

**RECOMMENDATIONS FOR
ASSESSMENT OF SAFETY, QUALITY
AND RELIABILITY IN A RADIATION
THERAPY PRACTICE**

Issued June 13, 2023



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Executive Summary

The procedures and processes of radiation therapy planning and delivery must incorporate the principles of safety, while the development and manufacturing of the devices used for radiation therapy ought to facilitate adherence to these principles.

The objective of this National Council on Radiation Protection and Measurements (NCRP) document is to define the characteristics of a radiation therapy practice that prioritizes safety. Safe and accurate patient treatment with radiation is achieved by a complex process of prescribing, planning, and treatment delivery. Considerable efforts have been made in recent years to refine quality and safety principles in radiation therapy. While there have been many safety-focused documents published in the past decade regarding radiation therapy, the NCRP recognizes that there has not been a thorough examination of reviewable safety indicators. The intent of this document is to provide recommendations on external assessment (or audit) of a radiation therapy practice in terms of quality and safety. However, the same principles outlined for external audits may also be utilized by a practice for internal self-assessments or audits.

Audits, be they external or internal, may confirm a radiation oncology practice's rigorous commitment to safe radiation therapy. They may also reveal opportunities for improvement with respect to patient and staff safety, quality, and system reliability.

The five tables in this Statement present 44 essential indicators grouped by program development area, i.e., program development; safety barriers; external calibration and validation; adequate staffing, support, and environment; and equipment records.

The recommendations in this Statement are designed to accommodate external beam and brachytherapy procedures, independent of the practice environment (*e.g.*, private, academic, and nonacademic hospital-based) or practice size. Radiotherapy with unsealed radioactive sources is not addressed in this Statement.

The document may be utilized by radiation therapy practices as a source of practice improvement initiatives, by facilities for the assessment of accreditation readiness, and by external reviewers for safety assessment purposes.

Introduction

Radiation therapy is characterized by highly complex and dynamic processes, where a multidisciplinary team works together using sophisticated imaging, planning, and delivery systems to provide efficient, accurate, and safe patient treatment. A comprehensive assessment of safety in radiation therapy should extend beyond an assessment of patient care. Therefore, this Statement considers the broader aim of delineating indicators supporting safe operations and processes.

This Statement offers guidance on evaluating key indicators of patient and staff safety, as well as the quality and reliability of treatment¹ within a radiation therapy practice. The implementation of these essential items will require investments of time, money, and resources. This Statement is meant to complement the extensive literature of the past several decades that has delineated the critical characteristics of safety-focused radiation therapy [such as in Royal College of Radiologists and World Health Organization (RCR/SCR/IPEM/NPSA/BIR 2008; WHO 2008)]. A series of articles in the *New York Times* by Walt Bogdanich,

¹Patient and staff safety, quality, and reliability are intertwined and, throughout this document, may simply be referred to as safety when used in a general sense.

beginning with “Radiation Offers New Cures, and Ways to Do Harm” (Bogdanich 2010), brought attention to medical errors and emphasized the significance of these initiatives. This led to innovations in radiation therapy safety reflected in the literature (*e.g.*, Marks et al. 2013, 2015; Thomadsen et al. 2014; Evans et al. 2016; ASTRO 2019; Hayman et al. 2019; Das et al. 2022; Moran et al. 2023; Qi et al. 2023). Much of this literature has been drawn upon while developing this Statement, with particular attention given to process indicators that ensure the quality and reliability of treatment and the safety of patients and staff.

Relevant systems that impact safety include the electronic health record, oncology information system (OIS), treatment simulation system, treatment planning system, and radiation delivery system. Beyond the safety features of each of these systems, the key to ensuring that patients receive the prescribed treatment correctly is an integrated quality control and quality assurance (QA) program. QA must also be performed for ancillary systems (such as patient set-up verification systems) and for test equipment (such as dose measurement systems for establishing radiation output from the treatment machine). Verification of device interoperability and review of the workflow transactions among staff members are additional elements of comprehensive quality review.

The tables in this Statement list indicators that ***should*** or ***shall*** be in place at all clinical practices, where:

- ***shall*** (or ***shall not***) indicates a recommendation from NCRP that is necessary to meet the currently accepted standards of radiation protection;
- ***should*** (or ***should not***) indicates an advisory recommendation from NCRP that is to be applied when practicable or practical (*e.g.*, cost-effective); and
- ***may*** indicates a reasonable practice that is permissible.

Background

The focus on quality and safety in radiation therapy has largely proceeded in parallel with the more widespread focus on safety across medicine, for which the publication of *To Err is Human* (Kohn et al. 2000) represents a major milestone. Many freely available publications have promoted principles and tools that enhance the safety and quality of practice in radiation therapy (WHO 2008; Ford et al. 2015; Huq et al. 2016; ASTRO 2019). These references are indicative of the increasing emphasis in radiation therapy on prospective tools, human factors engineering, and retrospective tools to assess safety-relevant technical processes.

Prospective risk-analysis tools include failure mode and effects analysis and fault tree analysis, among several other approaches and tools, which may enable one to identify the most serious error types and precipitating steps within a process (Huq et al. 2016). Prospective tools like failure mode and effects analysis and fault tree analysis complement established test activities, such as acceptance testing, commissioning, and end-to-end testing, that commonly precede human use.

Human-factors engineering considers human capabilities and limitations in the design of tools and processes and is an essential approach for clinical processes in radiation therapy. These processes and techniques include:

- practices: safety culture, just culture, simulation-based training, and crew resource management including effective communication;
- tools: checklists; standardization, such as standard operating procedures (SOPs), defined roles and responsibilities; and
- engineered safeguards: such as forcing functions and automation.

Many of these techniques have been applied successfully to radiation therapy settings, including through standardized naming conventions (Mayo et al. 2018) and the many safety barriers (added process steps to prevent errors) employed in radiation therapy: physicists' plan checks; weekly chart checks; time outs; per-patient, pretreatment dosimetric verification; and automated calculation check programs, to name a few.

Retrospective analysis of events allows the development of modified workflows to prevent falling into error pathways or out-of-tolerance situations. A few examples of approaches to such retrospective analysis include monitoring trends in device QA data, causal analysis (*e.g.*, root cause analysis) following incidents and close calls, responsive mechanisms to address staff concerns, peer review, the use of an incident-learning system, and internal and external audits.

A multidisciplinary committee charged with quality improvement *should* oversee the implementation of quality and safety processes (ACR 2018; ASTRO 2019) and *shall* have a direct line of communication with institutional or practice leadership. This committee *should* ensure the timely completion of all quality-improvement projects and continued monitoring of the effectiveness of any quality-improvement interventions.

In response to the need for normative guidance, the American Association of Physicists in Medicine (AAPM) routinely publishes Medical Physics Practice Guidelines (MPPGs) for various clinical contexts. These documents are typically adapted from technically detailed AAPM task group reports; the MPPGs are well-suited to facilitate clinical implementations and audits. It is essential to periodically review revisions and additions to the AAPM MPPGs, AAPM task group reports, American College of Radiology (ACR) practice parameters and technical standards, and American Society for Radiation Oncology (ASTRO) clinical practice guidelines and safety white papers. The American Society of Radiologic Technologists and American Association of Medical Dosimetrists also have posted documents that provide practice guidance (ASRT 2021, 2022; AAMD 2022).

Development and Structure of an External Audit Tool

The NCRP audit tool consists of five tables covering broad areas of quality and safety in radiation oncology practice. This report was drafted by NCRP Scientific Committee 4-10 on Error Prevention in Radiation Therapy, herein referred to as the "Committee." To benchmark the content of the five tables, the Committee solicited input from a group of stakeholders (listed at the end of this Statement), drawing on the experience and expertise of the representatives from the regulatory, accreditation, scientific, and professional communities.

A virtual meeting was held for stakeholders on January 8, 2022, during which pairs of members from NCRP facilitated parallel breakout sessions, each with three or four of the stakeholder representatives, with each session focusing on discussion of the tables that are included in this Statement. Efforts were made to ensure that the groups considered prospective, human factors, and retrospective tools to enhance quality and safety within the radiation therapy practice. Groups were rotated three times during the Stakeholder meeting to maximize the breadth of interactions among the participants. The perspectives, suggested references, and recommendations from the breakout sessions were then iteratively revised, based upon Committee discussions, to produce a working draft. Further revisions were made based on the recommendations of NCRP reviewers and community subject matter experts during the review process. Based on the input received, the Committee arrived at a consensus for each of the items listed in the tables of this Statement.

The five audit tables move from high-level factors in Tables 1 and 2 to specific process and work product factors in Tables 3, 4, and 5. Table 1 focuses on support from institutional and practice leadership, including process management and workplace culture, prospective analysis, and incident learning. Table 2 covers the appropriate safety barriers for ensuring clinical

processes with a high likelihood that errors will be caught before reaching the patient. Table 3 addresses the proper calibration of radiation treatment devices and external accreditation (Hendee and Herman 2011). Table 4 covers staffing levels, environmental considerations, and other items that may require institutional support. Table 5 focuses on shielding design calculations, survey measurement documents, acceptance testing documentation, commissioning documentation, and ongoing QA.

Patient and caregiver involvement during treatment is a unique, essential component of quality healthcare. A focus on patients and caregivers is evidenced through the presence of accessible educational materials, available translators, and adapting to the needs of those with limited English proficiency. Attention to the role of the patient and caregiver appears in Table 1, item e.

Use of the Audit Tool

Each auditable item is divided into three parts: an assessment, a method of assessment, and an evaluation metric. The Assessment column provides a label for the item to be evaluated. The Method column shows the techniques that can be used to gather information for the assessment. The following techniques are drawn from for making the evaluation:

- interviews with clinical team members;
- review of policy documents;
- the presence of reports (*e.g.*, causal analysis, commissioning);
- minutes from meetings (including attendance);
- review of SOPs;
- evidence of working processes (*e.g.*, in clinical documentation);
- clinical protocols and data tables (*e.g.*, planning objectives by target site); and
- observation of activities.

The audit should focus on the ***shall*** statements as items for compliance with community standards and ***should*** statements as opportunities for improved quality activities. The assessments are phrased in a manner most applicable to megavoltage external beam photon and electron treatment delivery. Some interpretation will be necessary to accommodate these items for the other common treatment modalities, which include low- and high-dose rate brachytherapy (when not specified in the table), electronic brachytherapy, superficial and intraoperative radiation therapy, proton therapy, and particle therapy.

Those assessment tools that require access to patient medical records ***shall*** adhere to appropriate privacy regulations. Use of the tool is secondary to regulatory compliance and practice performance for accreditation metrics.

Recommendations to Manufacturers

Manufacturers can aid external reviewers by supporting robust audit mechanisms to assess compliance with the individual items listed within the tables (Table 2; Table 4, items b, c, and d). Several items in Tables 2 and 4 could be reviewed in the OIS when the practice has taken steps to document those items. OIS, treatment planning system, and treatment delivery machines ***should*** allow electronic documentation of physician and medical physicist review of key process steps as well as their physical presence, when required, during a procedure. Similarly, OIS systems ***should*** provide an auditable log of user overrides of safety interlocks of the treatment device. By reviewing these auditable data, a practice can assess process compliance and facilitate awareness of process deviations among staff members. Discussions with stakeholders from national societies and advisory and standards organizations revealed a need for wider access to, and awareness of, safety notices and software release

TABLE 1—*Program development factors for safe, high quality and reliable radiation therapy practice.*

Assessment	Method	Evaluation
a. Safety culture and just culture	Interviews with the radiation therapy team members; review of policy documents, if available.	Management should take documented steps to instill safety culture and just culture in the workplace (Dekker 2012; NRC 2011). Safety culture example: all physicians, physicists, other staff, and trainees feel free to raise questions and to pause a procedure at any time. Just culture example: nonpunitive policies encourage reporting events and issues related to safety, quality, and reliability.
b. Quality Improvement Committee (ACR 2018) or Quality Assurance Committee (ASTRO 2019) among other possibilities	Review of policies, procedures, and internal audits by the committee. Review of minutes (including attendance) from meetings during which quality improvement issues are addressed.	The Committee shall be interdisciplinary, including at least one physician, radiation therapist, dosimetrist, physicist, and nurse or physician extender. A radiation safety officer or member of the radiation safety committee should attend. Meetings should be conducted at least quarterly. The Committee should oversee the investigation of events and monitor changes made to improve patient safety.
c. Processes follow SOPs	Review of the SOPs.	SOPs shall exist for safety-critical procedures, including general actions to take when a therapy device malfunctions. Each SOP should specify which staff types are authorized to make decisions and to carry out the task. Checklists can help users follow procedures.
d. Effective communications, including handoffs	Timely clinical notes; mechanisms to export and import medical data, access to prior radiation records, review of communications protocols; documentation of each patient’s pregnancy, pacemaker, and prior radiation status; observation of staff communications during treatment-related activities.	Communication expectations throughout the facility should be established by coordination of all practice stakeholders. Initial consultation notes, follow-up notes and treatment summaries (that include prescribed and delivered dose, treatment tolerance, and any deviations from plan and follow-up plan) shall be available to health care providers involved in the patient’s care.
e. Patient and caregiver communication	Patient access to educational materials; culture of openness and the opportunity to ask questions of all staff; compliance with informed consent requirements.	Written and verbal patient instruction and education should reasonably attempt to accommodate the language, reading level, and health literacy of the patient.

f. Adequate resources	Discussion with clinical and technical staff.	Equipment and instrumentation should satisfy recommendations from professional organizations, including at least two systems to measure absolute dosimetry and the possession of patient-specific QA equipment and machine QA tools. For staffing, see Item a. in Table 4.
g. Risk-analysis guidance of procedure designs	Review of documentation.	Prospective process development techniques should be used (<i>e.g.</i> , Huq et al. 2016).
h. Incident learning	Review of the internal incident submission record and corrective actions; evidence of regular feedback to all clinical staff about lessons learned.	A facility's incident learning should actively encourage staff participation and feedback to staff members. Submission to and engagement with an external incident learning system, such as a Patient Safety Organization, is encouraged.
i. Causal analysis performed for incidents with actual patient harm and significant risk of patient harm	Review of causal-analysis reports and follow-up.	Each incident shall be reviewed and its finding communicated in a written report. When the analysis and corrective actions cannot be immediately implemented, intermediate actions shall be taken to mitigate the potential recurrence of the problem.
j. Reporting of medical events to regulatory bodies	Review of reportable errors in treatment delivery, including near misses; causal-analysis reports if such incidents have occurred; and follow-up actions.	The policy for reporting medical events should include who will be contacted (<i>e.g.</i> , attending radiation oncologist and management) in the practice and who will contact the radiation safety officer.

TABLE 2—*Important safety barriers to intercept process errors.*

Assessment	Method	Evaluation
a. Sufficient time and appropriate environment for contouring of targets and organs at risk, treatment planning, physician plan review, physics checks, QA, and therapists' checks	Review of SOPs (if available); staff interviews.	Depending on clinical urgency, staffing, and workflow processes (Mazur et al. 2012), the physicist should have at least one day to complete plan review. The therapists shall have adequate time to review the plan after physics review. Some procedures may require these tasks to be completed on the treatment day (Muller et al. 2020; Wilson et al. 2019).
b. Peer review of planning and contouring before commencement of treatment (<i>e.g.</i> , chart rounds)	Inspection of records of peer review, attendance, and peer recommendations. If feasible, observation of chart rounds.	Peer review of the treatment intention and plan shall occur before or shortly after the treatment course commences (Marks et al. 2013). Cases requiring urgent or emergent short-course radiotherapy may complete treatment before peer review is performed.
c. Use of clinically appropriate normal tissue tolerance constraints on dose	Review of tables of normal tissue tolerance constraints.	Individualized intent for prescribed dose and normal tissue dose constraints shall be communicated to the dosimetrist and physicist for conventional, hypofractionated, and stereotactic radiosurgery treatments. Dosimetry should be assessed for adherence to this intent. Reference normal tissue dosimetric constraints should be available for guidance (Wright et al. 2019).
d. Independent dose calculation checks	Review of dose-calculation-check-program reports in patient charts.	An independent method shall be commissioned and used by the physicist to assess the correctness of the planned dose delivery, such as monitor units for linear accelerators (Stern et al. 2011; Zhu et al. 2021) or dwell times for high-dose rate units.

e. Patient-specific delivery verification for intensity modulated radiation therapy and other complex plans	Review of QA records in patient charts.	Patient-specific QA shall be performed for treatments using intensity modulated radiation therapy, stereotactic body radiation therapy, and stereotactic radiosurgery. The required form of this QA may depend on evolving community standards, reimbursement practices, and regulatory policy.
f. Treatment plan physics evaluation	Review of planning document (electronically) signed by a qualified medical physicist (or equivalent) indicating review and approval.	Physics treatment plan evaluation should be completed before the patient's first treatment and an electronic approval system should ensure the prevention of unapproved treatments. Essential components of the initial chart review include clinical suitability of the radiation therapy prescription, contours, treatment plan, secondary monitor unit calculation, and OIS information (Ford et al. 2020; Xia et al. 2021).
g. Use of set-up tolerance tables or equivalent	Direct inspection of values contained in the OIS.	For external beam therapy, limits on the variation of setup from planned values for couch position and gantry and collimator angles should be configured in the OIS.
h. Verbal time outs (universal protocol)	Review of universal protocol policy. Direct observation of time out. Review of verification documentation of time out.	Verification of correct patient and procedure (including daily treatment) shall be performed with two independent identifiers, including matching of patient identity to the plan selected on treatment device.
i. On-treatment imaging verification	Review of pretreatment imaging policies and a sample of approved images. Direct verification during treatment delivery.	Radiological imaging shall be sufficient for the technique (ACR 2019; Qi et al. 2023). Commissioning shall verify that the imaging protocols used are compatible with the precision and accuracy desired.
j. On-treatment and post-treatment chart review	Inspection of documentation by a qualified medical physicist. Interview with physicist.	Weekly on-treatment and final chart checks shall be performed as per professional guidelines and institutional policy (ACR 2020a).
k. <i>In vivo</i> patient dosimetry (measurement of dose during treatment delivery)	Availability of <i>in vivo</i> dosimetry; review of SOP for use of <i>in vivo</i> dosimetry; review of <i>in vivo</i> dosimetry reports.	<i>In vivo</i> dosimetry should be available upon physician's request.

TABLE 3—*Evaluation criteria for calibration and accreditation.*

Assessment	Method	Evaluation
a. Primary dosimetric equipment calibration traceable to a primary standards laboratory	Inspection of Accredited Dosimetry Calibration Laboratory (ADCL) calibration record and use of ADCL calibration coefficients in absolute calibration measurements.	Absolute dosimetry shall be based on the appropriate calibration coefficient (<i>e.g.</i> , Nath et al. 1997; Almond et al. 1999; IAEA 2017).
b. Initial and periodic independent check of dosimetric accuracy	Review the independent dosimetry reports. In the United States, several dosimetry laboratories provide dosimeter-by-mail services for common beam qualities.	The practice shall ensure periodic third-party verification of absolute dosimetry, either through a by-mail service or on-site measurement with separate dosimetry equipment by an independent qualified medical physicist.
c. Radiation therapy accreditation audit and review	Inspection of external accreditation audit and review report.	Practices should seek accreditation (Hendee and Herman 2011). It is required by some states and strongly encouraged when not required. The ACR, American College of Radiation Oncology, and ASTRO provide accreditation services.

TABLE 4—*Evaluation parameters for adequate staffing, support and environment.*

Assessment	Method	Evaluation
a. Physician, medical physicist, medical dosimetrist, and radiation therapist staffing level commensurate with professional guidance	Comparison of staff levels and patient load with ratios recommended by professional societies.	Staffing levels should comply with recommendations provided by ASTRO’s “Safety is No Accident,” the ACR Accreditation Guide, and the American College of Radiation Oncology accreditation guide. Staffing levels should be scaled for complexity, or the proportion of different pathologies treated at any given clinic (ASTRO 2019).
b. Routine presence of at least two therapists per therapy unit for all megavoltage external beam photon and electron procedures, and as appropriate for other modalities	Inspection of policies, staffing logs and direct observation.	For megavoltage external beam photon and electron procedures, two or more therapists should participate in treatment setup and delivery. For emergent clinical situations or unexpected absences, one therapist may administer treatments as a temporary measure, but such cases should be tracked. Appropriate staffing guidance should be sought for other modalities.
c. Radiation oncologist and physicist presence and availability before and during stereotactic radiosurgery and stereotactic body radiation therapy treatment	Inspection of policies and procedural notes or logs; direct observation of physician and medical physicist review of pre-treatment setup verification images and immediate availability during the procedure.	Secondary to any regulatory requirements, a radiation oncologist and medical physicist shall review pre-treatment setup verification images and provide immediate availability during the procedure (Halvorsen et al. 2017; ASTRO 2020; ACR 2021; Das et al. 2022).
d. Physician and physicist presence during high-dose rate brachytherapy procedures	Direct observation. Evidence of staff signatures on treatment documents.	Secondary to any regulatory requirements, a radiation oncologist and medical physicist shall provide immediate availability during the procedure (ACR 2020b).
e. Environment during treatment free of distractions such as noncritical calls, staff interruptions, conversations not related to treatment, cell phones, web browsing	Direct observation, query of staff, and review of policies.	All members of the care team directly involved in the procedure shall be empowered to mitigate any potential or real distractions, or interruptions, to promote a “sterile cockpit.”

TABLE 4 (continued)

Assessment	Method	Evaluation
f. Each professional present for treatment (radiation therapists and possibly physicist or physician) has assigned roles to support the necessary tasks for treatment	Direct observation in a clinical environment; review of SOP for physician and physicist participation in stereotactic radiosurgery, stereotactic body radiation therapy, and high dose procedures.	Staff roles during treatment delivery should be established to address crew resource management issues such that necessary tasks are not inadvertently neglected.
g. Physician retrospective peer review	Review of documentation for retrospective clinical practice review.	Periodic independent (intra-institution or cross-institution) retrospective review of randomly selected patient clinical and treatment records should occur at least annually and assess adequacy of work-up, documentation of disease, and appropriateness of treatment based on objective criteria.
h. Physicist peer review	Documentation of shared work or one physicist reviewing and signing off another's work. Review of external peer review report.	Solo physicists should arrange for an outside medical physicist to provide a written review (Halvorsen et al. 2005), while multi-physicist practices should ensure that cross-checks occur.
i. Continuing education and competency assessment	Records of training and competency assessments. Evidence of ongoing vendor-supplied training, in-service training, and workplace training.	Staff shall receive the necessary training before participating in any procedures that are new to the staff member. Ongoing clinical competency assessments may occur (Pavord et al. 2016). Training may include radiation safety, Occupational Safety and Health Administration training, and magnetic resonance imaging safety for applicable personnel.
j. Well-being	Review accessibility of psycho-social resources and employee awareness of these resources (query staff). Records of anonymized well-being self-assessments and responsive actions by management.	Psychosocial resources should be accessible to employees who should know how to access these resources. Proactive measures are important after an incident causing harm.

TABLE 5—*Review guidance for initial and ongoing equipment records.*

Assessment	Method	Evaluation
a. Radiation shielding calculation prior to any new or replacement device installation	Review of documentation.	The document shall designate its completion date and reference shielding design goals and regulatory dose limits (NCRP 2004, 2005).
b. Radiation shielding survey before first clinical use and, in the case of radiation sources, after installation of a new source or repairs that could compromise the radiation safety of the device.	Review of documentation.	The document shall list the measurement equipment, measurement location, results, and comparison against shielding design goals and regulatory limits (NCRP 2004, 2005).
c. Simulation system	Review of documentation, including image quality, spatial accuracy, and safety consideration both for computed tomography and additional magnetic resonance imaging or positron emission tomography capabilities.	Commissioning and QA should be compliant with AAPM (Mutic et al. 2003) or its successor. It should include both spatial resolution and computed tomography number assessments.
d. Acceptance testing for all treatment and planning devices (<i>e.g.</i> , simulator, linear accelerator, treatment planning system, brachytherapy units)	Review of documentation.	The signed copy of the vendor’s acceptance testing document should be retained. The signatory should be a qualified medical physicist.
e. Treatment machine commissioning demonstrating customization for clinical use	Review of documentation.	The treatment machine commissioning report should meet applicable professional recommendations (<i>e.g.</i> , Das et al. 2008).
f. Treatment planning system	Review of documentation.	The initial commissioning of the treatment planning system report and documentation of annual testing shall be available (Geurts et al. 2022). The commissioning and QA reports shall include custom computed tomography number conversion for use in dose calculations.
g. Hardware and software post-upgrade testing reports and clinical release notes	Review of documentation.	The documentation of testing should be commensurate with the nature of the upgrade.

TABLE 5 (continued)

Assessment	Method	Evaluation
h. End-to-end testing	Review commissioning report.	Testing should use phantom-based studies from simulation through treatment planning to delivery with verification measurements. Special attention should be given to testing consistent data interpretation between systems, such as the coordinate system used (Siochi et al. 2021).
i. Log of machine faults, issues, and service	Review log of machine faults and issues, service records, and preventive maintenance records.	The physics staff should maintain and review therapy machine user logs so that problems do not unnecessarily persist.
j. Ongoing QA records (to be retained for at least three years or in accordance with applicable regulations)	Review of documentation (radiation therapy delivery equipment, treatment planning systems, ancillary hardware and software systems).	QA shall demonstrate compliance with the appropriate AAPM MPPG or task group report (Mutic et al 2003; Smith et al. 2017; Geurts et al. 2022). Variations from the applicable professional recommendations and regulations may be justified but should be explainable. Periodic QA shall result in adjustments or repairs when repeatedly outside the tolerance limits, be available for audits, and include analytics such as trending analyses of key parameters.

notices, preferably accessible from the software used by clinical staff. Software and hardware systems *should* adhere to norms for effective machine-user interfaces so that the mental burden of using the software or hardware is reasonable. Besides adherence to U.S. Food and Drug Administration requirements, manufacturers of radiation therapy devices *should* comply with recommendations promulgated by advisory and standards organizations including Integrating the Healthcare Enterprise - Radiation Oncology, the International Electrotechnical Commission, and the International Standards Organization. Furthermore, widescale incident learning systems (*e.g.*, RO-ILS and SAFRON) provide reports on frequent error pathways that may lead vendors to design safer products.

Conclusions

This statement provides recommendations on the assessment of key elements of a program of safety, quality, and reliability in radiation therapy practices. The recommendations are based on input solicited during a stakeholder meeting of radiation therapy professionals and on previously published recommendations. Broadly, the listed quality indicators are intended to facilitate a variety of assessments of clinical practices in these areas, *e.g.*, for external accreditation audits and internal reviews. Specific recommendations include indicators of safety, quality, and reliability, grouped by program development area, namely, department culture, communication, and oversight; safety barriers; external calibration and validation; adequate staffing, support, and environment; and equipment records. For each indicator, corresponding example methods of assessment and elaborating comments are provided. Additionally, the Statement provides explanations of key concepts and definitions of terms.

Abbreviations

ADCL	Accredited Dosimetry Calibration Laboratory
MPPG	Medical Physics Practice Guideline
OIS	Oncology Information System
QA	quality assurance
RO-ILS	Radiation Oncology - Incident Learning System (American Society for Radiation Oncology and American Association of Physicists in Medicine sponsored)
SAFRON	Safety in Radiation Oncology (International Atomic Energy Agency sponsored incident learning system)
SOP	standard operating procedure

Glossary of Terminology

audit: A review of a radiotherapy program “to assess the whole process, including aspects such as organization, infrastructure, and clinical and medical physics components,” or a subset thereof (IAEA 2022).

chart rounds: A physician-led weekly meeting of radiation oncology professionals to provide ongoing peer review of patients prior to or just beginning radiation treatment.

checklist: A short list of reminders to ensure that no steps are omitted in a specific process.

clinical linear accelerator (linac): A radiation therapy device that uses a compact linear accelerator mounted on a ring or an arm that can be rotated around the patient to provide a uniform distance from the beam source to the isocenter location.

clinical release note: Vendor-supplied documentation about the features and limitations of the associated software or hardware.

crew resource management: A framework of goals and tools (including communications, situational awareness, problem-solving, decision making, and teamwork) to optimize staff performance by reducing the effect of human errors.

- event:** An incident that occurs during the process of providing health care that results in or potentially results in a suboptimal clinical outcome.
- failure mode and effects analysis:** A prospective process design tool in which process maps are created to identify potential failure modes, which are then prioritized by assessing likelihood, potential severity, and difficulty in detection.
- fault tree analysis:** A prospective process design tool in which a logic diagram is used to determine the sets of conditions under which a fault mode would occur.
- high-dose rate brachytherapy:** Treatment using brief insertion of a radioactive source from a remote-afterloader device.
- incident:** An unwanted or unexpected change from a normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment (Ford et al. 2012).
- incident learning system:** A system for recording medical events and close calls at one or multiple institutions and identifying opportunities for process improvement for quality and safety.
- initial chart review:** Under the guidance of a Qualified Medical Physicist, an assessment of the clinical suitability of the radiation oncology prescription, contours, treatment plan, secondary monitor unit calculation, and oncology information system information.
- interoperability:** The capability of two or more pieces of medical equipment to safely and effectively communicate, minimizing the need for data re-entry and subsequent opportunities for error.
- just culture:** A workplace environment that promotes equity and fairness while holding individuals accountable for reckless behavior, but not for system failing or error-prone processes outside their control.
- medical event:** An improper administration of radiation or radioactive material to a patient or human research subject that requires reporting to the appropriate regulatory authority.
- oncology information system (OIS):** An electronic patient record system specialized for oncological treatments.
- on-treatment:** Pertaining to the period between the beginning of a course of treatment and the end of the last treatment session.
- peer:** A person with the same professional qualification, as signified by board certification in radiation therapy or therapeutic medical physics.
- peer review:** The evaluation of work by other people in the same field to enhance quality. Radiation therapy peer review may also be in a multidisciplinary context (Marks et al. 2013).
- process mapping:** A prospective process design tool in which all the steps in a process are sequentially laid out, including branches and return loops.
- quality (in healthcare):** The ability of a process to achieve the desired outcome.
- reliability:** The ability of a process to be completed without failure.
- root cause analysis:** A methodology to identify administrative, clinical, or technical causes of patient errors or mismanagement.
- safety (in healthcare):** The prevention of harm to patients.
- safety barrier:** A process step that serves as a tool to prevent errors. Safety barrier must fulfill the following six criteria: 1) clear ownership, 2) traceability to policies and procedures, 3) auditability, 4) specificity to which threats it is designed to protect against, 5) independence (does not rely on other checks to be effective), and 6) effectiveness (as a record of actual audits) (Mullins et al. 2019).
- safety culture:** The attitudes and beliefs of staff with regard to addressing potentially unsafe conditions, reporting errors and near misses without fear of punishment to the reporter or staff member in question, and mutual trust between staff and management with regard to the importance of safety.
- sterile cockpit:** A human factors concept from the aviation industry in which staff members refrain from nonessential activities during critical phases of operation. Corollary to this, the environment is maintained free of distractions and interruptions.
- time out:** A systematic procedure for confirming patient identification, procedure, and treatment site prior to simulation or treatment.
- tolerance table:** An oncology information system feature that allows values to be assigned to field setups to ensure that the treatment couch, gantry, and collimator are all suitably close to their planned positions.

weekly chart check: A review of treatment documentation by a medical physicist to ensure that ongoing treatment continues to match the physician's intent, including prescription parameters such as bolus use, therapists' machine overrides, and accumulated dose.

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Acknowledgments

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The Committee wishes to thank the following for their participation in our stakeholder's meeting on January 8, 2022: Joseph Brock (American Association of Medical Dosimetrists); Lisa Bruedigan (Conference of Radiation Control Program Directors); Britt Buchner (Radiation Oncology Safety Stakeholders Initiative); Jennifer Elee (Conference of Radiation Control Program Directors); Lynne Fairbent (U.S. Food and Drug Administration); Patrick-John Hann (U.S. Nuclear Regulatory Commission); Steven Hardy (American Society of Radiologic Technologists); Grace Kim (American Association of Physicists in Medicine); Stephen Kry (University of Texas MD Anderson Cancer Center; nominated by NRG Oncology leadership); Michael Martin (Health Physics Society); Jeff Michalski (American Society for Radiation Oncology); Firas Mortada (American Brachytherapy Society); Matthew Pacella (American College of Radiology); James Welsh (American College of Radiation Oncology); and Jean Wright (ASTRO Accreditation Program for Excellence).

The Council wishes to express its appreciation to the Committee members for the time and effort devoted to the preparation of this Statement.

NCRP gratefully acknowledges financial support provided by U.S. Food and Drug Administration (PO# 75F40121P00583), the American Board of Radiology Foundation (ABRF) and the Conference of Radiation Control Program Directors (CRCPD). The contents of this Report are the sole responsibility of NCRP and do not necessarily represent the views of FDA, ABRF, or CRCPD.

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