Theory and Practice of Risk Management in the RUMED

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Huge investments are made in medical device reprocessing to eliminate risks to operators, users and patients. Risk identification and risk management are thus essential components of the primary mission, and are underpinned by the legal and administrative requirements and quality management systems based on international standards. Risk management inevitably has economic implications, too, since risk insurance coverage is becoming increasingly more expensive, in particular in the healthcare sector. This paper now describes the aspects of risk management in the Reprocessing Unit for Medical Devices (RUMED) deemed by the authors to be most important at the present time (2016).

Regulatory requirements for risk management

Regardless of any institution's internal considerations and specifications relating to risk management, there are certain regulatory requirements that must be observed. Below are listed a number of such requirements applicable to Germany.

- Based on the German Biological Substances Ordinance (BioStoffV), the biological substances used in the RUMED must be identified and assigned to risk categories. As stipulated by the German Occupational Health and Safety Act (ArbSchG), risk assessment and protection level classification must be performed. Further details of such provisions are given in the German Technical Regulations TRBA 250 and TRBA 400 and are generally implemented in close collaboration between the RUMED and the institution's Health and Safety Department.
- Based on the KRINKO/BfArM Recommendation*, the medical devices to be reprocessed must be assessed and classified in respect of the risks arising during reprocessing and subsequent use.
- When reprocessing medical devices which belong to the "critical C" group and for which no specific manufacturer's instructions are available on a low-temperature sterilization process, the KRINKO/BfArM Recommendation stipulates that a certified quality management system based on EN ISO 13485 be used, while drawing attention to that effect to risk management pursuant to EN ISO 14971. The German Medical Devices Operator Ordinance (MPBetreibV), in its 2014 version, states that a quality management system based on EN ISO 13485 should be used in principle for reprocessing medical devices belonging to the "critical C" group, but it does not provide explicit details of risk management.
- In cases where "medical devices are reprocessed with methods other than those specified by the manufacturer", the KRINKO/BfArM Recommendation states that decision-making must be based on the principles of risk management as set out in EN ISO 14971.
- The risk management measures specified in the KRINKO/BfArM Recommendation for prevention of transmission of Creutzfeldt-Jakob disease (CJD) and variant CJD (vCJD) via medical devices are directed, in particular, at the medical personnel (identification of risk groups, risk tissues and risk procedures). For their part when faced with a situation where there is no discernible risk, RUMED personnel must take the measures generally in place for medical device reprocessing for prevention of transmission of pathologic prion protein. As a rule, since the RUMED will not dispose of a process endowed with complete prionicidal activity, medical devices used on patients with a confirmed CJD/vCJD diagnosis are mainly discarded. While such procedures must be formulated in the RUMED they have little bearing on risk management in the RUMED.
- If a quality management system based on EN ISO 13485 is in operation, risks must be identified and taken into account with regard to the "safety or performance of medical devices or compliance with the applicable regulatory requirements". That relates to virtually all processes ("risk-based approach"). In specific terms this means that at the planning stage the RUMED "must document one or several processes for risk management of medical device reprocessing", and "records must be kept of

* KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

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activities related to risk management". However, Section 7.5 "Production and provision of services" does not list any specific requirements for risk management. This "risk-based approach" marks a clear distinction between the current 2016 version of EN ISO 13485 and previous versions which had been based on ISO 13485:2003. In the earlier versions of EN ISO 13485 the regulations and records governing risk management were essentially confined to "product realization". The additional references and requirements incorporated into the current version of the standard for dealing with risks are clearly presented with regard to the processes to be organized by the RUMED.

– As regards implementation of risk management, EN ISO 13485 makes references to EN ISO 14971 but without calling for mandatory implementation pursuant to EN ISO 14971.

Guide to conduct of risk management

Despite the somewhat non-binding references made to EN ISO 14971, the latter is the key standard for risk management in relation to medical devices.

This standard defines risk as a "Combination of the probability of an event and its consequences" and advocates for risk management the use of a coherent process comprised of

– Risk analysis
– Risk assessment and
– Risk management.

Since it is acknowledged that only rarely can risks be fully eliminated, assessment of an acceptable residual risk is an indispensable part of the method described in the standard.

Any consideration of EN ISO 14971 in the light of risk management in the RUMED must bear in mind that the standard is primarily intended for medical device manufacturers who have to manage risks throughout the entire life cycle of a medical device. The documentary requirements are tailored to that demand. In the RUMED we focus on only part of a medical device's life cycle and the RUMED is not able to exert any influence on certain aspects of risk minimization (e.g. design-based enhancement of the integrated safety) since it deals essentially only with the finished product. The RUMED can, and must, pass on comments to the manufacturer but these can only be taken into account for the next generation of the respective medical device. However, the RUMED is entitled to refuse to reprocess a medical device if it has design features that are likely to present unjustifiable risks.

Notwithstanding the above, the fundamental principles of EN ISO 14971 are applicable. Moreover, the annexes to the standard give practical and helpful tips on implementation, while also drawing attention to typical hazards.

Hazards are also the focus of the German regulation VDI 5700. For example, VDI 5700 Form 1 deals with risk management for medical device reprocessing and implements the requirements enshrined in EN ISO 14971 for this special area.

VDI 5700 Form 1 identifies

– functionality
– cleanliness and low microbial state or sterility
– biocompatibility as well as
– occupational and health protection

as being essential features of a medical device.

These features can be jeopardized by the most diverse influences, e.g. by changes in the mechanical or chemical properties of a medical device or incorrect labelling of the medical device released for use. VDI 5700 Form 1 provides detailed information on the hazards, associated risks and control measures. However, it does not essentially give any additional details of the actual risk management process apart from those set out in EN ISO 14971.

VDI 5700 Form 2, which has now also been released, gives a draft of a training programme for personnel entrusted with risk management.

Important partial processes of risk management include the identification, analysis and assessment of risks. Often, this entails analysis of the causes of damage or the consequences of adverse events. For more complex issues it is advisable to have recourse to tried and tested analysis techniques. For example, the causes of an adverse event (hazardous situation or damage) can be pinpointed and analysed by means of fault tree analysis (FTA). The effects of faults are generally analysed through Failure Mode and Effects Analysis (FMEA). The term Failure Mode, Effects and Criticality (FMECA) is used when the critical impact of individual effects is also investigated.

EN 31010 gives an insightful overview of systematic methods of risk assessment as well as a guide, thus underpinning in that respect ISO 31000. Neither of the two standards is specifically tailored to medical devices. Nonetheless, EN 31010, in particular, is very helpful when planning the risk management process.

Risk management practices in the RUMED

To date, occupational health and safety risks in the RUMED (assessment of workplace risks and resultant protective measures) as well as risk assessment and classification of medical devices are treated as more or less independent processes and are not integrated into an overall risk management system. In general, that approach works well but greater transparency would be assured if attention were drawn to these risk-related activities in the context of risk management. After all, risk management techniques are employed when deciding to deviate from the manufacturer's reprocessing instructions (for example because such instructions are completely inadequate).

Where implemented, risk management as understood in the context of a comprehensive quality management system, is generally conducted on the basis of an extensive FMEA process.

Here "process" refers to the (medical device) reprocessing process whose entire complement of partial processes is subjected to risk analysis. In most cases to prioritize remedial measures the criticality is also evaluated, generally as a formula (product of the magnitude of the impact of a consequence and the likelihood of occurrence).

FMECA is generally formulated by an interdisciplinary risk management team and is modified and updated by the same teams as follows:

– whenever warranted (e.g. in the light of new scientific knowledge or particular claims)
– and routinely at regular intervals (mainly yearly).

Where a comprehensive quality management system is in place a report is produced, generally on an annual basis, on the current situation with regard to risk

management and important conclusions are drawn and incorporated into the yearly management assessment report.

At first glance, comparison of various FMEA or FMECA models from different RUMEDs reveals that the structures (columns) of analysis are always similar but never equivalent to each other. Such an analysis technique permits flexible adaptation of the structure and this is availed of in the RUMED.

In terms of the content, one notes how similar are the analyses used for several basic risks. In view of that, one possible course of action would be to have all these fundamental risks analysed together by the German Society of Sterile Supply (DGSV) and the results presented in the form of a guide or best practice technical specification. That would mean that the RUMED would only need to address and deal with risks arising at the specific site.

Differentiation vis-à-vis error and complaints management

The findings of an error and complaints management system provide useful insights into risk management.

However, despite the fact that the latter also employs some of the analysis techniques used in risk management, integration of error and complaints management into the risk management process does not appear advisable. Error and complaints management entails an important, often daily recurrent, process which must be well organized on the basis of an open mistakes' culture to assure the quality of the sterile supplies.

Conversely, risk management is a comparatively strategic task. But here, too, it is no doubt advisable to set out the relationships and interactions between the two processes in the quality management system. ■

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