IAEA-CN-85-223

QUALITY ASSURANCE IN RADIOTHERAPY

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Abstract

Quality assurance in the management of a patient receiving radiation therapy and the role of the radiation oncologist and medical physicist in this process is described. The constraints on available personnel is recognised and the need for further education resources and IAEA activities in education for both groups described. IAEA activities in the clinical and dosimetric aspects and the resultant publications and education have contributed to a culture of quality assurance.

1. Introduction

Radiotherapy involves the use of ionizing radiation in the treatment of cancer patients. It is a multi-disciplinary speciality involving the use of complex equipment and procedures. It includes many phases, from diagnosis to clinical decision to undertake treatment, treatment delivery and follow-up. A systematic and comprehensive approach to quality assurance (QA), covering all these phases, is of vital importance to ensure optimum treatment of patients. Such QA programmes have been recommended by many professional bodies such as ESTRO [1] and AAPM [2], and should follow the guidelines given in the Basic Safety Standards (BSS) [3] and by WHO [4]

The main rationale and justification for quality assurance in radiotherapy is to ensure that not only does the patient receive good quality treatment but is also protected from accidents and errors (random and systematic). QA aims at minimizing the occurrence of random errors and at eliminating large systematic errors, contributing to the minimization of the morbidity rate and maximization of the cure rate of radiotherapy patients. This concept is emphasized in the BSS [3]. Patient safety is therefore integrated within the overall QA programme of radiotherapy [5].

At the national level, the establishment of a QA programmes should take into account international recommendations and existing national guidelines. To ensure that radiation therapy centres have a common basis for developing and implementing their quality assurance programmes, professional bodies representing radiation oncologists, medical physicists and medical radiation technologists should develop national guidelines or standards for radiation therapy quality assurance and set out a uniform quality assurance program to be adopted by all radiation therapy centres, taking into account the level of practice in the country. Several major issues should be considered before the establishment of a national quality assurance program for radiation therapy, including the licensing and regulation of radiotherapy equipment, the accreditation process, if it exists, the problems with the review process and compliance, the cost-benefit analysis of setting up an independent external quality assurance programme, the need to maintain confidentiality of patient records and the need to respect professional standards.

The IAEA assists its Member States to establish and implement national QA programmes through its programmatic activities and Technical Cooperation projects. The IAEA assistance is directed to national regulatory bodies for the establishment of a regulatory framework, which complies with the BSS, to standards laboratories for metrological traceability, and to end users at hospitals for the development and implementation of QA programmes. Traceability of radiation measurements for radiotherapy dosimetry and quality audit services, run jointly with WHO, such as the IAEA/WHO postal TLD service for the verification of the

clinical beam output, are also offered by the IAEA to the Member States. To coordinate its activities in QA in radiotherapy, close cooperation is maintained with other international organizations and professional bodies such as WHO, ICRU, ESTRO and IOMP.

2. Requirements for QA

QA in radiotherapy encompasses all procedures which aim to ensure a consistent and a safe fulfilment of dose prescription to the target volume while minimizing the dose to normal tissue, minimal exposure to personnel and the public. It involves all clinical, physical and technical, and safety procedures. The QA programme should be established by professionals working in the field of radiotherapy, taking into account the level of practice in the country and following international recommendations and guidelines. Either voluntary quality assurance guidelines or mandatory regulations could be used to achieve national uniformity. In both cases, however, a peer review program to audit the compliance with the national standards, if they exist, or international guidelines, should be established. If necessary, compliance with the national standards can be made as a condition of the licensing process.

The IAEA has established guidelines, taking into account clinical, medical physics, radiation protection and safety considerations, for designing and implementing radiotherapy programmes at the national level [5].

3. Staff requirements

The clinical use of ionizing radiation is a complex process, involving highly trained personnel. It is important that all staff dealing with patients, radiation sources and equipment have the necessary education background, adequate training and recognition of their status. The main categories of staff required and their responsibilities and training requirements are given elsewhere [2, 6, 7].

The shortage of professionals in the field of medical physics in developing countries is fully recognized. In the northern part of Africa, the number of medical physicists in radiotherapy per million population, is less than 0.3 whereas it fluctuates from 2 to 15 in Europe (according to data published by the European Federation of Organizations of Medical Physicists in Europe (EFOMP) [21]). In addition, the competency and qualifications of medical physicists in Europe are wellcontrolled through national regulations and the European Directive [22]. This is not the case in many developing countries where in reality the number of "qualified medical physicists" may be even lower. Consequently, the development and implementation of QA programmes in radiotherapy in many developing countries can be severely hampered by the lack of professionals in the field of medical physics.

A similar situation exists in the clinical field where, in some developing countries, a radiation oncologist may be responsible for upwards of 500 new patients per year in contast to 250 in developed countries.

4. Radiation protection and safety aspects

The general requirements include the review and approval by the regulatory authority aiming at ensuring radiation protection and safety of sources. These requirements cover all aspects described in the BSS and regulatory guidance [19]. In addition to administrative requirements, the control of exposure (occupational, medical and environmental), the safety of sealed radiation sources and equipment, including accessories, require conformity with ISO [10, 11, 12] and IEC standards [8, 9], respectively.

National regulatory bodies should apply the requirements of the BSS, together with national regulations, to review radiotherapy practice.

Radiotherapy centres can use the guidance provided in the BSS or propose alternative measures with an equivalent level of protection and safety [19].

5. Clinical aspects

This process commences with patient registration. Besides the domiciliary and medical records, the pathological diagnosis should be part of a national and institutional cancer registry. Pre-treatment evaluation with combined clinical assessment has a vital role in selecting the optimal management strategy within the limitations of resources. The patients' rights through informed consent must be respected. Psychosocial problems need to be addressed during and after treatment, both for the patients' benefit and to assure their compliance. Treatment planning and daily treatment need to be accurate and to be recorded. During the treatment period, the patient must be examined periodically and the treatment plan modified if required. Finally, an established patient follow-up procedure is required to pre-empt or manage complications and as a long-term assessment of the efficacy of management.

The two major tools to assist in achieving this clinical quality assurance are: firstly an institutional protocol manual clearly identifying the clinical management practice for the institution in all its multidisciplinary aspects, respecting the constraints within an institution, and secondly a departmental procedure manual, covering both clinical (immobilisation, simulation) and physical procedures.

6. Physical and technical aspects

The physical and technical aspects of the QA programme are usually performed under the responsibility of the medical physicist and cover the following areas: quality control of equipment including acceptance testing and commissioning; beam dosimetry including traceability of measurements and use of a code of practice; treatment planning and patient treatment including final verification of the accuracy of the delivered dose. The details of such QA programmes are described extensively by IAEA [5], AAPM [2] and ESTRO [1].

7. Organizational relationship and responsibility for quality

At the institutional level, the organizational structure of a radiotherapy centre should be well defined. An essential element is the establishment of an organizational chart, which should clearly show all hierarchical, functional and operational relationships. All responsibilities, tasks and competencies of each staff member must be clearly defined. For each task, a responsible person must be designated. In particular, the organizational structure should indicate who could stop radiotherapy treatments. It is a general practice to have the medical practitioner (radiation oncologist) be the responsible person for the medical exposure [20], including the protection of the patient. It is also usual practice for the medical practitioner to delegate parts of this responsibility to qualified persons. The medical physicist usually takes responsibility for the physical and technical aspects of QA [2, 5, 7].

At the multi-institutional level, there is a need to coordinate activities related to the external QA programme. It is well established that metrology institutions, such as Secondary Standards Dosimetry Laboratories (SSDLs), are usually competent to check the beam calibrations.

External QA groups which include experts from the metrology institution and radiotherapy centres should be set up at the national level. The IAEA has helped 12 countries to establish External Audit Groups (EAGs) through a Research Coordinated Project [23].

8. IAEA activities in support of QA in radiotherapy

The IAEA activities in support of QA in radiotherapy cover a large spectrum. In particular, the IAEA Division of Human Health provides:

- services to Member States for metrological traceability and external quality audits to radiotherapy centres, in collaboration with the IAEA Laboratories in Seibersdorf,
- research and development to foster exchange of information and help in the transfer of know-how in the field of QA in radiotherapy, covering clinical, physical and technical aspects, and
- support to technical cooperation projects in the field of radiotherapy and medical radiation physics, including training and education of staff.

Through its research and development activities in the clinical aspects of QA, both potentially optimal treatments and resources-sparing treatments are investigated. In the physical and technical aspects of QA, the IAEA Division of Human Health promotes standardization and harmonization of codes of practices and procedures used in QA, in close cooperation with other international organizations and professional bodies.

Education is the foundation for all quality assurance. To this end, the IAEA is in the process of developing a distance-learning programme to assist in the training of the basic sciences of radiation oncology intended primarily for radiation oncologists and therapy technicians.

9. Traceability and quality audit services

In the framework of the international measurement system the IAEA, in collaboration with the Bureau International des Poids et Mesures (BIPM), provides the metrological link through its IAEA/WHO network of Secondary Standard Dosimetry Laboratories (SSDLs) for traceable calibrations needed in radiotherapy. The IAEA's support is accomplished with the transmission of calibration factors for national measurement standards from the BIPM or Primary Standards Dosimetry Laboratories (PSDL) linked to the international measurement system. Each year, the IAEA provides traceability for radiotherapy dosimetry to about 20 Member States, mainly to those countries who are not members of the "meter convention" and do not have access to a PSDL. As a second step, dose quality audits and follow-up programmes are implemented to help the Member States ensure that the standards transmitted to hospitals are kept within the levels required by the international measurement system [14]. These programmes include intercomparisons of ion chamber calibrations made by SSDLs and dose quality audits using mailed Thermo Luminescent Dosimeters (TLDs). The intercomparison programme is available to the member laboratories of the IAEA/WHO SSDL Network, while dose quality audits are provided to radiotherapy centres through the IAEA/WHO TLD postal dose service. Both programmes are essential for assuring high accuracy in clinical dosimetry.

Ionization chambers are used in the intercomparison programme to assess the ability of the SSDLs to calibrate their own as well as hospital's dosimeters. About 40 SSDLs participated in this programme with 90% of the results within the acceptance level of ±1.5%. The TLD programme for SSDLs annually checks about 80 beam calibrations by 60 laboratories with 95% of the results within the acceptance level of ±3.5%. The TLD programme for hospitals

aims at ensuring proper calibration of radiotherapy beams. The IAEA is responsible for the technical aspects of the service and WHO (or PAHO) takes care of the mailing and distribution of the TLD capsules to radiotherapy hospitals. This service checks approximately 400 clinical beams per year and has checked a total of more than 3500 radiotherapy beams in approximately 1000 centres. At present, about 80% of the results are within the acceptance level of ±5%, compared to 65% in the past. Subsequent follow-up actions in centres with poor results have helped the radiotherapy centres resolve the discrepancies, thus preventing further mistreatment of patients.

10. Codes of Practice

The IAEA has maintained an interest in standardization and development of Codes of Practice (CoP) for radiotherapy dosimetry going as far back as the seventies, resulting in several publications in the field. The IAEA has published the first CoP in 1970 [15], followed by "Absorbed Dose Determination in Photon and Electron Beams" (TRS-277) in 1987 and updated in 1997 [16]. Another Code of Practice (TRS-381) for radiotherapy dosimetry on "the Use of Plane-Parallel Ionization Chambers in High-Energy Electron and Photon Beams" was published in 1997 to update TRS-277 and complement it in the field of parallel-plate ionization chambers [17]. Following the world trend in radiation dosimetry, the IAEA had developed a new Code of Practice, based on absorbed dose to water standards, under the framework of a Co-ordinated Research Project. This CoP has been endorsed by WHO, PAHO, and ESTRO and will be published soon by the IAEA on behalf of these organizations as TRS-398 [18].

The Codes of Practice developed by the IAEA on absorbed dose determination in radiotherapy beams [TRS-277, TRS-381] are presently used by many physicists involved with dosimetry in radiation therapy, and have been adopted by several countries as their national dosimetry protocol.

11. Technical co-operation projects

The IAEA's Technical Co-operation Programme is based on an assessment of the development priorities and conditions in each specific country or region. The programme also includes regional and interregional projects that are developed to improve the efficiency of implementation or to utilize better the collective experience and resources of multiple Member States. During 2000, the IAEA Division of Human Health provided technical assistance to 64 national projects to support the establishment of radiotherapy services or to improve QA of the operational radiotherapy centres in the Member States. In addition, 10 regional projects, aiming at solving common problems in the geographical region mainly through training courses or workshops were also supported. Twelve IAEA Regional Training Courses, covering clinical, physical and technical aspects of QA in radiotherapy, were organized during 2000.

Taking into account the shortage of medical physicists in developing countries, support for the development of university degrees in medical radiation physics has become an important goal. This has been implemented with success, under a technical cooperation project in the Latin American Region and may be extended to East Asia and Africa. In addition, training courses and workshops, covering all aspects of QA, are organized each year by the IAEA. These training courses are directed towards radiotherapy staff, i.e. radiation oncologists, medical radiation physicists, maintenance engineers, and radiographers, including technicians. In addition, attendance at training courses provided by ESTRO is supported by the IAEA.

Through training courses on clinical topics, the IAEA promotes an awareness of the best evidence-based standards of management of clinical problems and encourages subsequent development of the relevant protocol and procedure manual entries. Concerning the physical and technical aspects, the training courses and workshops provide a unique opportunity to physicists to harmonize procedures and for continuous upkeep of knowledge and exchange of experience in QA.

12. Conclusion

There are many indicators that the IAEA through its different activities is assisting the Member Sates in the development and implementation of QA programmes in radiotherapy. These activities also help disseminate not only the technical knowledge but also the basic ingredient of the QA culture. The IAEA maintains close contacts and cooperation with other international organizations and QA networks to coordinate its activities and avoid duplication of efforts.

References

[1] European Society for Therapeutic Radiology and Oncology, Quality Assurance in Radiotherapy, Report to the European Union for the "Europe Against Cancer Programme", (1994)

[2] American Association of Physicists in Medicine, Comprehensive QA programme for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group-40, Med.Phys. 21 (1994) 581-618

[3] International Atomic Energy Agency, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[4] World Health Organisation (1988) Quality assurance in radiotherapy. WHO, Geneva

[5] International Atomic Energy Agency, Design and Implementation of a Radiotherapy Programme: clinical, medical physics, radiation protection and safety aspects, (IAEA-TECDOC-1040). IAEA, Vienna (1998)

[6] Inter-Society Council for radiation oncology in integrated cancer management (blue book), report of the ISCRO, 1991.

[7] Belletti & al, "QA in radiotherapy; the importance of medical staffing level", Recommendations from an ESTRO, EFOMP joint task group, Radiotherapy &. Oncology. 41 89-94, (1996).

[8] International Electrotechnical Commission, Medical Electrical Equipment. Part 1: General requirements for safety, Pub. IEC-601-1, IEC, Geneva, (1988).

[9] International Electrotechnical Commission, Medical Electrical Equipment. Part 2: Particular requirements for the safety of radiotherapy simulators, Pub. IEC-60601-2-29, IEC, Geneva, (1993).

[10] International Organization for Standardization, Sealed radioactive sources-General, ISO-1677-1977, ISO, Geneva, (1977)

[11] International Organization for Standardization, Sealed radioactive sources-Leakage test methods, ISO/TR 4826, ISO, Geneva, (1979)

[12] International Organization for Standardization, Sealed radioactive sources-Classification, ISO-2919-1980, ISO, Geneva, (1980)

[13] Quality Assurance in radiotherapy, Rad Onc 35, 61-73, 1995 (10)

[14] Andreo & al, IAEA Dosimetry Programme: Report on Activities in 197-1998, CCRI (1), 1999

[15] International Atomic Energy Agency, Manual of Dosimetry in Radiotherapy, (TRS-110), IAEA, Vienna, 1970
[16] International Atomic Energy Agency Absorbed dose determination in photon and electron beams: An international Code of Practice, 2nd edn. (TRS 277). (1997), IAEA, Vienna
[17] International Atomic Energy Agency The use of plane parallel ionization chambers in high energy electron and photon beams (TRS 381). (1997), IAEA, Vienna
[18] International Atomic Energy Agency, Absorbed Dose Determination in External Beam Radiotherapy: an International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water, (TRS-398), IAEA, Vienna in press.
[19] International Atomic Energy Agency, Regulatory Guidance: Radiation Protection and Safety in Radiotherapy, to be submitted for publication as Interim Report for Comments, IAEA, Vienna
[20] European Commission, Implementation of the "Medical exposure directive" (97/43 Euratom), Proceedings of an International Workshop, Madrid, 27 April 1998.
[21] K.A Jessen, the role of EFOMP in the European structures, for implementation and harmonization of QA programmes in radiotherapy, Proceedings of an IAEA-ISRO joint meeting, 8-9 May 1995, IAEA TECDOC-989, (1997), IAEA, Vienna
[22] European Communities Council. Directive 84/466/Euratom, 3 September 1984. Off. J. Eur. Commun. 5 October 1984, 27, L 265/1.
[23] Report of the first Research Coordination Meeting for the Coordinated Research Project on Development of a Quality Assurance Programme for Radiation Therapy Dosimetry in Developing Countries, SSDL Newsletter No. 39, (July 1998), IAEA, Vienna.