NCRP DRAFT STATEMENT No. XX

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

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Executive Summary

This Statement provides recommendations for internal and external audits of radiation therapy practices with respect to safety, quality, and reliability. Safe and accurate patient treatments with radiation are achieved by a complex process of prescribing, planning, and delivering treatments; this requires considerable quality assurance and strategically placed safety barriers to ensure safety and high-quality.

An external audit may confirm a radiation oncology practice's rigorous commitment to safe radiation therapy. It may also reveal areas for improvement with respect to patient and staff safety, quality, and system reliability. The five tables in this Statement present essential safety, quality, and reliability indicators grouped by program development areas, i.e., safety barriers; external calibration and validation; adequate staffing, support, and environment; and equipment records, with 44 indicators.

In addition to external audits, the Statement may help guide radiotherapy practices in performing internal audits. The recommendations in the Statement were designed to accommodate both external beam and brachytherapy procedures independent of the practice environment (private, academic, and non-academic hospital-based) or practice size. Radiotherapy with unsealed sources is not addressed in this Statement.

Introduction

This Statement provides normative guidance on assessing the presence of essential indicators of the safety of patients and staff, and the quality and reliability of treatment[1] within a radiation therapy practice. It is meant to complement the extensive literature of the past twenty-five years that has delineated the critical characteristics of safety-focused radiation therapy (e.g., ASTRO 2019, Donaldson 2007, Marks 2015, World Health Organization 2008). Particular attention is given to process indicators that ensure quality and reliability of treatment and the safety of patients and staff.

A comprehensive assessment of safety in radiation therapy should extend beyond an assessment of patient care. Therefore, this Statement considers the related but broader aim of delineating indicators that support safe operations and processes. For example, relevant systems that impact safety include the electronic health record (EHR), oncology information systems (OIS), treatment simulation systems, treatment planning systems (TPS), and radiation delivery systems (AAPM TG 201). Quality assurance (QA) must be performed for additional systems (such as patient set-up verification systems) and test equipment (such as dose measurement systems for establishing machine output). 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 safe, high quality, and reliable clinical practices.[2]

Considerable progress has been made in recent years to increase the safety, quality, and reliability of radiation therapy. This Statement has been designed to facilitate external assessments of radiation therapy practices for safety, quality, and reliability. Moreover, this Statement can also help guide internal periodic reviews and quality management.

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

[2] Three terms used in the Statement have special meaning as indicated using ***bold italics***:

- ***shall*** and ***shall not*** are used to indicate that adherence to the recommendation is considered necessary to meet accepted standards of protections;
- ***should*** and ***should not*** are used to indicate a prudent practice to which exceptions may occasionally be made in appropriate circumstances; and
- ***may*** or ***may not*** indicate 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 oncology (AAPM 2016, ASTRO 2019, Ford et al. 2015, WHO 2008).

Specifically for medical physics, there has been an emphasis on prospective tools, human factors engineering, and retrospective tools to assess technical processes of relevance to safety. Prospective risk-analysis tools include failure mode and effects analysis (FMEA) and fault tree analysis (FTA), among several other approaches and tools, which may enable one to identify the most serious error types and precipitating steps within a process. In one common approach, a practice starts by prospectively analyzing one process and building from there. These tools go beyond the established test activities that commonly precede human use such as acceptance testing, commissioning, and end-to-end testing. 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 tools and processes include: training, such as in crew resource management and safety and just culture; checklists; effective communication; 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 oncology settings, including standardized naming conventions (AAPM TG 263) and the many safety barriers (see Glossary) employed in radiation therapy: plan second check; weekly chart checks; time outs; checklists (as noted above); per-patient, pre-treatment dosimetric verification; and automated calculation check programs, to name a few.

Retrospective analyses of events allow the development of modified workflows to prevent falling into error pathways or out-of-tolerance situations. Example approaches include monitoring trends in device QA data, causal analyses following incidents and close calls (e.g., Root Cause Analyses), responsive mechanisms to address staff concerns, peer review, the use of an incident-learning system, and internal and external audits.

A quality-improvement committee ***should*** oversee the implementation of quality and safety processes (ACR 2018). 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 (MPPG) for various clinical contexts. These documents are typically distilled 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, American Society for Radiation Oncology (ASTRO) practice guidelines, and American College of Radiation Oncology (ACRO) guidelines. The American Society of Radiologic Technologists and American Association of Medical Dosimetrists also have posted documents that provide practice guidance (ASRT 2019, ASRT 2022, AAMD 2022).

Development and Structure of the Audit Tool

The Committee drafted a series of tables delineating essential safety, quality, and reliability indicators for radiation oncology practices. The content of these tables was discussed in a full-day virtual meeting with stakeholders (listed in the Acknowledgements) from national societies and advisory and standards organizations. Based upon stakeholder feedback, these tables were edited for the final draft of this Statement. Through a series of video-conferences and email exchanges, the Committee arrived at a consensus for each of the items listed in the tables of this Statement.

The audit tool consists of five tables covering broad areas of quality and safety in radiation oncology practice. It was developed by a group of subject matter experts drawing on the guidance of representatives from the regulatory, accreditation, scientific, and professional communities. This guidance was collected during a full-day Stakeholder meeting. To minimize siloed perspectives on the audit criteria, pairs of members from the development team facilitated parallel breakout session discussions of the Tables, each with three or four of the stakeholder representatives. Efforts were made to ensure that the groups considered prospective, on-treatment, 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 reviewed by the development team until a consensus was reached. Further revisions were made based on the recommendations of NCRP reviewers and community subject matter experts during the review process.

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; the use of an Accredited Dosimetry Calibration Laboratory (ADCL) to determine calibration coefficients traceable to the National Institute of Standards and Technology (NIST) for equipment used in the absolute dosimetry calibration of radiation therapy treatment devices; independent external confirmation of treatment device calibration; 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 quality assurance.

Patient and caregiver involvement during treatment is an essential component of quality healthcare. A focus on patients and caregivers is evidenced through the presence of assessable 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.

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

Assessment	*Method of Assessment*	*Comment*
a. Safety and just culture	Interviews with clinical team members; review of policy documents, if available.	Examples: All physicians, staff, and trainees feel free to raise questions and to pause a procedure at any time. Non-punitive policies encourage reporting events and issues related to safety, quality, and reliability. NRC includes nine items in their definition of Safety Culture (USNRC 2011).
b. Quality Improvement (QI) Committee* (ACR 2018)	Review of policies, procedures and internal audits from committee. Minutes (including attendance) from meetings during which QI issues are addressed.	The Committee ***shall*** include at least one physician, nurse, radiation therapist, dosimetrist and physicist. Meetings ***shall*** be conducted at least quarterly. A radiation safety officer or member of the radiation safety committee ***should*** attend. *Alternate names include "Quality Committee" and "Quality Assurance Committee" among other possibilities.
c. Existing processes follow standard operating procedures (SOPs)	Review of the collections of SOPs.	Each SOP ***should*** identify the person(s) (by position) responsible for each step in a process, provide a guide to the steps in the process and state what information needs to be communicated to whom. Checklists can help users follow procedures.
d. Effective communications,	Timely clinical notes; mechanisms to export and import medical data, access to	Communication expectations throughout the facility ***should*** be established by coordination of all practice stakeholders.

including handoffs	prior radiation records, review of communications protocols,	Initial consultation notes, follow-up notes and treatment summaries (that include prescribed and delivered dose, treatment tolerance, 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; the opportunity and culture of openness to ask questions of all staff; compliance with informed consent requirements.	
f. Adequate resources	Staffing, equipment, and instrumentation satisfy recommendations from professional organizations.	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, e.g., the report of AAPM TG 100.
h. Incident learning	Review of the internal incident submission record and corrective actions.	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 patient harm and	Review of causal-analysis reports, if performed, and follow up.	When the analysis and corrective actions cannot be implemented immediately, review evidence that intermediate actions are in place.

high risk near misses		
j. Reporting of medical events to regulatory bodies	Review of policies for reporting medical events and of reports submitted.	The policy for reporting medical events ***should*** include who is to be contacted (with contact information) in the department and who has the responsibility to contact the RSO.

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, Items a, b, c, h, i, and j; 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, TPS, and treatment delivery machines ***should*** allow electronic documentation of physician and medical physicist review of key process steps as well as their presence, when required, during a procedure. Similarly, 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 (see Acknowledgements) from national societies and advisory and standards organizations revealed a need for wider access to, and awareness of, safety notices and software release 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 FDA requirements, manufacturers of radiation therapy devices ***should*** comply with recommendations promulgated by advisory and standards organizations including Integrating the Healthcare Enterprise - Radiation Oncology (IHE-RO), the International Electrotechnical Commission (IEC), and the International Standards Organization (ISO). 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.

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

Assessment	*Method of Assessment*	*Comment*
a. Sufficient time and appropriate environment for treatment planning (including contouring of targets and organs at risk), physician plan review, physics checks, quality assurance, and therapists' checks	Review of SOPs (if available).	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 ***should*** have adequate time to review the plan after physics review. When resources allow, 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 (e.g., 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 dosimetry and physics team for conventional, hypofractionated, and SRS treatments, and dosimetry ***should*** be assessed to ascertain

		adherence to this intent. Reference normal tissue dosimetric constraints ***should*** be available for guidance. (Wright 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 (1) validate that the monitor units generated by the TPS are appropriate (e.g., following AAPM TGs 114 and 219 as appropriate) for external beam radiation and (2) assess the correctness of the planned dose delivery for brachytherapy (AAPM TG 56).
e. Patient-specific delivery verification for IMRT and other complex plans	Review of QA records in patient charts.	Consistency with AAPM guidance on QA of IMRT and other treatment situations.
f. Treatment plan physics evaluation	Review of planning document (electronically) signed by a qualified medical physicist (or equivalent) indicating review and approval.	Essential components of initial chart review: clinical suitability of the radiation oncology prescription, contours, treatment plan, secondary MU calculation, and OIS information. (AAPM TG 275, AAPM MPPG 11).
g. Use of set-up tolerance tables or equivalent	Direct inspection of values contained in the OIS.	Limits on the variation of setup from planned values for couch position and gantry and collimator angles.

h. Verbal time outs (Universal Protocol)	Review of Universal Protocol policy. Direct observation of time out. Review of documentation.	Verification of correct patient and procedure (including daily treatment) ***shall*** be performed with two independent identifiers, including matching of patient identity to plan selected on treatment device.
i. On-treatment imaging verification	Review of pre-treatment imaging policies and a sample of approved images. Direct verification during treatment delivery.	Radiological imaging ***shall*** be sufficient for the technique (ACR 2019). 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.	On-treatment and final chart checks ***shall*** be performed as per professional guidelines and institutional policy.
k. *In vivo* patient dosimetry	Availability of *in vivo* dosimetry; review of SOP for use of *in vivo* dosimetry; review of *in vivo* dosimetry reports.	*In vivo* dosimetry ***should*** be available upon physician's request.

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

Assessment	*Method of Assessment*	*Comment*
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 (e.g., AAPM TG 51, IAEA TRS 483, AAPM TG 56).
b. Initial and periodic independent check of dosimetric accuracy	Review report. In the US, services are provided by the Imaging and Radiation Oncology Core (IROC), the MD Anderson Radiation Dosimetry Services (RDS), and the University of Wisconsin for common beam qualities.	Requirements for dosimetry verification assessment and frequencies can be found in regulatory rules and professional society recommendations,
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, ACRO, and ASTRO provide accreditation services.

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

Assessment	*Method of Assessment*	*Comment*
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 **shall** comply with minimum recommendations provided by ASTRO's "Safety is No Accident," the ACR Accreditation Guide, and the ACRO 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 procedures	Inspection of policies, staffing logs and direct observation.	Two or more therapists ***should*** participate in treatment setup and delivery, although for emergent clinical situations or unexpected absences, one therapist ***may*** administer treatments as a temporary measure.
c. Radiation oncologist and physicist presence and availability before and during SRS and SBRT treatment	Inspection of policies and procedural notes or logs; direct observation.	The level of presence and supervision (i.e., present at the treatment console vs. readily available within close proximity) ***shall*** follow regulatory (e.g., NRC) requirements and at a minimum ***shall*** involve

		physician presence prior to treatment to verify patient set-up and physicist presence prior to the first fraction (Das 2022, ACR 2021, ASTRO 2020).
d. Physician and physicist presence during HDR brachytherapy procedures	Direct observation. Evidence of staff signatures on treatment documents.	Physician and physicist presence ***shall*** be in accordance with regulatory (e.g., NRC) requirements. (ACR 2020b)
e. Environment free of distractions such as non-critical calls, staff interruptions, conversations not related to treatment, cell phones, web browsing during treatment	Direct observation and query of staff and review of policies.	Radiation therapists ***shall*** be empowered to mitigate any potential or real distractions, or interruptions, to promote a 'sterile cockpit.'
f. Each professional present for treatment (radiation therapists and possibly physicist and physician) has assigned roles to support the necessary tasks for treatment	Direct observation in a clinical or simulated environment.	Addresses crew resource management 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, assessing for

		adequacy of work-up and 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 (AAPM TG 103), while multi-physicist departments ***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 as appropriate, which ***may*** include radiation safety, Occupational Safety and Health Administration (OSHA) training, and magnetic resonance imaging (MRI) safety for applicable personnel.	Procedures requiring a level of training that exceeds that of any staff ***shall*** require the necessary training. Ongoing clinical competency assessments ***may*** occur (Pavord et al. 2016).
j. Well-being	Review accessibility of psycho-social resources and employee awareness of these resources (query staff). Records of anonymized well-being self-assessments.	Psychosocial resources ***should*** be accessible to employees who ***should*** know how to access these resources. Proactive measures

		are important after an incident causing harm.

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

Assessment	*Method of Assessment*	*Comment*
a. Radiation shielding calculation prior to any new or replacement device installation	Review of documentation.	The document ***should*** designate its completion date and reference shielding design goals and regulatory dose limits [NCRP 151, NCRP 147, NCRP 149].
b. Radiation shielding survey before first clinical use	Review of documentation.	The document ***shall*** list the measurement equipment, measurement location, results, and comparison against shielding design goals and regulatory limits [NCRP 151, NCRP 147].
c. Simulation system	Review of documentation.	Commissioning and QA ***should*** be compliant with AAPM TG 66 or its successor. It ***should*** include both spatial resolution and CT number assessments.
d. Acceptance testing for all treatment and planning devices (e.g. simulator, linear accelerator, TPS, 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 (e.g.

		AAPM TG 106) and regulations.
f. Treatment planning system	Review of documentation.	The initial commissioning of the treatment planning system report and documentation of annual testing ***shall*** be available [AAPM MPPG 5]. The commissioning and QA reports ***shall*** include custom CT 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.
h. End-to-end testing	Review commissioning report.	This reports phantom-based studies from simulation through treatment planning to delivery with verification measurements. Special attention ***should*** be given to testing expected communication between medical devices [AAPM TG-201].
i. Log of machine faults, issues, and service	Review of documentation.	The physics staff ***should*** maintain and review therapy machine user logs so that

		problems do not unnecessarily persist.
j. Ongoing quality assurance records (to be retained for at least three years or in accordance with applicable regulations)	Review of documentation (RT delivery equipment, treatment planning systems, ancillary hardware and software systems). Variations from the applicable professional recommendations and regulations may be justified, but should be explainable.	QA ***shall*** demonstrate compliance with the appropriate AAPM MPPG or TG report [AAPM MPPG 5, AAPM MPPG 8, AAPM TG- 66]. Periodic QA results ***shall*** be regularly reviewed, specify if results were acceptable or any remediation if applicable, be available for audits, and include analytics such as trending analysis of key parameters.

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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 the consensus of the Committee, a review of previously published recommendations, and the experience of the authors. Broadly, the recommendations are intended to facilitate a variety of assessments of clinical practices in these areas, e.g., for external accreditation audits and internal reviews. These recommendations are applicable to a wide variety of practice sizes and types that utilize medical accelerators and sealed isotopic sources (programs for unsealed sources are outside the scope of this statement). Specific recommendations include indicators of safety, quality, and reliability, grouped by program development area, namely, 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. In addition, key concepts are explained, and terms are defined.

Abbreviations

AAPM: American Association of Physicists in Medicine
ACR: American College of Radiology
ACRO: American College of Radiation Oncology
ADCL: Accredited Dosimetry Calibration Laboratory
ASTRO: American Society for Radiation Oncology
CBCT: Cone beam computed tomography
FMEA: Failure modes and effects analysis
FTA: Fault tree analysis
IGRT: Image guided radiation therapy
IMRT: Intensity modulated radiation therapy
IROC: Imaging and Radiation Oncology Core - Houston Quality Assurance Center
OIS: Oncology Information System
OSLD: Optically stimulated luminescent detector
QI: Quality improvement
RO-ILS: Radiation Oncology – Incident Learning System (ASTRO and AAPM sponsored)
SAFRON: Safety in Radiation Oncology (IAEA Sponsored incident learning system)
SBRT: Stereotactic body radiation therapy
SRS: Stereotactic radiosurgery
TPS: Treatment planning system

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 2007).

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: Each person in the control room has assigned tasks. For example, if three therapists are working, one may be responsible for delivery and audiovisual monitoring, another therapist responsible for field shape monitoring and audiovisual monitoring, and a third responsible for documentation and queuing.

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 (FMEA): 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 (FTA): 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 (HDR) 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 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 MU calculation, and OIS 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 holds 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: 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 oncology 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: Prospective process design tool in which all the steps in a process are sequentially laid out, including branches and return loops.

Root cause analysis: Methodology to identify administrative, clinical, or technical causes of patient errors or mismanagement.

Safety barrier: An added 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 relay on other checks to be effective), and 6) effectiveness (as a record of actual audits) (Mullins et al. 2019). Per this statement, we aspire for all suggested safety indicators to achieve the level of safety barrier per the above definition.

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 refrains from non-essential 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 and treatment site prior to simulation or treatment.

Tolerance table: An OIS 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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