

# Recommendations by the Quality Task Group (36) Risk Management in the CSSD

Risks are associated with all human actions. They are the result of imperfect information. One would like to know the risks posed by a particular action in order to minimise them, and detect risks although no damage has yet been done. If, nonetheless, damage does occur, measures must be taken within the framework of quality management.

Medical devices are used or operated in or on humans. Such products call for a particularly high level of safety. Hence the aim of Council Directive 93/42 /EEC of 14 June 1993 concerning medical devices is to protect the health of patients and users.

But only on publication of Processing Recommendations by the Robert Koch Institute (RKI) has, for example, the term "risk assessment" attracted interest among the general public. This RKI Recommendation advocates classification of medical devices before processing, while taking account of certain risks.

A number of risks must be borne in mind when processing medical devices (processing contaminated hollow devices, etc). As a rule there are measures to tackle these problems in practice. → **RISK MANAGEMENT IN THE CSSD** goes further than this classification. It focuses on all risks encountered during processing (e.g. does the rotary arm of the washer-disinfector really rotate, does the value furnished by the temperature sensor in a steriliser deviate too much?). To be borne in mind is DIN EN ISO 14971 regarding "Applying Risk Management to Medical Devices", as stipulated in the appendix to the Processing Recommendations.

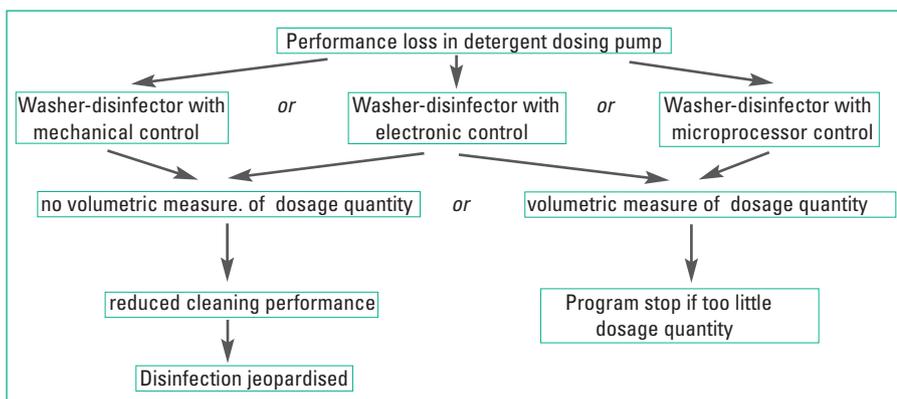
This standard views the risks relating to the manufacturer when using medical devices. Risk is a combination of the probability of fault or damage occurring and the severity of such damage. The aim of risk management is to avoid and minimise risks.

In a risk management process the operator's responsibility is defined and personnel qualification identified. A → **RISK MANAGEMENT PLAN** must be drawn up to initiate a risk management process. All documents must be filed in a folder.

The risk management process is broken down into: risk analysis, risk assessment and risk control.

→ **RISK MANAGEMENT IN THE CSSD** focuses on all risks encountered during processing.

→ **A RISK MANAGEMENT PLAN** must be drawn up.



**Application of a decision tree for risk analysis**

Risk analysis using a decision tree: Performance loss in detergent dosing pump

### Risk Analysis

The medical device must be described and identified when carrying out risk analysis. The identity of the staff responsible for analysis must be defined. "For the respective medical device or accessories the manufacturer must describe the intended use and any misuse that can be reasonably expected" (e.g. no not use motor oils for instrument care). The principle task of risk analysis is to estimate the risks posed in a normal situation as well as under faulty conditions.

### Risk Assessment

Following risk analysis, risk assessment helps to arrive at a decision about the justifiability of the risks and determine whether risk minimisation must be carried out.

### Risk Control

Risk control involves conducting an overall risk assessment and describes how measures for implementing risk minimisation and outlines any residual risk.

The basic rationale for risk management is thus to detect and document risks, estimate consequences and take → **MEASURES** before occurrence of a fault or damage to pre-empt such damage or ensure only minimal consequences. For example, it must be ensured that a medical device that is faulty, unsuitable or non-sterile is not used. On the basis of risk management, risks should be identified at the outset and measures taken to minimise them.

It is clear that risk management is not confined to the classification of medical devices; rather, it calls for a documented overall appraisal of the potential risks posed by processing. At first glance this appears to be an onerous activity, but closer scrutiny reveals that there are only slight risks encountered in processing. Besides, important measures have already been taken for areas such as verification of the sterilisation process (e.g. processing in line with the RKI Recommendation, process validation with servicing and additional tests).

This topic thus warrants close scrutiny.

**Risk analysis, risk assessment and risk control are all parts of risk management**

→ **MEASURES** have to be taken to avoid damage or minimise consequences