Development of a self-sufficient QMS to manage the MPE activity in radiological diagnostics

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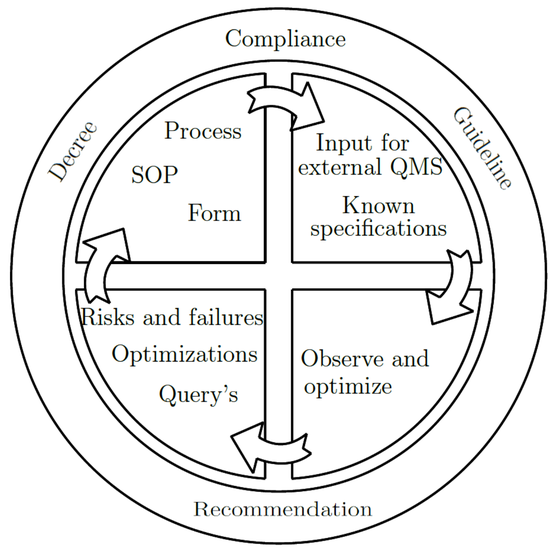
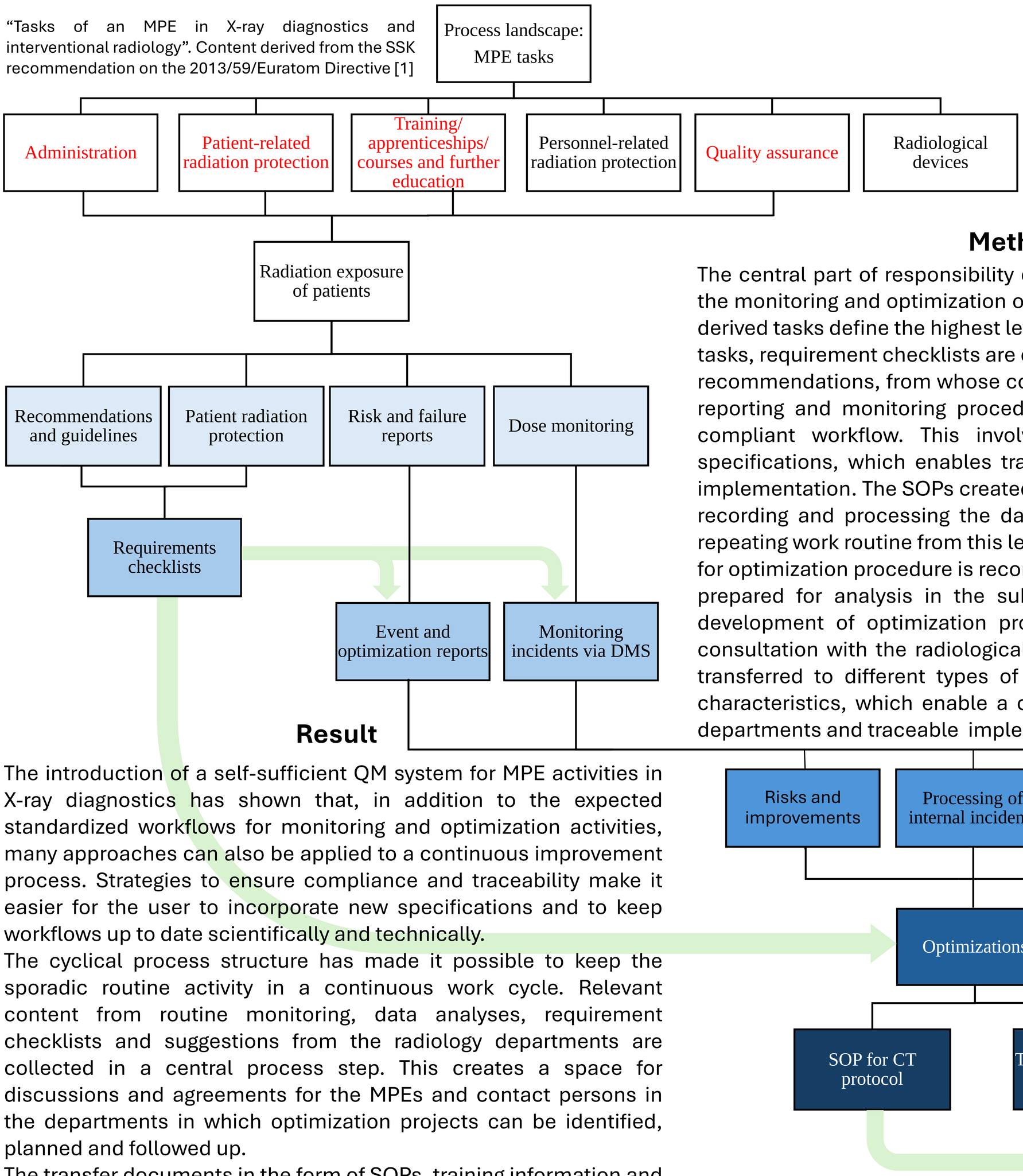
Introduction & Motivation

The involvement of a medical physics expert (MPE) is a new requirement in many radiology departments, which is why established processes from clinical routine typically do not exist. Monitoring, optimization and training in the area of radiation protection is an interface activity and should cause as few disruptions to the process as possible in the tightly scheduled clinical routine. An additional problem arises from supporting several departments with different quality management and individual processes and equipment. In order to address this problem, a quality management system (QMS) tailored to MPE activities is being developed. This is intended to define interfaces and information paths in the clinical routine and map a cyclical work routine, whereby the idea of a continuous improvement process (CIP) is implemented.



Circular flow of QM Structure
Idea of continuous improvement processes

"Tasks of an MPE in X-ray diagnostics and interventional radiology". Content derived from the SSK recommendation on the 2013/59/Euratom Directive [1]



Method

The central part of responsibility of MPE activity in X-ray diagnostics is the monitoring and optimization of "radiation exposure of patients". The derived tasks define the highest level of the process structure. For these tasks, requirement checklists are created for applicable regulations and recommendations, from whose content processes, SOPs and forms for reporting and monitoring procedures are derived and thus reflect a compliant workflow. This involves harmonization with applicable specifications, which enables traceability between requirements and implementation. The SOPs created in this way specify the procedure for recording and processing the data and give the process a cyclically repeating work routine from this level onwards. The information relevant for optimization procedure is recorded through protocols and forms and prepared for analysis in the subsequent optimization process. The development of optimization projects takes place in meetings and consultation with the radiological departments. Optimizations can be transferred to different types of communication depending on their characteristics, which enable a coordinated implementation with the departments and traceable implementation status.

Result

The introduction of a self-sufficient QM system for MPE activities in X-ray diagnostics has shown that, in addition to the expected standardized workflows for monitoring and optimization activities, many approaches can also be applied to a continuous improvement process. Strategies to ensure compliance and traceability make it easier for the user to incorporate new specifications and to keep workflows up to date scientifically and technically.
The cyclical process structure has made it possible to keep the sporadic routine activity in a continuous work cycle. Relevant content from routine monitoring, data analyses, requirement checklists and suggestions from the radiology departments are collected in a central process step. This creates a space for discussions and agreements for the MPEs and contact persons in the departments in which optimization projects can be identified, planned and followed up.
The transfer documents in the form of SOPs, training information and transfer documents have proven to be an important means of successfully transferring optimizations into clinical routine. The CT protocol SOPs are particularly helpful in this regard, as they reflect both the literature-based recommendation and the respective device situation. Furthermore, this enables a clear separation between the internal QM system and that of the respective department and the standardization of the QM content can be reduced to a relevant level.
At the end, the lower stages of the process allow the output of completed analysis and optimization activities to flow back into higher-level process structures, thereby closing the process cycle and implementing the CIP concept.

Diskussion & Conclusion

Due to the discontinuous nature of the work, the QM system has proven to be helpful asset in the implementation of MPE tasks. The system shows its strengths particularly in communication with the radiology departments, which are very busy, as an orderly and result-oriented analysis and transfer structure enables smooth agreements. However, continuous development and consistent application of the structures is essential, as otherwise the system will quickly become outdated and no longer applicable. Therefore, when introducing such a maintenance-intensive system, a clear decision must be made for consistent implementation.

[1] Strahlenschutzkommission; „Hinzuziehung eines Medizinphysik-Experten bei medizinisch-radiologischen Tätigkeiten – Umsetzung der Anforderungen der Richtlinie 2013/59/Euratom"; 09-2017

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