatures higher than 100°C contribute to inactivation. With steam sterilisation for instance, bioindicators are inactivated after a few seconds at 134°C and, as a result, do not allow any conclusions to be drawn regarding the requisite retention time of 3 to 18 minutes (required for prions).

Consequently, while the complementary use of biological indicators can make sense, they are no substitute for validation.

For the selection, use and interpretation of results of biological indicators pursuant to the standard series DIN EN ISO 11138 , guidance DIN EN ISO 14161 is available.

Specific guidance on the use of chemical indicators

Chemical indicator are mainly used to

1. distinguish between sterilised and non-sterilised products (process indicator)

and

2. for the steam penetration test

as well as internal indicators.

Chemical indicators show a visible change (e.g. colour change) when exposed to defined values of the critical variables during the sterilisation process (product information). Poorly changing chemical indicators can flag up risks in connection with the use of a sterilisation process (e.g. absence of the sterilant): for instance, chemical indicators can reliably distinguish between saturated steam and air of the same temperature. This is because accumulations of non-condensable gases (NCG, such as air) prevent steam sterilisation.

Part 1 of DIN EN ISO 11140 distinguishes between several classes of chemical indicators with different tasks. However, this classification is no hierarchical rating (no "better" or "worse").

Class 1 process indicators must be used to distinguish goods that are not yet sterilised from treated ones. Properly responding process indicators show that the packaging was exposed to conditions that are only present in a steriliser.

Indicators used in packages or mesh trays can flag the position of vulnerable points and/or confirm that the stipulated values of the critical variables (product information) were reached at these points.

Class 2 indicator systems are needed for special tests that are required in standards governing sterilisers, they are made up of a process challenge device (PCD) and the indicator. According to DIN EN ISO 17665-1, 12.1.6, a steam penetration test (e.g. Bowie-Dick-Test) must be conducted each day before using the steriliser, when air is being removed from the sterilising chamber to allow quick and even penetration of the steam into the steriliser load.

Chemical indicators for testing steam penetration are standardised in parts 3 and 4 of DIN EN ISO 11140 . Chemical indicator systems for testing air removal and steam penetration in small steam sterilisers are standardised in part 5 of DIN EN 867.

Process challenge devices have been developed to each simulate a specific challenge to steam penetration in a sterilisation process. The challenge level is matched to the type of sterilisation process. There is no one universal PCD that is suitable for all process types and purposes. DIN EN 285 and DIN EN 13060 each define several different process challenge devices. These process challenge devices do not represent specific products.

The challenge level of class 2 indicators results from the combination of the chemical indicator and the PCD components. Each variation, e.g. the use of another indicator, can lead to malfunctions going undetected. Therefore, components may only be combined as intended by the manufacturer. This also applies to systems with reusable process challenge devices.

A medical device simulator (MDS) only shows that air removal and steam penetration are sufficient for the specific medical device. A medical device simulator (MDS) is not intended to test the sterilisation process and does not provide any sound evidence that the product simulated by the MDS has actually been sterilised. A MDS can usually be used instead of the

specific medical device for the **intended/defined** purpose in the performance assessment. Evidence of suitability of a MDS is described in DIN 58921 .

In steam sterilisation, for instance, non-condensable gases in the steam and transient leaks can occur unexpectedly. Such malfunctions are only detected through periodic testing (e.g. "Bowie-Dick Test), if they happen to occur while the test is ongoing.

An error warning system that is used in every sterilisation cycle ("batch control") can consist of a process challenge device and a physical or chemical detector. General recommendations for the use of error warning systems can not now be issued since there are no generally accepted methods for verifying their performance/efficiency (relevant standard project/work item proposal is under preparation).

For the selection, use and interpretation of results of chemical indicators, guidance DIN EN ISO 15882 is available.

Annex 5 Overview of requirements for reprocessing units for medical devices

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

(The relevant provisions concerning health and safety at work are also applicable.)

reprocessing unit category	A	B	C
classification of MD to be reprocessed up to	**semi-critical A, critical A**	**semi-critical B, critical B**	**critical C**
examples of use of reprocessed MD	dressing changes, dental/medical examination und treatment[1]	invasive procedures/surgery, endoscopy	invasive procedures/surgery using MDs of group critical C or their reprocessing for other establishments
examples of establishments concerned	doctors' surgeries[2], dental surgeries[1]	ambulatory surgery centres, dental surgeries, endoscopy, hospitals	selected hospitals, reprocessing units for other establishments[4]
structural and functional requirements	designated area[5] segregated dirty/clean/storage zones (temporal separation possible)	designated reprocessing rooms[3],[5] segregated dirty/clean/storage areas	- separate dirty/clean/storage rooms[3] - specific requirements depending on the technical effort required
examples of technical equipment	depending on reprocessing profile (for the use of washer-disinfectors and small steam sterilisers see annexes 3 and 4) ultrasonic cleaner, if appropriate	depending on reprocessing profile washer-disinfectors endoscope washer-disinfectors ultrasonic cleaner sealer appropriate testing instruments appropriate steriliser water treatment facility, if appropriate	depending on reprocessing profile (endoscope) washer-disinfectors ultrasonic cleaner sealer appropriate testing instruments devices for specific sterilisation processes water treatment facility

Annex 6 Subject knowledge of staff

Annex applicable in conjunction with the Recommendation from the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene Requirements for the Reprocessing of Medical Devices".

Requirements regarding the subject knowledge of staff in charge of the reprocessing in reprocessing units according to category A and B (see annex 5)

The subject knowledge about the reprocessing of medical devices (section 4 subsection 3 of the German Medical Devices Operator Ordinance) includes:

- fundamentals of instrumentation (department-specific, if applicable)
- knowledge of hygiene/microbiology (including transmission routes)
- Risk assessment and classification of medical devices according to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".
- Priorities governing reprocessing:
  - appropriate preparation (pre-treatment, collection, pre-cleaning, disassembling)
  - cleaning, disinfection, rinsing and drying
  - verifying the cleanness and intactness
  - maintenance and repair
  - functional tests
  - labelling
  - packaging and sterilisation
  - documented approval of medical devices for use/storage
- spatial and organisational aspects of reprocessing
- development of procedure and working instructions for reprocessing
- knowledge of the law (Act on Medical Devices, German Medical Devices Operator Ordinance, Biological Agents Ordinance)

A person is considered qualified if **evidence of education or training** in a relevant medical profession which covers these topics as part of the framework curricula can be provided and if this education or training has been successfully completed. If some topics have only been partly covered or not addressed at all as part of the education or training, this knowledge has to be supplemented or updated through adequate training.

A specialist training is necessary if there is **no evidence of education or training** in a relevant medical profession - this could be based on the specialist training courses according to the qualification frameworks of the German Society for Sterile Supply or covered through training by associations of medical professions or public institutions.

Furthermore, public bodies and scientific societies, such as the German Society for Sterile Supply, provide information about the requirements regarding subject knowledge.

Annex 7 Measure for minimising the risk of a transmission of CJD/vCJD through medical devices

Applicable annex to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".

Introduction

The sporadic Creutzfeldt-Jakob Disease (CJD) occurs at a prevalence rate of 1-2 cases per one million population per year, making it a rare disease in humans. Nevertheless, the transmission of CJD through contaminated medical devices has been reported in individual cases. Furthermore, the disease is usually fatal. The occurrence of a new, BSE-linked variant of CJD (vCJD) in humans also means that this topic has to be specifically addressed because the pathogens show a high tolerance against usual reprocessing procedures for medical devices [1-3].

Information about the epidemiological and pathogenetic background can be found in Beekes 2010 [1] and up-to-date data about the prevalence of CJD/vCJD can be accessed under www.rki.de> Infektionsschutz > Infektions- und Krankenhaushygiene > Themen von A-Z > CJK/vCJK (in German only).

CJD has a long incubation period which is not known for each individual case. Patients in the asymptomatic stage of a progressing CJD, i.e. who have continuously multiplying pathological prion proteins (PrP^{TSE}) [4] in their body while not yet showing any clinical symptoms can present a currently neither identifiable nor quantifiable risk for iatrogenic transmission of TSE pathogens. Another factor are cases where invasive surgery is being performed and where the disease pattern or the genetic or other risk (see 1.1) has not been recognised as such.

The aim of the measures described hereafter is to minimise the risk of human-to-human transmission for all forms of transmissible spongiform encephalopathies (TSEs), including the variant CJD (vCJD) through contaminated medical devices.

According to what has been established above, the measures can be divided into

1) measures in case of an identifiable (or presumed) risk (i.e. diagnosis of potential or clinically probable CJD/vCJD or a rapidly progressing dementia) (procedure I) or
2) measures in the case of no identifiable risk (procedure II).

(also see table I)

The risk of transmission through appropriately reprocessed medical devices which have been used on asymptomatic or unidentified carriers is currently not objectively quantifiable but considered low by all estimations [1] and generally depends on:

a) the prevalence of the illness in the general population and
b) the co-occurrence of

- a previous contamination of a medical device (intervention on pathogen-infected tissues of an asymptomatic or unidentified carrier of CJD/vCJD),
- the incomplete removal (decontamination) or inactivation of the CJD/vCJD pathogen through cleaning/disinfection and, if applicable, sterilisation of the instruments used during the intervention and
- the use of a medical device that is still contaminated (contagious) on the next patient, resulting in transmission, whereby the probability of an infection not only depends on the residual pathogen load on the medical device but also on the susceptibility of the tissue into which the TSE pathogens are being inserted.

Main parameters of the risk analysis and risk evaluation also include knowledge of

- the pathogen load of different tissues [5],
- the effectiveness of different decontamination and inactivation procedures (also see table 2)

and
- the initial protein burden on the used surgical or endoscopic instruments (see table 3).

The deduction of risk minimisation measures is also based on these considerations.

For risk management purposes, it is essential to identify

a) people at risk (risk groups 1.1) and
b) high-risk interventions (high-risk surgery 1.2).

1.1 Risk groups

People at risk of CJD/vCJD can be divided into the following risk groups: