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Benefits of ISO 9001/2000 Certification:GreaterTransparency Leads to Improved Workflow

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ISO 9001:2000 is a quality management system that promotes greater responsibility among staff, better use of time and resources, risk and failure management, as well as greater traceability of products and services. The department of Nuclear Medicine and Special Endocrinology (NMSE), PETCT centre Klagenfurt, Austria has been accredited according to ISO 9001:2000 since December 2003. In this article, we will explain how setting up the Quality Management (QM) system has led to a more transparent and comprehensible presentation of processes and workflows in the department for diagnosis, therapy and follow-up of diseases.

Setting up a QM system has enabled the state hospital Klagenfurt to develop quality goals shaped with respect to four levels of what we call the “Balanced Score Card”, or “People, Processes, Learning and Development, and Budget”. During this process, responsibilities and competences were defined. Inputs and outputs of each process, as well as the process owner and the action holder of each subtask were listed. Finally, quality scores and measurement categories were defined which were consecutively used to control and check overall compliance at regular intervals.

Mistakes based on lack of information were avoided by structuring the flow of information and implementing regular team and process meetings that allowed us to encourage communication and specific feedback. Documentation was structured and streamlined and templates for fast and efficient reporting implemented. Thus, risks were identified and prevented, and errors resolved in an efficient way.

Processes, Tasks and Information

To increase traceability of services, the main tasks performed at the NMSE were depicted as process charts (see fig. 1).

Each step in the process was determined, and necessary responsibilities documented. Here I will use the PET-CT examination workflow as an example to depict process charts generated and process descriptions set in place.

The process depicted in Fig. 2 and Fig. 3 describes and regulates the patient's management, the PET/CT investigation itself and the reporting of investigation results during PET-CT. In total, process information defined and documented for each single process comprises of:

• A short method description of the process itself;

• Aim and goal of the process, and

•A definition of the final output/results expected at the end of the process.

Measurable key quality data and quality scores determining the performance quality of the process are used to check the effectiveness of each process later on. This also includes actions to be taken in case of perceptible deviations or interferences in the process flow and the nomination of a person who is responsible overall, for correct process work.

Quality Goals and Traceability

This process enabled the department to define a clear mission and vision (see fig. 4). Its specific goals were defined and actions set to optimise goal realisation by considering the four levels of the Balanced Score Card and taking local and international laws into account (see fig. 5). To enable the measurement of each single goal achievement, relevant and efficient quality scores (key quality data) were defined, which in succession led to more controllable processes and fast and traceable optimisation of work.

The quality understanding of the department is shaped by the principle that technical and service quality is defined through “a set of inherent characteristics”. Thus, services provided must fulfil both objectively measurable parameters, as well as subjective expectations of the customers. Customer contentment is regularly questioned via patient questionnaires, and continuous learning and development guaranteed. The management defined quality goals for all areas of the department and all professions were defined with clear actions and projects set in place to achieve them.

Risk and Failure Management Tools

To use ISO 9001:2000 as a process for continuous improvement in the most effective way, various risk and failure management tools were implemented. Amongst these, internal and external process audits to check compliance, root cause analysis (RCA) to analyse mistakes and Failure Mode Effect Analysis (FMEA) for preventative quality assurance.

Internal audits, performed by local QM representatives, take place at least once a year. Audits are carried out in all areas of the department. Results, failings and necessary correction measures are reported by the audit leader and affected employees informed. The head of the department can delegate partial management tasks to staff, and is responsible for correction measures. Supervision of the conversion occurs through the QM representative who documents the effective elimination of the cause of error in the audit divergence report. Also, an annual external audit of the QMS is performed by accredited institutions.

The head of the department examines the total QMS once a year. In this management review, available relevant information like audit reports, process protocols, quality scores, internal and external communication issues, regular quality conversations and corrective and preventative actions taken are critically examined/ appraised. The goal is to identify necessary system improvements early on and enable suitable changes.

Benefits of ISO 9001:2000 Certification

Depicting all main processes and workflows of the department in detail as well as underlying tasks with clear responsibilities and competences, has promoted a greater responsibility and quality consciousness among staff and led to a greater consistency and traceability of services. Certification has resulted in more exact definition of processes, competences and responsibilities, better management of medical and non-medical interfaces and greater consistency of medical services.

Clearly defined interfaces (for example between medical and non-medical staff) have improved and eased communication. Process driven meetings result in prevention of mistakes, faster detection of errors, more rapid and efficient handling of errors, better adaptation to new requirements and a more purposeful information exchange..

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