

Role of Quality Audits: View from the IAEA

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Introduction

Comprehensive quality assurance (QA) programs, or quality management systems, in radiotherapy include all components of radiation therapy practice (World Health Organization 1988). A wide range of QA recommendations and guidelines that describe procedures, tests, and tolerances for specific parts of the practice is available (Kutcher et al. 1994; Thwaites et al. 1995). In addition to maintaining the quality of patient treatment and the outcome at the required level, QA is also necessary to reduce the likelihood of dose misadministration, that is, reduce the likelihood of the actual delivered dose being substantially higher or lower than intended (International Commission on Radiological Protection 2000; International Atomic Energy Agency 2000). This is particularly important because radiotherapy is a potentially high-risk procedure.

The quality audit is recognized as an essential element of QA systems in radiotherapy. It is a method of checking that the quality of activities in a radiotherapy center adheres to the standards of good practice. The standards may be recommended nationally or internationally and should be derived from up-to-date evidence-based cancer management data.

The ultimate objective of the quality audit is quality improvement and the tool used is an assessment of a practice, or an activity, by an independent body. The quality audit is equivalent to peer-review or independent evaluation of the practice. The audit involves fact-finding and the interpretation of findings in the context of the evidence-based criteria for good practice. Deficiencies in structure, gaps in technology, or deviations in procedures will be identified by the auditors in the review process. This way the areas for improvement will be documented and a set of recommendations will be formulated for implementation by the center being audited. It is generally considered that the findings of

the audit and its outcome are confidential between the auditing body and the audited center.

It is worth mentioning that the quality audit in radiotherapy is not designed for regulatory purposes and the auditors have no power to enforce any actions based on their findings; they can only report their findings and give recommendations. The audit should be understood solely as an impartial source of advice on quality improvement (International Atomic Energy Agency 2007a). Therefore, it is the audited center that decides on any actions required for the implementation of the audit recommendations. A feedback system incorporated in the audit scheme should be in place in order to monitor the changes and to organize a reaudit when appropriate. With this approach, the auditing cycle will stimulate and promote continuous improvement for the benefit of the patient.

Scope and Focus

Quality audits are of a wide range of types and levels, either reviewing the whole radiotherapy practice (comprehensive audit) or selected, important parts of the practice (partial audit). A comprehensive audit, also called a clinical audit (Euratom Directive 97/43 1997), will cover the whole clinical pathway of the patient including all interconnected stages of radiotherapy. It addresses the three main elements of the practice: structure, process, and outcome. In contrast, a partial audit has a limited scope and only specific parts of the radiotherapy practice are reviewed. This may be a partial audit of structure (e.g., staffing levels and qualifications) or a process (e.g., a dosimetry audit checking the beam calibration in external beam radiotherapy). Another example of a partial audit is credentialing for entry into cooperative clinical research studies (Kron et al. 2002; Molineu et al. 2005), which examines the compliance of center's proce-

