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Review

Organizational, technical, physical and clinical quality standards for radiotherapy

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ABSTRACT

Background: Indisputably, radiotherapy has become an entirely interdisciplinary specialty. This situation requires efficient planning, verification, monitoring, quality control and constant improvement of all aspects of service delivery, referring both to patients' (including diagnosis, prescription and method of treatment, its justification, realization and follow up) and organizational, technical and physics matters.
Aim: The aim of this work was to develop technical, physics and clinical quality standards for radiotherapy. This paper presents chosen standards for each of the aforementioned category.
Materials and methods: For the development of quality standards the comparison analysis of EU and Polish acts of law passed between 1980 and 2010 was conducted, the universal industrial ISO norm 9001:2008 referring to quality management system was reviewed. Recommendations of this norm were completed with detailed quality standards based on the author's 11 year work experience and the review of articles on quality assurance and quality control standards for radiotherapy published between 1984 and 2009 and the review of current recommendations and guidelines of American, International, European and National bodies (associations, societies, agencies such as AAPM, ESTRO, IAEA, and OECI) for quality assurance and quality management in radiotherapy.
Results: As a result 352 quality standards for radiotherapy were developed and categorized into the following three groups: (1) organizational standards, (2) physics and technical standards and (3) clinical standards.
Conclusions: Proposed quality standards for radiotherapy, can be used by any institution using ionizing radiation for medical procedures. Nevertheless standards are only of value if they are implemented, reviewed, audited and improved and if there is a clear mechanism in place to monitor and address failure to meet agreed standards.

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1. Background

The development of radiological technologies that has been going on in the areas of diagnostic imaging, treatment planning systems, high-tech irradiation equipment, has caused radiotherapy to become an interdisciplinary domain involving staff of various backgrounds: physicians, radiotherapists, medical physicists, electronic engineers, dosimetrists, quality experts, and radiation technologists. This allows steady improvement in therapy results, but at the same time the diagnostic and therapeutic process grows more complex and complicated requiring that every stage of it is planned, organized and controlled so as to assure the quality of services provided.[1]

In its simplest and yet the most meaningful definition, quality is doing the right thing, in the right way and at first go. Simple as it might seem by this definition, quality is, however, a very broad concept applicable to all areas of activity of a health care institution. Quality standards encompass the whole life of a hospital, from nurse's polite approach to management's decisions. It is also a relative concept which does not exist for its own sake. Quality must always be associated with a goal it is meant to serve, be it patients' satisfaction, prevention of irregularities, errors and adverse events, timely treatment, reduction of in-house infection rate, safe therapy conditions, etc. It would be wrong, therefore, to consider quality only in terms of effects achieved, i.e. treatment efficacy and adequacy, notwithstanding their undeniably crucial role. Other important factors include:

- conditions in which services are provided (sanitary state of wards, temperature, décor of waiting rooms, type of facilities, medical supplies);availability and flexibility (working

Table 1 – Organizational standards.

Category	Standard
Policy and management	
Quality management system (QMS)	1. The institution has established, documented, implemented and maintained quality management system in radiotherapy and constantly improves its effectiveness in accordance with legal requirements (national and European) and patients' needs and expectations, as well as other requirements accepted by the institution, e.g. ISO 9001:2008, accreditation program, etc. 2. The institution reviews its management system on a regular basis.
Organization's goal	1. The institution has defined the goal and extent of its activity (extent of services), with due account taken of other organizational units within the hospital and practicability of performing or coordinating such services within the regional or national network of oncological and clinical centers, in order to provide each patient with best possible radiotherapeutic care and treatment. 2. The organization has defined its goal in the context of its resources (equipment, infrastructure, staff, etc.) and current demographic, social, financial, geographical and epidemiological conditions as well as QMS requirements. 3. The institution's activity shall be consistent with legal requirements and local and national guidelines. 4. The institution has set its short- and long-term quality objectives. 5. The institution's objectives shall be consistent with its policy, systematically reviewed and updated.
Organization's policy	1. Organization's quality policy has been defined and documented in the context of current demographic, social, financial, geographical and epidemiological conditions as well as QMS requirements. The quality policy is systematically reviewed and updated. QMS development and improvement program (including investment, services, staff training) has been established and documented in line with the quality policy and its objectives.
Organization's structure	1. The institution has a strictly defined organizational structure, each employee knows and understands his or her position in the structure. 2. The institution has defined its organizational relationships and hierarchy structure, both functional and operational, between particular organizational units and management members. 3. The institution has appointed persons responsible for particular processes (process owners) and responsibilities of process participants. 4. The institution has identified processes covered by QMS and defined and documented systemic relationships between them (process mapping).
Management's involvement	1. The management has established, maintained and improved QMS in radiotherapy. 2. The management has defined institution's quality policy and objectives. 3. The management ensures necessary resources for the institution to carry out its activity and implement QMS. 4. The management shall monitor institution's costs in the context of annual budget planning. 5. Representative for QMS has been appointed. 6. Committee for QMS in Radiotherapy has been appointed. 7. Representative for QMS shall chair the Committee. 8. Positions (persons) and responsibilities in QMS have been defined.

Table 2 – Organizational standards.

Category	Standard
Documentation and records	
QMS systemic documentation	1. The institution has put in place a QMS systemic documentation in line with national requirements, i.e. (a) quality book including: • QMS scope (e.g. radiotherapy), • quality policy, • quality plan(s), • quality objectives, • tools to measure achievement of objectives, • process map (description of basic and support processes being executed and relationships between them), • procedures, instructions and other systemic documents or references thereto; (b) general procedures including: • supervision over documentation, • supervision over records, • internal audits, • procedure for non-conformities, • corrective and preventive actions, • code of diagnostic, interventional or therapeutic procedure, applicable to a given organizational unit, developed in compliance with legal requirements, (c) handling instructions and user manuals of radiological equipment, (d) information concerning testing methods for internal controls of physical parameters of radiological equipment and accessory devices, (e) information concerning results of tests of internal controls of physical parameters of radiological equipment and accessory devices, and acceptance tests, (f) information concerning personnel qualifications and training, (g) description of methodology used for internal clinical audits, (h) information concerning results of internal clinical audits and any corrective or preventive measures, (i) information concerning interim reviews of quality management system, (j) standards for describing examination results and procedures applicable to the results and other documentation, 2. The institution shall develop and document individual record templates (forms, schedules, plans). 3. All systemic documents shall be up-dated, authorized and archived according to QMS requirements and national laws. 4. Out-of-date documents and records shall be withdrawn and destroyed. 5. Archival copies shall be held exclusively by Representative for QMS in Radiotherapy. 6. Systemic documentation shall be systematically reviewed, updated and improved (at least once a year). 7. Documentation updates shall be authorized, dated and numbered. 8. The institution shall hold annual management review schedules – management meetings. 9. Input data for management reviews include: • audit results, • patient satisfaction survey analyses, • process functioning and treatment effectiveness, • event and non-conformity reports, • corrective and preventive action status, • results of follow-up measures, • comments, conclusions, points for improvement.

hours, waiting time, diagnostic examination, phone and Internet appointments, convenient access roads, car park facilities, clear signs and directions in hospitals),

- time of response, work organization (consistence, efficiency, personnel accountability, teamwork, legibility of records, process-oriented and systemic approach to tasks performed); action standardization (homogeneity, repetitiveness and reliability), safety (compliance certificates, acceptance tests, equipment controls and measurements, protective clothes, personal safeguards, radiological protection)
- meeting patients' needs and expectations (comfort of treatment, continuity of health care, access to information)
- meeting legal requirements (national and international standards, legal responsibility, directives, regulations)
- availability of information on services (Internet, bulletins, information boards)
- psychosocial factors (attitude, reputation, empathy, personnel politeness, respect for personal dignity, trust, friendliness, honesty)[2];
- ethical and cultural factors (consent to be treated, freedom of culture and religion); and

Table 3 – Physics and technical standards.

Category	Standard
Documentation and records	1. The following shall be subject to detailed documentation: (a) results of acceptance tests, (b) results of control measurements, (c) equipment acceptance protocols, (d) equipment failures and repairs, (e) equipment exploitation log (including: daily operating conditions, breakdowns, stoppages, repairs, etc.), (f) schedule of technical inspections, (g) schedule of equipment control tests (daily, weekly, monthly, quarterly, half-yearly, yearly), (h) certificates or confirmations of specialist training in operation of specific equipment taken by responsible staff. 2. Head of the radiotherapy unit shall keep a register and documentation of technical and dosimetrical failures and all inconsistencies between physical parameters and indications recorded in an irradiation sheet and actual parameters and indications during irradiation that may lead to A or B category radiological accidents. 3. The institution has implemented and documented: (a) control and measurement procedures for physical and technical parameters of radiotherapeutic and accessory equipment (e.g. treatment table, audiovisual communication system, air-conditioning), (b) control and measurement procedures for control and measurement equipment, (c) emergency procedures in case of detecting faulty operation or technical defects, (d) equipment operational instructions.
Physics parameters	1. Equipment physical parameters shall comply with national and international standards as to measured values, required measurement methods and tolerances and safety standards (e.g. *IEC*, *CENELEC*, *ICRU*, *IAEA*, *ICRP*, *Euratom*, *national standards*). 2. All calibration and dosimetrical operations shall be made or supervised by a qualified expert in medical physics. 3. The institution has introduced a list of tolerances admissible in technical inspection and periodical equipment control tests, as required by national regulations.
Technical failures	1. The institution has defined the technical failure of therapeutic apparatus. 2. The institution has implemented and documented an emergency procedures in case of a defect or faulty operation of therapeutic apparatus/measuring equipment. 3. In case of a technical failure of therapeutic apparatus, a responsible radiation technologist shall report the case to the person responsible for technical quality and efficiency of equipment in the institution. 4. Radiation technologist shall resume operation of the faulty apparatus only after receiving an acceptance protocol signed by head of the institution/authorized person. 5. In case of a technical failure, Head of the institution shall: (a) investigate into the cause and circumstances of the failure or non-conformity, (b) report the failure or non-conformity to his or her immediate superior. 6. Take measures to eliminate the cause of the failure or non-conformity.

- competences (professionalism, professional abilities) and personnel reliability (efficiency, punctuality, accuracy).
- these are all significant components and evaluation criteria of health service quality [3,4].

What health care institutions offer these days are complex services involving professionals of different disciplines and positions, numerous types of specialist equipment, and a wide variety of medical materials, reagents and preparations. In consequence, the final quality of a health service, understood as a therapeutic effect, is a resultant of all necessary components. The bigger an institution, the more components there are and the more complicated it becomes to manage the quality of the diagnostic and therapeutic process. Therefore, quality should be a norm constituting an integral part of organization's activity, rather than an outcome of a series of uncontrolled coincidences.

At present, radiotherapy is an interdisciplinary field using advanced therapeutic and imaging apparatus and computerized therapy planning and simulation systems. This means that both the patient-related aspects (diagnosis, selection, treatment indication, justification, referral, planning, therapy, follow-up) and the control and measurement procedures forming the technical part of the treatment process should be subject to regular planning, verification and, most importantly, constant improvement.

While, as of late, quality assurance in radiotherapy has been believed to play a key role in ensuring safe and effective treatment in the physical and technical context (efficient equipment, in vivo dosimetry, portal imaging), now, a more holistic (systemic) approach to quality is beginning to prevail. This, however, calls for designing, implementing, maintaining and improving formalized quality systems or, in other words, implementing versatile quality management systems to cover all areas of activity (administrative, organizational, physics,

Table 4 – Physics and technical standards.

Category	Standard
Product specification	1. The institution has developed product specifications including working parameters, tolerances and compatibility of equipment purchased with existing therapeutic machinery. 2. The institutions shall purchase equipment that can be integrated into the existing therapeutic line. 3. The institution has performed and documented technical acceptance of the equipment, confirming that all components delivered by manufacturer are consistent with the specifications.
Quality control of physics, technical, mechanical and geometrical parameters of • therapeutic equipment, • imaging systems, • simulators, • radiotherapy planning system, • radiotherapy management system.	1. Control tests shall comply with national regulations in terms of extent and frequency. 2. Medical physics units performing control tests of equipment physical parameters have put in place requirements of PN-EN-ISO 17025. 3. The institution has appointed a person responsible for quality assurance and control as well as technical status and efficiency of the equipment (notwithstanding that particular control tasks are assigned to different persons – physicist, engineer, technician, etc., it is recommended that overall responsibility for the equipment functioning and the QA and CC program be assigned to one person, preferably a medical physicist AAPM, 1994). 4. The institution shall perform acceptance tests of equipment or software (SPL) after its installation and before putting it into operation and clinical use, and after each major defect, repair or modernization, in order to confirm the consistence of its physical and technical parameters with manufacturer or repair specification. 5. Acceptance tests shall cover: calibration and acquisition of beam data, in the case of treatment planning system – entry of beam-related data and testing the system by direct measurements and calculation methods. 6. Acceptance tests shall be made either by manufacturer or in-house medical physicist or medical engineer. 7. The institution shall perform acceptance tests in line with agreed and implemented procedure. 8. The institution shall perform systematic equipment controls and measurements according to requirements of national regulations. 9. The institution has defined the scope of its controls and measurements, as required by national regulations. 10. Controls and measurements shall be made on daily, weekly, monthly and yearly basis and after each repair, ensuring an adequate level of independence between the repairing team and persons responsible for proper functioning of the equipment after repair. 11. The institution shall perform a systematic calibration therapeutic beam. 12. The institution performs systematic authorized maintenance of its equipment (authorized technical inspections). 13. The institution shall perform regular tests of the mechanical and geometrical parameters of simulators (as for therapeutic apparatus, with similar tolerances and frequency of critical parameter assessments). 14. Geometric and mechanical features of simulators shall be compatible with those of therapeutic apparatus. 15. The institution performs regular quality tests of computed tomography units, used to plan radiotherapy,[1] planigraphic attachments and other imaging systems, e.g. MRI and USG.

technical, and clinical) of a health care unit applying ionizing radiation for medical purposes.

2. Materials and methods

A model of quality management in radiotherapy was proposed and a detailed list of organizational, physics and technical, and clinical standards compiled basing on EU directives[5–7] and Polish legal acts published in 2002–2010,[8–23] Quality Assurance in Radiotherapy published by the World Health Organization in 1988,[24] Recommendations for a quality assurances programme in external radiotherapy published by the European Society for Therapeutic Radiology and Oncology (1995)[25] and AAPM Report no 13 on Physical aspects of quality assurances in radiation therapy published by the American Association of Physics in Medicine (1994),[26] Requirements for Quality Management System by PN-EN ISO 9001:2001[27] then 9001:2008,[28] International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources Safety series no. 115 published by the International Atomic Energy Agency (1996),[29] Guidelines for comprehensive audit of radiotherapy practice: a tool for quality improvement published by the International Atomic Energy Agency (2005)[30] Clinical Assessment Guide elaborated by the Organization of European Cancer Institutes in 2003,[31] as well as literature of the subject.[32–89]

3. Results

As a result 352 quality standards for radiotherapy were developed and categorized into the following three groups: (1) organizational standards, (2) physics and technical standards and (3) clinical standards.

Table 5 – Clinical standards.

Category	Standard
Referral for treatment/treatment decision/treatment indications	1. Institution's patients shall be subjected to medical exposure for diagnostic or therapeutic purposes, only on recommendation of a medical practitioner. 2. Examination or treatment involving ionizing radiation require a written referral issued by a practitioner authorized to prescribe examination or treatment involving ionizing radiation. 3. Examinations involving ionizing radiation shall be made without doctor's referral only under medical screening projects. 4. Decision on radiotherapy shall be made on the basis of a patient interview, assessment of patient's health and psychosocial status, results of physical and pathological examination results, assessed stage of cancer advancement, and patient's medical documentation. 5. Results of diagnostic tests shall form an integral part of patient's medical documentation and remain available before, during and after treatment. 6. The institution shall evaluate patient's psychosocial condition and accordingly adjust its health care and treatment options. 7. Referral for radiotherapy shall be made in writing and duly authorized (by signature, stamp and date) by a medical practitioner specializing in oncological radiotherapy. 8. Recommendation for radiotherapy shall include planning target volume, gross tumor volume and clinical target volume (PTV, GTV, CTV) according to the rules provided *ICRU 50*, *ICRU 62*, and *ICRU 38* reports, total dose, method of fractioning, total duration of therapy, planned intervals, and description of treatment techniques pursuant to an applicable therapeutic protocol. 9. Recommendation for radiotherapy shall be forwarded to the team responsible for therapy planning (medical physicist, dosimetrist, radiation technologist) who do the necessary calculations and planning. 10. The institution holds treatment waiting lists.
Therapeutic protocol	1. The institution has established, implemented and documented a therapeutic protocol describing a treatment pattern for each type therapy, tumor location and disease. 2. The therapeutic protocol shall be consistent with the national model of clinical procedures and based on confirmed results of clinical, radiological or physical tests. 3. The institution has indicated sources of the clinical standards it applies (own guidelines, national or international guidelines, etc.). 4. Patients shall be treated in accordance with the established therapeutic protocol; any exemptions need to be accounted for and reasons recorded in patient's medical documentation (e.g. irradiation sheet). 5. Each therapeutic protocol shall provide for lowest possible exposure of healthy tissues (ALARA) and protection of healthy tissues wherever practicable and justified. 6. The institution has implemented and documented a therapeutic protocol for radiotherapy of pregnant women pursuant to national regulations. 7. Therapeutic protocols shall be systematically reviewed and updated to keep in pace with the progress in medical and clinical knowledge. 8. The institution shall hold regular meetings to review therapeutic protocols.

Organizational standards were divided into following sub-categories:

1.1. Policy and management
1.2. Documentation
  1.2.1. Documentation of quality management system
  1.2.2. Records and logs
  1.2.3. Registries (incl. cancer registry)
1.3. Resources
  1.3.1. Human resources
  1.3.2. Infrastructure, facilities and equipment
  1.3.3. Environment
    1.3.3.1. Radiation protection
1.4. Interdisciplinary approach

Physics and technical standards were divided into the following sub-categories:

2.1. Specification of products
2.2. Quality assurance
  2.2.1. Physics, technical, mechanical and geometrical parameters control of: therapeutic machines, imaging systems (CT, PET, PET–CT), simulators, treatment planning systems, radiotherapy management systems
  2.2.2. Quality control of gauges and control equipment and tools
2.3. Documentation and records
2.4. Parameters
2.5. Malfunctions
2.6. Improvement
2.7. Equipment audit
2.8. Dosimetrical audit

Clinical standards were divided into the following sub-categories:

3.1 Patient's referral/treatment prescription
3.2 Therapeutic protocol
3.3 Interdisciplinary approach
3.4 Communication

Table 6 – Clinical standards.

Category	Standard
Conduct of treatment	1. All treatment procedures and related diagnosis shall be performed specializing in oncological radiotherapy or supervised by them (when performed by doctors being trained in this specialty) and radiation technologist. 2. Radiotherapy procedures shall be planned and performed in such a way as to allow for stoppages of therapeutic apparatus causing deviation from accepted treatment standards. 3. The institution shall ensure enough time for a therapeutic session to be performed correctly. 4. One therapeutic apparatus may accommodate the maximum of five radical treatment patients within one hour. 5. Each irradiation fraction shall be preceded with patient identification, including the check-up of name, personal identification number or other identification number, date of birth, patient's photo, irradiation technique, irradiation parameters, irradiated area, tumor location, accessories used, etc. 6. At each stage of treatment, the institution shows full respect for patients' privacy and personal data protection. 7. Patient's irradiation sheet is available at a given apparatus during each irradiation fraction. 8. First irradiation fraction in radical treatment patients and – in justified cases – in palliative treatment patients is attended by a doctor specializing in oncological radiotherapy to verify patient's positioning and immobilization and provide them with psychological support. 9. Medical physicist participates in the radiation procedure at doctor's or RTT's request. 10. Patients shall be positioned and immobilized by two RTTs. 11. Patients shall be positioned and immobilized as accurately, repetitively and comfortably as possible (in each apparatus used in the treatment process), according to an instruction contained in treatment plan (as a text or diagram). 12. In the case of radical and palliative treatment, doctor specializing in oncological radiotherapy participates in the first irradiation session performed according to a pre-set treatment plan. 13. During radiotherapy, patient shall be monitored by an RTT (audiovisual system). 14. RTT shall confirm the consistence of physical parameters from the irradiation sheet with those actually realized, in particular monitor units (exposure time).

3.5 Treatment planning
3.6 Verification of treatment planning
3.7 Conduction of treatment
3.8 Verification of treatment
3.9 Treatment termination/cancellation
3.10 Radiological incidents and accidents
3.11 Quality control of treatment
3.12 Reference levels of radiation doses
3.13 Documentation and records
3.14 Follow-up
3.15 Clinical audits

For selected organizational, physics and technical, and clinical standards see Tables 1–6.

4. Conclusion

Proposed quality standards for radiotherapy, can be used by any institution using ionizing radiation for medical procedures. Nevertheless standards are only of value if implemented, reviewed, audited and improved, and if there is a clear mechanism in place to monitor and address a failure to meet agreed standards.

Therefore, it is equally important to develop and implement a quality management system that will also contribute to:

(a) improvement in work organization,
(b) improvement of service quality,
(c) reduction of costs owing to cost-effective supply management,
(d) patient-oriented approach,
(e) reduction in the number adverse effects, non-conformities, technical breakdowns and costs of repair,
(f) increase in patient and staff safety through on-going control of equipment and working place, as well as application of harmonized procedures and documentation,
(g) legible organizational structure in term of accountability for work outcome,
(h) strengthening of teamwork and cooperation between individuals and organizational units,
(i) increased employee involvement in institution's constant improvement and QMS.

Conflict of interest

None declared.

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