Strategies for effective physics plan and chart review in radiation therapy: Report of AAPM Task Group 275

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Background: While the review of radiotherapy treatment plans and charts by a medical physicist is a key component of safe, high-quality care, very few specific recommendations currently exist for this task.
Aims: The goal of TG-275 is to provide practical, evidence-based recommendations on physics plan and chart review for radiation therapy. While this report is aimed mainly at medical physicists, others may benefit including dosimetrists, radiation therapists, physicians and other professionals interested in quality management.
Methods: The scope of the report includes photon/electron external beam radiotherapy (EBRT), proton radiotherapy, as well as high-dose rate (HDR) brachytherapy for gynecological applications (currently the highest volume brachytherapy service in most practices). The following review time points are considered: initial review prior to treatment, weekly review, and end-of-treatment review. The Task Group takes a risk-informed approach to developing recommendations. A failure mode and effects analysis was performed to determine the highest-risk aspects of each process. In the case of photon/electron EBRT, a survey of all American Association of Physicists in Medicine (AAPM) members was also conducted to determine current practices. A draft of this report was provided to the full AAPM membership for comment through a 3-week open-comment period, and the report was revised in response to these comments.

Results: The highest-risk failure modes included 112 failure modes in photon/electron EBRT initial review, 55 in weekly and end-of-treatment review, 24 for initial review specific to proton therapy, and 48 in HDR brachytherapy. A 103-question survey on current practices was released to all AAPM members who self-reported as working in the radiation oncology field. The response rate was 33%. The survey data and risk data were used to inform recommendations.
Discussion: Tables of recommended checks are presented and recommendations for best practice are discussed. Suggestions to software vendors are also provided.
Conclusions: TG-275 provides specific recommendations for physics plan and chart review which should enhance the safety and quality of care for patients receiving radiation treatments. [https://doi.org/10.1002/mp.14030]

Key words: plan review, quality assurance, TG275

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1. INTRODUCTION

The review of radiotherapy treatment plans and charts by a qualified medical physicist is a key component to ensuring safe, high-quality care. This is potentially one of the most effective safety barriers for identifying errors and quality gaps.[1] It is called for in numerous society-level recommendations [e.g., American Association of Physicists in Medicine (AAPM) TG-40,[2] ACR-ASTRO Guidelines[3]]. It is also a reimbursable activity in many healthcare systems in the United States. Physics plan and chart reviews rely heavily on human inspection and there is some evidence of gaps in performance. A study by Gopan et al.[4] suggested that only 38% of errors that were potentially detectable on physics plan and chart review were actually identified in the review procedure. Similarly, a 2018 study of RO-ILS data from Ezzell et al.[5] identified three common error pathways, and showed that 25% to 37% of errors passed through normal checks. Some of this may be driven by workload stressors. Using a workload indicator developed by NASA, Mazur et al.[6] found that medical physicists have the highest workload indicators among all the professional groups in radiation oncology.

Based on the above considerations, plan and chart review is a critical safety step and a key part of the medical physicist's professional duties. There is, however, very little literature or guidance on the topic. The most relevant AAPM report, TG-40,[2] dates to 1994 and workflow and technology have changed in the years since. The goal of TG-275, therefore, is to provide practical, evidence-based recommendations on physics plan and chart review and thereby enhance the safety and quality of care for patients receiving radiation treatments.

In developing these recommendations for physics plan and chart review the Task Group has taken a risk-informed approach, namely, analyzing the potential risks in the process of care for the development of recommendations. This risk-based approach is supported by AAPM TG-100.[7] As a result, this report differs from most previous Task Group reports which have relied solely on consensus opinion to develop recommendations. A draft of this report was provided to the full AAPM membership for comment through a 2-week open-comment period, and the report was revised in response to these comments.

1.A. Charges of the Task Group

Charges of the Task Group were as follows:

1. Review existing data and recommendations that support the use of physics plan and chart review and to review the current recommendations on the qualifications for performing these.

2. Provide survey information on current practices in the community with respect to physics plan and chart review.
3. Provide risk-based recommendations for the effective use of the following physics reviews: initial plan and chart check, weekly chart check, and end-of-treatment chart check.
4. Provide recommendations to software vendors for systems design and operations that best facilitate physics plan and chart review.

This Task Group considers external beam radiotherapy (EBRT) with photons and electrons, and also proton radiotherapy. External beam radiotherapy encompasses all dose fractionation regimens and common treatment delivery methods including three-dimensional conformal radiation therapy (3DCRT), electron beams, proton beams, intensity modulated radiation therapy (IMRT), volumetric modulated arc therapy (VMAT), image-guided radiation therapy (IGRT), stereotactic radiosurgery (SRS), and stereotactic body radiation therapy (SBRT). The Task Group also considered brachytherapy but limits recommendations to HDR gynecological applications, which currently is the highest volume service in most practices. The report includes physics plan and chart review at three time points: initial, weekly, and end-of-treatment review. This report extends TG-40 Section 6 parts B and C (which apply to physics plan and chart review) similar to the way in which other sections of TG-40 have been refined and extended (Section 2 by TG-142,[8] Section 3 by TG-53,[9] and Section 5 by TG-59[10]).

This report is intended mainly for medical physicists in clinical practice or training. The report may also be useful for dosimetrists, radiation therapists, physicians and other professionals who are involved in the review of plans and charts, as well as those interested in quality management.

Disclaimer: The recommendations of this task group should not be used to establish regulations. These recommendations are guidelines for qualified medical physicists (QMPs) and others to use and appropriately interpret for their individual institution and clinical setting. Each institution may have site-specific or state-mandated needs and requirements which may modify their usage of these recommendations.

2. BACKGROUND

2.A. Physics plan and chart review: Definition of terms

Physics plan and chart review is defined as the review of a specific patient's radiotherapy treatment plan and patient chart by a QMP [as defined by AAPM Professional Policy 1-J] or, where appropriate, their designee, to help ensure safe, high-quality treatment.

There are many aspects to physics plan/chart review as outlined in this report. Examples of factors that are reviewed include technical parameters (e.g., data transfer integrity), accuracy of calculations, image guidance requests and their consistency with department procedure and best practices, plan quality, and proper consideration of technically related clinical factors. Some aspects of plan/chart review clearly lie outside the purview of the medical physicist. Examples include clinicians' consideration of the utilization of other treatment modalities (e.g., chemotherapy, surgery) and the review of diagnosis or pathology. Such items are either beyond the scope of medical physics and/or are not possible to review at the time of plan/chart review. These are highlighted in this report as they appear.

This report considers three aspects of physics plan/chart review: (a) initial review, that is, prior to the start of a patient's treatment, (b) weekly review during the course of treatment, and (c) end-of-treatment review performed upon completion of the treatment course. While the charges of this Task Group focus narrowly on the plan and chart review process, there are opportunities to improve quality assurance (QA) processes throughout the treatment planning process and these are highlighted and discussed at various points in this report. This forms one of the key recommendations of this report (Section 7): "Practices should work to incorporate physics reviews as early in the workflow as possible and not rely solely on review at the end of treatment planning".

This report makes reference to the "oncology information system" (OIS) which is a general term that includes the treatment management system, parts of the treatment delivery system (i.e., record & verify system), and the oncology-specific electronic medical record (EMR). The latter includes both radiation oncology (RO)-specific systems (e.g., Aria or Mosaiq) and also enterprise-wide systems (e.g., EPIC or Cerner). This terminology is consistent with that outlined by the AAPM Work Group on Information Technology.[11]

2.B. Data on physics plan/chart review

The physics plan/chart review is an important responsibility of the therapeutic medical physicist and is routinely performed in the clinical setting. In the U.S., there are related reimbursement charges, especially Current Procedural Terminology (CPT) Code 77336, which is one of only two CPT codes dedicated to medical physics work. This code is intended to cover all medical physics related work and often conveniently distributed on each weekly chart check time. Since the publication of the chart check guidelines provided in TG-40[2] in 1994, the field of radiation oncology has undergone a technological revolution that has resulted in vastly more complex treatments, increased variation between practices, and unique combinations of vendor solutions. These factors make for more, and varied, potential error pathways in the process of care.

The literature indicates that the majority of errors originate in the pretreatment process.[12,13] In one study, the authors analyzed 2506 incident reports in a large academic center spanning a 5-year period and found that more than half of the reported clinical incidents originated in the treatment preparation process.[12] Novak et al.[13] identified incident origination

and detection process steps for near-miss incidents. They found that origin point for near-miss incidents was most frequently (33%) in the treatment planning process and that errors with the highest risk index originated during the imaging and simulation process. Additionally, The Quarterly Report Q4 2016 from the Radiation Oncology Incident Learning System™ (RO-ILS) indicated that, of the 2681 incidents comprising the historical aggregate sum in that database, treatment planning was the most commonly identified process step where events occurred, which is consistent with other reports.[14] Since the largest number of errors appear to occur during the planning and other pretreatment processes, there is a need to improve the quality management processes that occur at this point in the workflow or before, that is, at or before the end-of-treatment planning and before patient treatment. There may also be opportunities to improve QA processes throughout the treatment planning process. One example might be a formal physics review of critical data prior to the start of treatment planning.

While physics checks appear to be among the most effective quality control (QC) checks, the sensitivity of detecting errors during physics checks has been shown to range from 38 to 75%.[1,4,5] Ford et al.[1] studied the effectiveness of 15 different QC tools for detecting high potential severity incidents identified from two incident learning systems. They found that the initial physics plan checks and the weekly physics checks were the first and second most effective QC checks respectively. Although these checks were effective relative to other QC checks, the sensitivity of the initial physics check was calculated to be only 62% and the sensitivity of the weekly check was calculated to be approximately 43%. Gopan et al.[4] analyzed 3 years of potentially severe near-miss events collected in an institutional incident learning system. One hundred and twenty-five incidents were identified that were potentially detectable by physics plan review but out of these 125 incidents, only 47(38%) were actually detected by the review. A 2018 study of RO-ILS data from Ezzell et al.[5] identified three common error pathways. Two of these were error types that originated prior to initial physics plan and chart review. Of these 25% and 37% of errors passed through all the normal checks, that is, physics and other checks. In most of these cases there were already checks in place to identify problems but they were not identified prior to the physics plan/chart review. Taken together, the results of these studies indicate a need to improve plan/chart review processes. Improvements are needed not only in the content of what is checked but also in the implementation of these checks to improve performance through various methods including standardization and automation.

Since physics plan checks are an important QC step between the planning process and patient treatment, efforts to strengthen their effectiveness is justified. The purpose of TG-275 is to provide guidance to the medical physics community that will increase the effectiveness of the physics plan/chart review process using the risk assessment framework provided by TG-100.[7]

2.C. Summary of society-level recommendations

In 1994, the AAPM Task Group 40 published comprehensive quality assurance (QA) for radiation oncology.[2] The report recommends that each institution should develop their own quality schedule and procedures for chart review and peer review activities; in addition, it provides details on the types of reviews to conduct and the chart components to be verified, including such items as patient identification data, approved prescription, planning documentation, and treatment field parameters.

TG-40 recommends a medical physicist to complete a review of initial plan calculations with the goal of identifying discrepancies in monitor unit (MU) calculations and to resolve any differences that are five percent or greater. The initial plan review should be completed prior to the third fraction or ten percent of the dose delivered, whichever comes first. Weekly chart reviews and end-of-treatment reviews are recommended. The weekly chart review process should include a comparison of treated fields against planned fields to detect discrepancies and to determine if any new fields or previously treated fields have been modified by the physician. TG-40 includes a list of items to review for new or modified treatment fields. The end-of-treatment completion review should verify that documentation was completed per departmental policy, prescribed dose was delivered, and a physician's treatment summary was created.

In addition to the AAPM TG-40 report, the American College of Radiology (ACR) in collaboration with the American Society of Radiation Oncology (ASTRO) and AAPM has published practice guidelines for radiation oncology.[3] The guidelines recommend the implementation of patient safety measures and processes for independent verification of treatment parameters by another qualified person or method and recommend that all relevant brachytherapy treatment parameters should be verified by the radiation oncologist and medical physicist independently before every treatment procedure. They recommend that medical physicists should create chart review protocols for reviewing plan implementation as well as reviewing treatment records on a continuing basis. The ACR-AAPM EBRT report specifically calls for verification of "treatment-planning system calculations of MUs" prior to the third treatment or prior to the first treatment if fewer than five fractions are being delivered[15] consistent with TG-40. The ACR-ASTRO practice parameters for IMRT do not provide guidance on physics plan and chart review but do state that "Patient-specific QA must be performed before clinical treatment begins."[16] ACR-AAPM recommend that continuing chart checks be performed at least weekly.[15]

The forthcoming Medical Physics Practice Guideline (MPPG) 11 from AAPM also considers the topic of plan and chart review. MPPG 11.a, approved by AAPM to be developed contemporaneously with TG275, will consider professional responsibilities for plan and chart review, the timing of such review and provide minimum required

checklists. The scope extends to external beam radiotherapy and HDR brachytherapy. TG275 differs somewhat in scope because it provides not only recommendations but also, perhaps more importantly, data to inform the recommendations. These data include a formal risk assessment (Section 4) and also a survey of current practices of plan and chart review (Section 3).

2.D. A review of automation and tools to support review

Due to the rapid advancement of new technology and the increasing complexity of patient treatments, the present method for reviewing charts is likely to be different than the one that will exist 10 years into the future. Already, the current paradigm is changing. Simple parameters such as jaw and multileaf collimator (MLC) positions or couch vertical are difficult or impossible to verify as the jaw/MLC becomes dynamic or the couch moves from four to six degrees of freedom. This is further compounded by the wide scale adoption of volumetric modulated arc therapy (VMAT), the integration of adaptive radiotherapy and the deployment of magnetic resonance (MR)-guided technologies. As these changes occur there is likely to be an increasing reliance on automation to perform a variety of functions related to the physics plan/chart review.

In reviewing the literature there are a number of examples of what this automation may look like. To our knowledge the first report of automatic error detection was the 2007 study of Azmandian et al.[17] which used a clustering algorithm to detect outliers in beam energy and MU as applied to four-field box treatments of prostate cancer. Since then there have been numerous studies of various auto detection approaches operating in the treatment planning system (TPS), the OIS, or both.[18–28] Researchers at the University of Iowa have designed a system that queries the treatment management system to automate a number of checks including detection of treatment overrides, inconsistencies in delivery, scheduling, and deviations in couch position, and other verification checks.[26] The system is used to prescreen chart checks such that more time can be spent investigating events and less time searching for them. Researchers at the University of Michigan have developed a similar system where the intention is to offload repetitive checks to the computer system. Ideally, the time saved by this automation is spent on the evaluation of plan quality, a task that requires a higher level of human interaction and knowledge-based decision making.[18] Researchers at Washington University in St. Louis have designed an expansive software system which focuses on the verification of technical details and data transfer.[24,27,28] Such items that involve number-to-number comparison or simple logical testing are ideal candidates for automation which can improve the reliability of these checks. While the system is notable in terms of its size and scope, it also highlights a fundamental challenge which is the incorporation of several different types of data across several different software platforms. The problem ultimately requires custom software which can be difficult to develop outside a large academic setting. Researchers at Massachusetts General Hospital have attempted to address this disparity through the development of a universal framework for acquiring, organizing, checking, and displaying data.[21] The versatility of the system is afforded through PDF parsing which is used to compare plan documentation with the treatment management system. The framework allows for much of the custom coding to be exported so long as the format of the documentation remains the same. In this way, automation helps drive standardization. As of 2016, the system had been implemented at eight separate facilities and provided over 8000 plan checks.[22] There are other studies on automated checking in addition to those cited above. Dewhurst et al.[19] developed a series of 31 checks operating within a TPS. Similarly, Covington et al.[18] present an automated plan checking tool and show that the number of errors identified was improved after the implementation of this system. Another area of automation is in the QA of contours using machine-learning algorithms.[29,30] Based on a review of these prior publications and other considerations, Table S1.A.ii includes an estimation of the types of checks that might be automated.

In addition to locally developed programs, there are a number of vendor-provided solutions that automate certain aspects of the physics plan/chart review (e.g., "ClearCheck", Radformation Inc., "Mobius3D/MobiusFX", Varian Medical Systems, and "PlanCheck/PlanIQ", Sun Nuclear Corp.) The basic features of these programs are the ability to communicate with software systems familiar to the radiation oncology clinic, the extraction and classification of data, and the comparison of the data to relevant baselines. Examples include the comparisons of dose-volume histogram (DVH) metrics against established constraints and the comparison of plan parameters (algorithm, dose rate, etc.) with those set by departmental guidelines. Another novel feature is the ability to perform treatment delivery QA based on machine log files and/or electronic portal imaging device (EPID) dosimetry.[31,32] The results can be presented in terms of a gamma analysis or more directly as a modified DVH. Finally, the IHE-RO initiative (Integrating the Healthcare Enterprise — Radiation Oncology) has proposed a system where the treatment delivery device (e.g. linac) queries a QA manager application (TPS or independent software) just before treatment and verifies that essential delivery parameters are consistent with the stored "gold" version of the delivery (see the IHE-RO profile http://ihe-ro.org/doku.php?xml:id=profiles:qapv). This may represent a future direction for automation and data integrity checking.

In addition to improving the reliability and efficiency of the plan/chart review, automation facilitates the collection of "big data" which can be used to identify errors that may not be easily visible to a human reviewer. Two methods which have been used for this purpose are statistical process control (SPC)[17,20] and machine learning using Bayesian networks.[23,33] In the former, clustering methods are used to identify outliers based on both inter-plan and intra-plan comparisons. In the latter, probability distributions for individual

treatment parameters are linked through a predictive network construct. The probability of any given variable state can then be compared to error detection thresholds derived for specific treatment paradigms. SPC and machine-learning models offer a depth of analysis that goes beyond what is currently achievable through an isolated review of the patient's chart.

While automation holds great promise for improving the efficiency and effectiveness of plan and chart review, it is important to be aware of its limitations. If it is not properly implemented or tested it could lead to errors being systematically unidentified.

3. SURVEY OF CURRENT PRACTICES FOR PLAN & CHART REVIEW

An important charge of the Task Group was to conduct a survey among the medical physicist community to determine current practices for the initial plan check, weekly, and end-of-treatment chart check processes. To date, the only known data on this topic comes from the Medical Physics Community of Practice Chart Checking Practices Working Group (CCPWG) which conducted a survey of 15 cancer centers in Ontario, Canada[34] and from the 2015 AAPM Safety Profile Assessment which reported that an initial plan review was conducted in most of the responding institutions[35]. The purpose of the TG-275 survey is to provide a baseline of current practices using a large and diverse population sample across the AAPM membership from which to make recommendations that will apply to the medical physics community in general.

The TG-275 survey consisted of 103 multiple-choice questions; 55 were demographic characterizing the group or clinical practice of participants and 48 focused on plan/chart review processes for all external beam treatments (photons, electrons, and protons) which were presented in order of the clinical process map as drawn from the AAPM consensus document on incident learning.[36] In total 261 items to be checked or reviewed were distributed among the 48 process-focused questions: 151 during initial plan check, 52 during weekly chart check, and 15 during end-of-treatment chart check. Forty-three additional items were identified as proton-specific checks. Participants were instructed to select the items that they checked as part of their individual review process. The survey was released in February 2016 to all AAPM members who self-reported as working in the radiation oncology field and was kept open for 7 weeks. There were 1526 respondents, representing a 33% response rate (based on an estimated 4500 AAPM members working in radiation oncology). Of these 1310 were from the United States, 60 from Canada, and 107 from 35 other countries (49 participants did not respond to this question). Forty-seven participants reported to have a proton facility and also having experience in this treatment delivery technique — only these participants contributed to the additional proton section of the survey. The distribution of participants relative to the type of institution was: 39% from community hospitals, 31% from academic-affiliated hospitals, 19% free-standing clinics, 7% government hospitals, 2% consulting groups, 0.1% vendors, and 1.6% specified other. In terms of patient load, 39% of respondents were from centers with <50 patients per day on treatment, 34% between 51 and 100 patients per day, and 27% with >100 patients per day. The TG-275 survey achieved the goal of collecting data representing a large and diverse population of practices that is representative of practices as a whole in North America.

The design, development and detailed results of the TG-275 survey are beyond the scope and length-constraints of this report. Additional details and trends based on the survey will be published separately. Tables with aggregated results from the survey are available as Supplementary Material file Dataset-S4 with this publication.

4. RISK ANALYSIS

4.A. Risk analysis methods using FMEA

This Task Group takes a risk-based approach to developing recommendations. The rationale for this approach is that an understanding of the highest-risk issues can inform the recommendations that are developed. To assess and quantify risk, the methodology of Failure Mode and Effects Analysis (FMEA) was used as described in AAPM TG-100.[7] Briefly, this method consists of collecting potential failure modes (i.e. things that can go wrong in the process of care) and associated cause(s) for each. Identification of failure modes is often guided by a process map as advocated in TG-100, but due to variation among clinics the present Task Group found that it was not possible to generate a common process map at anything but a generic level and therefore individuals involved in the FMEA exercises were encouraged to develop and consult their own process map. Once the failure mode/causes are collected, they are scored for severity (S), occurrence (O) and detectability (D). For a given failure mode/cause combination, a low S score (e.g., 1) corresponds to minimal consequences, a low O score corresponds to a low likelihood of occurring, and a low D score corresponds to easy detectability. The product of these three values ($S \bullet O \bullet D$) is the Risk Priority Number, RPN, which is used to rank the failure modes. This risk-ranked list can then be used to inform recommendations around the review of plans and charts. For more information on FMEA and the scoring system see Section 5.B of the TG-100 report.[7]

To support this work, a web-based FMEA software tool was developed by AAPM headquarters IT staff in collaboration with TG-275. The tool allows for the collection of failure modes, FMEA scoring by multiple users, averaging and calculation of scores, and the generation of ranked lists. Though the tool was designed for the purposes of TG-275, it may also useful for Task Groups and other applications.

Separate FMEA efforts were conducted for (a) photon/electron EBRT, (b) proton radiotherapy, and (c) brachytherapy (HDR for treatment of gynecological malignancies).

4.B. Collection of failure modes and validation against a national database

One of the first and most important steps in FMEA is to identify the potential failure modes and associated causal factors. For photon/electron EBRT and proton therapy, this was accomplished by first collecting candidate failure modes from the Task Group members. Task Group members with in-house incident learning systems also queried their databases to collect relevant failure modes. The international voluntary incident reporting system, Safety in Radiation Oncology (SAFRON) run by the International Atomic Energy Agency, IAEA,[37] was also queried for relevant failure modes. The list of failure modes/causes was further refined by gathering information from other professional staff at the clinical sites of each Task Group member.

The failure modes for photon/electron EBRT and proton therapy were separated out into those that pertained to the initial plan/chart review and those that pertained to weekly or EOT review. There were some cases where the failure mode pertained to both (i.e. might be identified on either an initial or weekly review).

The photon/electron EBRT failure mode list was validated by comparing against incidents in the RO-ILS™: Radiation Oncology Incident Learning System, a national system sponsored by ASTRO and AAPM.[14,38] This was conducted as a special project approved by the administering Patient Safety Organization. Events were included over the 2-year time period January 2014 to December 2015 which included about 170 facilities at that time. In this period there were 1,295 total RO-ILS reports and, of these, 203 (16%) were rated as being high-priority EBRT-related events by at least one reviewer from the advisory council. Of these 203 reports, 113 were judged to be potentially detectable in initial physics plan/chart review (note that other events were not detectable because they either occurred after the review, e.g. setup of the patient, or were out of the scope of physics plan and chart review). These failure modes were then cross-compared with the EBRT failure modes identified by the Task Group as outlined above. Good agreement was found. Of the 113 reports identified in RO-ILS, 97 were already identified by the Task Group with identical causal patterns. The additional 16 RO-ILS failure modes yielded 10 new failure modes and six new causes to existing failure modes. In subsequent scoring, however, all of these new failure modes were found to have very low *RPN* scores. Though future efforts may improve FMEA by identifying more failure modes through RO-ILS or other systems, this exercise provided evidence for the validity of the Task Group failure mode collection method.

Due to the diversity of brachytherapy applications this report focuses on the technique that is most widely used, namely HDR for the treatment of gynecological malignancies (HDR-GYN). This decision was discussed and approved by AAPM review committees. A high-level process map was created that included five process steps: (a) applicator placement, (b) imaging, (c) treatment planning, (d) pretreatment QA, and (e) posttreatment QA. Several subprocesses were identified within these categories and used to help guide the collection of failure modes. In considering the relationship between the process map and the responsibilities of the medical physicist, there are three QA actions where failure modes may be detected, the initial plan review, pretreatment QA, and the end-of-treatment chart review. For this study, the focus was specifically on aspects pertaining to the plan and chart review and thus failure modes were collected only for steps 1–3 above (i.e. failure modes that apply to the initial physics review) and those in step 5 (i.e. those that apply to end-of-treatment checks). Failure modes that occur during step 4 (i.e. wrong transfer tube) would be very difficult to assess during an end-of-treatment chart review and thus were not included in the FMEA. Also note that since HDR brachytherapy is often limited to a few fractions, the weekly chart check typically does not occur until the patient has finished treatment. The Task Group recommends that each clinic develop a policy and procedure around on-treatment physics chart review for HDR brachytherapy treatments. For example, centers with a relatively small number of HDR brachytherapy treatments might elect to review each chart after the first treatment delivery, while centers with a higher number of HDR brachytherapy treatments may find some other solution for ensuring early review.

Failure modes were first identified based on the collective experience of the Task Group members in collaboration with volunteers from the AAPM's Brachytherapy Subcommittee. A review of HDR events included in the Nuclear Regulatory Commission (NRC) Nuclear Materials Event database provided further inputs as did events found within local incident learning systems. Finally, a literature review was performed in order to validate the collection of failure modes with those previously published for gynecologic HDR and brachytherapy treatment planning. To do this, these failure modes collected by the Task Group were compared to failure modes listed in the literature on this topic.[39–41] Good agreement was found with differences mainly attributed to the broader scope of failure modes found in the literature which included items not applicable to a physics plan/chart review such as patient falls. Each failure mode has multiple causes and, in theory, these each should be scored separately (the frequency of occurrence especially can vary for different causes). Here only the highest ranking failure mode-cause combinations were considered in scoring.

4.C. Scoring failure modes

Failure modes were scored by the members of the Task Group and other volunteers including 15 volunteers from various institutions, including eight radiation therapists, three physicians, and three dosimetrists. Scores were averaged over all respondents. The 10-point scoring system outlined in TG-100 was used for final scoring.[7] In assigning a severity score the failure mode was considered as if it went unidentified and affected the patient(s). The score assumed the most reasonably likely scenario (i.e., not worst case scenario which nearly always returns a score of 10). For

EBRT, the severity scores should arguably be different for SRS/SBRT vs other fractionation schemas, but these were not considered separately here. Detectability scores were assigned for the failure mode up to the point of the review, that is, the review itself was not included in the detectability score of the event since the goal is to inform best practices for the review itself. Occurrence scores rate the estimated occurrence frequency up to the point of physics plan/chart review. Instructional guidelines were sent to all reviewers prior to scoring.

For photon/electron EBRT, scoring was conducted in two phases. In the first phase *S*, *O,* and *D* scores were returned on a three-point scale (low/medium/high, 1/2/3). This approach was chosen in order to facilitate scoring since the initial list of failure modes was very long (594 failure mode/causal pairs). The Task Group then selected a subset of the highest-ranked failure modes for further analysis and scoring with the ten-point scales advocated by TG-100. Note that this method of scoring (3-point followed by ten-point) is a nonstandard method and does not appear elsewhere in the literature, but was employed here out of necessity because of the very large number of failure modes and the numerous people providing scores. Note that FMEA results from the Task Group represent an averaging across the various clinical systems and experiences of the Task Group's members and so outliers in one clinic (i.e., very high scores) may not be reflected in the averages.

The top 40% of failure modes (by *RPN*) were selected as well as all failure modes with severity scores ≥ 2.4 (on the three-point scale), referred to below for simplicity as "high-risk" failure modes. The three-point scoring exercise also indicated that in most cases causal factors could be collapsed. That is, failure modes with multiple different causes could be grouped for scoring. Though theoretically these should be separated (i.e., various causal factors for the one failure mode could have different occurrence scores), it was found that in practice the differences were not significant. Scoring for photon/electron EBRT weekly, proton radiotherapy, and brachytherapy proceeded in a similar fashion, although with different groups of volunteers with specific expertise in the techniques. Ten-point TG-100 scoring scales were used in all cases.

Proton therapy FMEA scoring was performed by 11 volunteer clinical medical physicists who currently work in proton therapy centers across the US. Each volunteer accessed the AAPM web-based scoring system and reviewed/scored the failure mode with a cause in terms of severity, occurrence, lack of detectability with the ten-point scales. When adaptive planning is used the detectability score assumed regularly scheduled plan evaluation using repeat CT/CBCT images which is considered routine in most proton therapy centers. Of note is the fact that proton radiotherapy is evolving rapidly and the hardware and software are less standardized across different centers or different vendor implementations. As a result, workflow and FMEA scores could vary, depending on in-house implementations adopted at each center. Nevertheless, this set of failure modes represents the broad experiences of numerous centers and serves as a place to start for further, more detailed analyses.

For HDR-GYN, scoring was completed in a single phase using the ten-point TG-100 scoring system. Scores were provided by members of the Task Group in addition to four volunteer medical physicists from the AAPM membership who frequently perform HDR-GYN brachytherapy (see acknowledgements).

The final lists have the following numbers of high-risk failure modes: 112 in photon/electron EBRT initial review, 55 in photon/electron EBRT weekly and end-of-treatment review, 24 for proton therapy (though note that many of the photon/electron EBRT failure modes also apply), and 48 in HDR brachytherapy.

Table S1.A.i lists failure modes relevant to photon/electron EBRT initial plan/chart review, ranked by *RPN*. Only failure modes with $RPN \geq 100$ (corresponding to the top 46 out of 112) are listed and the full list is available as supplemental data. A value of 100 was chosen in order to select roughly half of the highest-ranking failure modes. Failure modes relevant to photon/electron EBRT are shown in Table S1.B.ii for weekly check and in Table S1.C.ii for end-of-treatment (EOT) checks.

Table S2.A.i shows additional failure modes for proton radiotherapy initial plan/chart review. Note that many failure modes for photon/electron EBRT also apply to proton radiotherapy. Several of these are included in Table S2.A.i since the FMEA scores can be very different in the context of proton therapy vs photon/electron therapy. It should be noted, though, when considering failure modes for proton therapy the photon EBRT failure modes (Table S1.A.i) should also be considered.

Table S3.A.i lists failure modes for HDR-GYN brachytherapy inclusive of both the initial plan review and end-of-treatment review as discussed above in Section 4.B. The *RPN* value of the top ten failure modes ranged from 78.9 to 131.8. This represents a decrease in comparison with the top failure modes collected for EBRT, primarily due to lower scores in severity.

4.D. FMEA results and cross-correlation with survey

In the case of photon/electron EBRT, it was possible to cross-correlate the result of the FMEA risk assessment with the survey on current plan/chart review practices (Section 3 in this report). For this purpose, survey data were used only from the 1370 respondents who identified as practicing in the US or Canada. This subset was selected in order to match with the failure modes which were developed from input from clinics in this setting and also the fact that most respondents were from the US or Canada. For each failure mode it was possible to identify which checks could address that failure mode. Table S1.A.ii shows the relationship between each check and the failure mode(s) that it addresses. Most of the checks address more than one failure mode. On average there were 2.9 failure modes per check item (range 0–12), see

Table S1.A.ii. Conversely, each failure mode had an average of 4.1 checks (range 0–29), see Table S1.A.i.

Figure 1 shows the relationship between the *RPN* of the failure mode and the frequency of use of each check item (as measured on the survey). In the cases where multiple failure modes apply to a particular check, only the highest *RPN* value is plotted. Of interest is the upper right quadrant of this plot (i.e., $RPN \geq 100$ and use rate $\geq 60\%$) since this represents high-risk failure modes for which there is a check that is in routine use across centers. Also of interest is the lower right quadrant with high-risk failure modes which do not have checks routinely in place. Some of these failure modes are outside the scope of a physics review such as failure modes related to patient assessment which are best addressed by physicians and others. Other failure modes in this quadrant, however, are clearly within the purview of medical physics and represent opportunities for improvement in the check process that are highlighted in this report.

The lower-left and upper-left quadrant of Fig. 1 are also worth consideration. These represent low-risk failure modes for which there are checks in place. In particular, the RPN = 0 modes are of interest since these represent very low risk and one might question the value of performing a check if the risk is truly zero. In this context two questions may be helpful. First, is the risk truly zero? In some clinics the RPN = 0 score from TG275 may not be correct since the processes, procedures and systems may differ. Secondly, does the check act on different failure modes? The analysis from this task group shows that many checks operate on more than one failure mode (average of 2.9 failure modes per check item, range 0–12). Therefore, a check that operates on an RPN = 0 failure mode may also operate on a different higher-risk failure which would make it an important check.

Another point to note is that many failure modes have more than one check in place which could identify them (on average there are 4.1 checks per failure mode). However, there are some failure modes with very few checks in place (sometimes only one). These failure modes may deserve special note because there is more reliance in these instances that the check operates effectively.

It was out of the scope of this Task Group to conduct a survey on plan/chart review practices for HDR-GYN brachytherapy. For the purposes of this report, therefore, The Task Group assembled a compendium of brachytherapy checklists which identified items most commonly checked during a physics plan review. These checklists were provided by Task Group members, volunteers from the AAPM membership, and documents made available by the American Brachytherapy Society. Table S3.A.i shows the association between the HDR-GYN failure modes and the corresponding master checklist item. Among the 53 failure modes, 27 could be directly linked to QA checks found in the master checklist. Many of the failure modes not included on the master checklist were related to the quality of the applicator placement which is an area that requires coordination with the treating oncologist to QA properly. Several other failure modes were technical in nature including "incorrect selection of connector end vs tip end," "wrong fiducials inserted into applicator or not inserted fully," and "plan normalized incorrectly." These items represent targets for improvement in addition to the top failure modes ranked by *RPN* value.

5. RECOMMENDATIONS FOR PLAN/CHART REVIEW

This section presents the recommendations of this Task Group for best practices in plan/chart review. The recommendations are supported with a series of tables. Electronic files with these tables and checklists are available as Supplementary Material Tables with this publication. These recommendations are not intended to be prescriptive, but should be adapted to individual practices. The members of the Task Group and others who have contributed to this work represent a cross-section of the medical physics community and have experience with a range of software and treatment delivery systems. However, with the numerous combinations of simulation processes, treatment planning systems, EMRs, and treatment delivery systems, it is beyond the scope of this report to address every possible scenario and provide recommendations that would identify all errors. Also the recommendations were based on risk scenarios for particular clinics surveyed and so not all recommendations will be relevant to every clinic. The Task Group recommends that each practice examine the recommendations contained in this report and make adjustments to their plan/chart review process based on a formal risk assessment of the specific practices in their clinic. Additionally, a review of incidents within the institution should be performed to ensure that necessary checks have been implemented to address incidents. When new technologies or upgrades or changes in clinical processes are introduced, the plan/chart review procedures may need to be modified and this is best informed by risk analyses.[7] Finally, it is valuable to consider field-safety notices, bulletins from vendors and other organizations when formulating procedures for physics plan/chart review. By using all these tools, each clinic will be equipped to develop policies and procedures for physics plan/chart review and other support tools (e.g., checklists) that are suitable for its own environment.

This Task Group identified some high-risk failure modes that are out of the scope of practice or expertise of a medical physicist and/or are very challenging or impossible to identify at the time of plan or chart review. An example is peer review of treatment decisions (e.g., through a tumor board or peer evaluation). This is out of the scope of the medical physics profession. However, such failure modes are still included and presented in this report as the Task Group believes that these are worthy of consideration at a more department-wide level. The Task Group encourages the completion of the check prior to the first treatment in order to reduce the likelihood of errors reaching the patient. Specifying professional responsibilities for performing plan/chart reviews is beyond the charge of this Task Group, however the survey conducted by this Task Group provides a window on current practice.

When asked who is responsible for review, 92% of practices replied a QMP for initial plan/chart review and 92% of practices replied a QMP for weekly checks. However, additional staff were also indicated as having responsiblity in more than 20% of practices. These included a noncertified physicist (e.g., resident or junior staff) or a dosimetrist. In 19% of practices the initial plan/chart review was allowed by a noncertified physicist with no second check by a QMP; 1.5% allowed a dosimetrist with no second check by a QMP. In 24% of practices the weekly check was allowed by a noncertified physicist with no second check by a QMP; 11% allowed a dosimetrist with no second check by a QMP.

The forthcoming AAPM MPPG 11.a report on this topic considers professional responsibilities for plan/chart review and calls for initial review and end-of-treatment checks to be performed by a QMP, weekly chart review should be performed by a QMP or their designated personnel. Also of note is the more stringent requirement in the current standards from ACR and APEx practice accreditation programs which stipulate that weekly checks be performed by a QMP (https://www.acraccreditation.org/How-To/RO-FAQ-Physicist and https://www.astro.org/Daily-Practice/Accreditation/APEx-Process-Overview/APEx-Standards).

The survey data from TG275 indicate substantial variation in current practice. Given this, the Task Group recommends that if reviews are performed by someone other than a QMP, then that the work be supervised by a QMP (consistent with AAPM Policy PP-17 and PP-18B). The appropriate level of supervision is "general supervision", namely if the QMP provides training, their presence is not required during the procedure but they must be "available by phone" (see AAPM Policy PP-18B).

The plan/chart review process is often thought of as a single check performed at a discrete point in the workflow. For the initial review this is typically performed at the end-of-treatment planning. It may be possible to perform some of this review earlier in the workflow. An example of this might be a consideration of the immobilization at the time of simulation and whether it is appropriate for the particular type of treatment. There are several advantages to reviewing early in the workflow, including: (a) issues may be more easily identified, (b) changes may be more easily executed if the work is not yet complete, (c) wasted effort and rework may be avoided (which translates into time and cost savings), and (d) early review may allow for several shorter, more focused checklists rather than one very long checklist late in the workflow. Related to this may be the efforts of Atwood et al.[42] and others to involve medical physicists more directly in patient care and in more parts of the workflow. This is part of a larger "Medical Physics 3.0" effort within AAPM to guide the evolution of the profession (c.f. https://www.aapm.org/MedPhys30/).

As physicists are involved more directly in other parts of the workflow, communication becomes a priority. It is important to clarify who did which aspect of review and when. It is also important to structure the workflow and communication channels so that the review is able to be performed. The system should also include a hard-stop/forcing function to ensure that review tasks are complete. A hard-stop or forcing function is defined as "something that prevents the behavior from continuing until the problem has been corrected" (www.npsf.org). An example is a computer interlock that prevents a beam from being treated until the prescription is signed by a physician. Examples of measures that are not hard-stops or forcing functions are a policy around performing a check before treatment, or the use of a checklist or timeout. While all of these may help ensure safety, they can also be violated and so do not constitute a forcing function.

5.A. Photon/electron EBRT initial plan/chart review

Table S1.A.ii provides a list of checks for photon/electron EBRT initial plan/chart review with indications for status, i.e. those checks which are high-risk priority and in common usage (++) and those checks which may be targeted for improvement, that is, high-risk priority but not currently in common usage (+). To take an example, consider the review of the delineation of organs in the treatment plan (see Table S1.A.ii "TP-Q1a-2"). This is a priority check; it addresses three high-RPN failure modes (Failure mode 1, 7 and 18 on Table S1.A.i) and is performed by 69% of practices according to the survey. Another example is the review of structures used during optimization (Table S1.A.ii "TP-Q1a-5"). This relates to a high-RPN failure mode, but only 39% of survey respondents report performing this check.

Synthesizing all these data, Table S1.A.iii presents an example checklist for photon/electron EBRT initial plan/chart review based on the high-RPN failure modes. Checks with high frequency usage (>50%) are indicated with an asterisk. **We stress that this and other checklists are only provided as examples. They are not meant as definitive lists of all the items to be checked in any one clinic.** The Task Group tested this checklist by performing plan/chart reviews of sample cases and found it to be useable and consistent with current practice. The items on the checklist in Table S1.A.iii are presented in the order they occur in the workflow and not in the order they are typically accessed in the OIS. Ordering checklist items in the order accessed by OIS may be useful for some clinical practices. Following safety checklist best practices described by AAPM Medical Physics Practice Guideline (MPPG)-4, each practice needs to go through its own implementation and validation process to make sure that the proposed checklist would meet its particular needs and workflow.[43]

Of note are the checks of data transfer between software systems. ACR-AAPM technical standards for the performance of radiation oncology physics for external beam suggest that "If verify-and-record systems are used, the physics chart check protocol must include reviewing all treatment-related data recorded therein. Documentation of this review must be part of the patient's treatment record."[15] It is not specified, in detail, how this "review of data" should be conducted. In cases where separate software systems are used for treatment planning and the OIS, a detailed review of data transfer between the systems is appropriate. Issues of data integrity and transfer are dealt with in detail in AAPM TG-201.

A final issue to consider in terms of when plan/chart review is performed is the case of plan changes. Some actions

should clearly trigger a full plan/chart review such as recalculation or reoptimization (e.g., Table S1.A.iii checklist item "Full check if new plan generated"). Other actions may only need some form of abbreviated plan/chart review, such as the addition of a setup field or the renaming of a field. Each institution should determine the appropriate categorization as a function of their workflow, software, and hardware.

5.A.1. Practice recommendations for photon/electron EBRT initial plan/chart review

It is possible to make some observations and recommendations around the practice of photon/electron EBRT plan/chart review by drawing from society recommendations and the membership survey that was conducted.

When initial plan/chart review is performed: The survey results show that 89.6% of respondents complete the initial plan check prior to the first fraction, 9.5% within 3 days after the first fraction, and 0.9% within 5 days after the first fraction. The Task Group encourages the completion of the check prior to the first treatment because it would reduce the likelihood of errors reaching the patient. A physics plan/chart review of a new replan before the first fraction, for example, may have prevented the accidental fatal overdose in 2005 of a 41-year-old patient in New York receiving IMRT for oropharyngeal cancer with curative intent.[44]

There are, however, circumstances such as poor staffing levels which may prevent this from being feasible in some cases. If it is not possible to check every plan prior to the first fraction, it would be prudent to identify a subset of high-risk cases that would require an initial check prior to the first fraction. Examples could include patients with implanted devices, prior treatment to adjacent areas, high dose per fraction or few fractions, and other unusually complex cases. There may also be opportunities to improve review processes throughout the treatment planning process, that is, prior to when a formalized plan/chart review is performed. An example is a "physics pre-approval step" before the physician reviews and approves the plan. A key recommendation of this report (Section 7) centers around this issue, namely: "Practices should work to incorporate physics reviews as early in the workflow as possible and not rely solely on review at the end of treatment planning". Note that redundancy of checks is also important. High-risk or high-severity failure modes may benefit from multiple checks at different points in the process.

Who performs the initial plan/chart review: In the sruvey 91.5% of respondents report that a QMP completes the initial plan check. As noted above, it is the recommendation of this Task Group that if the review is performed by someone who does not meet the criteria to be a QMP then, at a minimum, this work should be supervised by a QMP (consistent with AAPM Policy PP-17).

Workload and time for the initial plan/chart review: The survey revealed that the majority (74.1%) of respondents check an average of 1–5 initial plans in one day, 17.7% check 6–10, and 8.2% check more than 11 charts in one day. Similar data were available from the survey for EBRT weekly and end-of-treatment checks (not presented here). Approximately one third (33.5%) of respondents have <1 day to complete the initial plan check and approximately two thirds (63.8%) have one to 3 days to complete the check.

It is beyond the scope of the charges of the report to provide guidance on what workload is excessive or

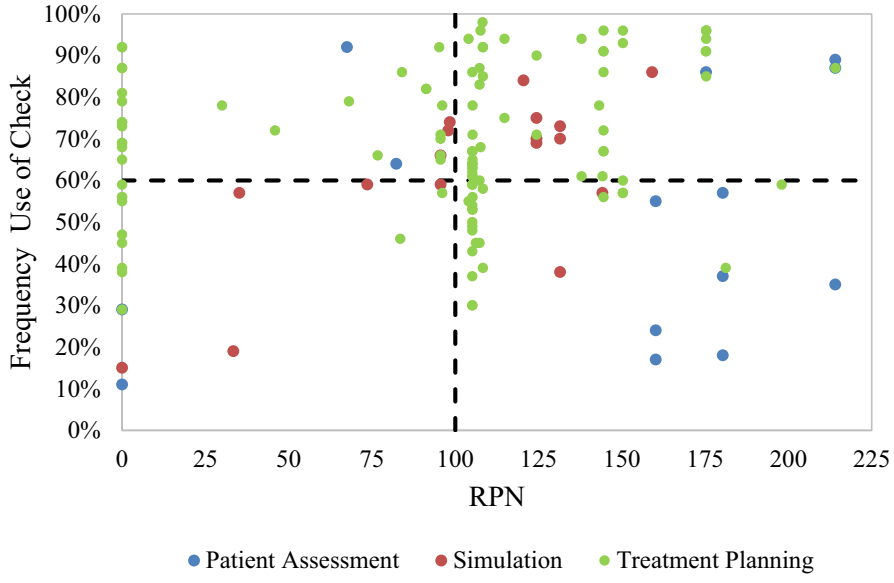

FIG. 1. Photon/electron external beam radiotherapy initial physics plan/chart review. Frequency use of each physics check vs the risk-score (*RPN*) of the corresponding failure mode that it addresses. The failure modes listed with *RPN* = 0 are those which were low risk and not scored in the full ten-point scoring exercise.

dangerous and indeed it may be very difficult to generalize. However, several general points are worth considering. Initial plan checks are a critical component of the radiation oncology quality management program and should be explicitly incorporated into the departmental workflow. Adequate time and resources should be devoted to this important process step. Compromising the allotted time for initial plan checks should be an exception rather than a routine occurrence. Time should also be incorporated into the workflow to allow feedback from the plan check process to the planning process to allow for corrections or improvement to plan quality. Additionally, time after the initial physics plan check should be considered and incorporated for downstream process steps such as therapist chart checks in order to prevent errors resulting from time constraints. To achieve these goals the workflow process and staffing should be evaluated and monitored to prevent too many plans from being reviewed by one person in a specific time frame. Of particular concern is the need to complete reviews very quickly due to patient scheduling. In addition, the person reviewing plans and charts needs an environment with minimal to no distractions (the "sterile cockpit"), enough energy and focus to perform the work, and adequate training to follow the procedure.

Policies and procedures for the initial plan/chart review: Of the survey respondents, 72.5% have a formal and written procedure describing initial plan checks, 64.2% use checklists to complete the initial plan check, and 52.1% reported using at least some form of automation for the initial plan check. Standardization is a key component of error prevention.[45,46]

To promote standardization, a formal initial plan check process should be incorporated into each institution's quality management (QM) program and followed by all medical physicists at the institution. Checklists may be a useful tool to facilitate such standardization.[43] Sample checklists are shown in the tables below. Care must be taken when adapting any sample checklists to institutional specific processes and workflows. While many OISs incorporate some level of automation to facilitate the weekly chart check process, the Task Group is not aware of any explicit error-check tools for the initial plan check. Several third party solutions have been developed to assist with the initial plan check process and are discussed in Section 2.D (Automation Section). Automation of components of the initial plan check shows promise in the areas of standardization and efficiency. Automation processes are, by their nature, standardized processes and would ensure that the included components of the check would be completed for each plan. Additionally, automated processes would more efficiently and effectively check specific components of the chart check such as planning target volume (PTV) and organ-at-risk (OAR) margins. Therefore, physicists would have more time to devote to other aspects of the chart check that do not lend themselves to automation such as overall plan quality, review of prior treatment, laterality confirmation, or issues related to image guidance.

Required approvals: Of survey respondents, 86.2% reported that the physicist is required to approve the treatment plan and/or fields prior to the first treatment. Approval requirements are beneficial in that they insert a forcing function into the process that prevents treatment without prior physics approval. Additionally, approval provides a permanent record of the plan and field parameters at the time of approval. Subsequent changes would require reapproval and would be included in a plan or field history.

58.2% of respondents reported that they have a set of forcing functions that prevent treatment without corresponding plan checks and approvals, 35.8% report relying on processes and good communication to ensure the checks have been completed, and 1.2% report having no preventive measures. When available, forcing functions are the optimal solution. "Forcing functions and constraints" are listed as the most effective quality management tool by TG-100.[7] The 2012 ASTRO report, Safety is No Accident,[46] also recommends incorporating forced functions into systems. Policies and procedures are sometimes thought of as a weaker control measure.[7,47] However, when they are supported by tools such as a checklist they can be very effective.

Initial plan/chart review and incident learning: Fifty-one percent of respondents reported recording near-misses and deviations during the initial plan checks. Incident learning systems have been proven to be a valuable source of information and should be used for process improvement.[48] The tracking of incidents during the initial plan check is strongly encouraged to facilitate improvement in both the planning process and the plan check process.

5.B. Photon/electron EBRT weekly and end-of-treatment chart review

By its nature, physics weekly chart reviews are less comprehensive than an initial plan/chart review and it is assumed that the most egregious failure modes were addressed during the initial/plan chart review. It is impractical to schedule as much time for a single patient's weekly chart review as for the initial plan/chart review. By definition, a weekly chart review involves a review of all patients currently under treatment. New or modified plans should undergo the more rigorous physics review covered under the initial plan/chart review.

A modern OIS provides a direct electronic record of the delivery parameters for each treatment including delivered MUs, gantry, collimator settings, couch coordinates and some treatment accessories (e.g., wedges) and also allows for electronic text entries; all of which can be efficiently reviewed during a weekly chart review. With a modern OIS, there is minimal chance of typos, inadvertent omissions or insertions, and no possibility of illegible texts or notations that plague paper charts.

Failure modes that might be detected in a physics weekly chart review fall into four categories:

1. Failure modes that were missed during the initial plan/chart review. Some institutions require stricter physics review at the first weekly chart review in the hope of reducing severity (S) by limiting the number of treatments affected by such failure modes. Examples include a calculation or plan for the wrong energy or a failure to account for previous treatments. If this failure mode was missed in the more rigorous initial plan/chart review, it would be difficult to catch it on a less rigorous weekly chart review (higher undectability score *D*). This is true of other failure modes, as well, including setup instructions or instructions for IGRT where *D* becomes higher for a physics weekly chart review, though some of these may be very low *D* for a therapist's chart review.
2. Information that was requested early in the treatment that was not obtained or documented (e.g., *in vivo* dosimetry measurements, specialized imaging, confirmation of anatomic measurements, etc.).
3. A change in a prescription that was intended but poorly documented or incorrectly executed.
4. Treatments that were incorrectly delivered in a way that can be traced by someone not present at treatment. An example is bolus not applied or applied incorrectly. This might be detected by a physics chart review if department policy requires therapist sign-off as documentation or the use of technology like barcode scanning to register bolus placement.

There were some failure modes that pertain to both the weekly and initial plan/chart review. In these cases, the failure modes were only kept on the initial list based on the goal of not duplicating efforts or making the weekly review impractically time-consuming. The Task Group did, however, identify some high-priority failure modes which would benefit from review when the first weekly checks are performed to provide redundant checks. These are indicated in Table S1.B.i as "first weekly only".

This Task Group compiled a list of 55 high-risk failure mode/cause combinations that might be detected by someone involved in the treatment workflow after treatment had begun, including detection on physics weekly or EOT chart reviews. These were consistent with checks that were reported in the survey. The *D* and *O* values assigned to these were particular to occurrence and detection in physics weekly or EOT chart reviews. Note that this method of scoring is different than that used for the initial plan/chart review, that is, considering detectability only up to the point of the check and not the check itself. This was done in order to reflect the differential detectability of the weekly check beyond the initial plan/chart review. That is, many failure modes would be identified on the initial plan/chart review which happens before the weekly review. By including the detectability of the check itself in scoring, we preferentially rank the failure modes that are more difficult to detect and might be missed in the initial review.***

Of these high-risk failure modes, a physics weekly chart review with a modern OIS system could reasonably detect 20 of them in the judgement of the Task Group (Table S1.B.i). Physics EOT chart review might detect four of the high-risk failure mode/cause combinations listed in Table S1.C.i.

The Task Group identified 31 failure mode/cause combinations that are clinically important but would be highly unlikely to be identified in a physics weekly chart review. Some of these might be detected by on-treatment reviews performed by physicians, therapists, or other staff members (Table S1.B.i part 2). One example is a case where a patient cannot maintain the simulated position at treatment. This should be detected and documented by therapists and corrected by direct interaction between the therapist and physician. Another is the delivery of a suboptimal plan that was not identified prior to treatment. Yet another is an undocumented change in treatment intent (including a purely verbal request), which would only be detected by the individual who was aware of the verbal discussion.

There are other means for detecting failure modes that lie beyond the purview of a medical physicist (c.f. items in Table S1.A.ii labeled "OP" for other professional, i.e. high-priority checks that are outside the domain of physics). Physicians and therapists also bear serious responsibility for continuing QA of plans and charts. Chart rounds and peer-review conferences are important opportunities for treatments to receive peer review early in a treatment course, including review of prescriptions, target and OAR contours, dose distributions and on-treatment imaging[49,50]. Physicians are responsible for the continued review of the prescribed imaging, which may be correct at the first session, but show problems later (tumor changes, patient weight loss, respiratory gating issues). The specific responsibilities and duties of the physician in this regard are outlined in the ACR-ASTRO practice parameter for image-guided radiation therapy[51]. Therapists are the last line of defense against incorrect or unclear setup instructions following the initial physics check. They may also be recipients of undocumented verbal prescription changes, scenarios such as potential patient/gantry collision and detecting the patient's inability to tolerate the simulated treatment position.

5.B.1. Practice recommendations for photon/electron EBRT weekly and end-of-treatment (EOT) review

There are several sources of existing recommendations for the weekly and end-of-treatment (EOT) review of photon/electron EBRT treatments. AAPM Task Group 40[2] recommended that chart reviews occur before the third fraction following the start of a new or modified treatment plan, at least weekly, and at the end-of-treatment (EOT). TG-40 outlined items to be reviewed, but did not specify the responsible personnel. ACR-AAPM "technical standards for the performance of radiation oncology physics for external beam"[15] recommends that a QMP perform chart review at least weekly and this review be documented in the patient's treatment record. The Joint Commission, through the Cooperative Accreditation Initiative, has a complementary agreement with the ACR and supports adherence to the recommendations

outlined by the ACR. Documentation of chart reviews is required, and billing codes are associated with these activities.

Existing recommendations for what should be included in EOT chart review are somewhat vague. AAPM TG-40 recommends a review of the following elements: prescribed dose delivered, chart properly documented according to department policy and treatment summary. ACR-AAPM "technical standards for the performance of radiation oncology physics for external beam"[15] recommends that the QMP review the entire chart to "affirm the fulfillment of the initial and/or revised prescribed dose" within one week of EOT and this review be documented in the patient's treatment record.

This Task Group has developed recommendations based for the items that should be reviewed based on high-RPN failure modes and frequency of use data from the survey. Table S1.B.iii presents an example checklist for physics weekly chart review.

Most of the failure modes that may be detected on an EOT involve documentation as opposed to high-S failure modes with anticipated health consequences. Occasionally a failure mode that escaped detection during the entire treatment may be detected on EOT, leading to a review of potential gaps in the initial or continuous review processes. Since it is the recommendation that a physics EOT review be performed within one week of EOT, if a medium or high-S failure is found in an EOT, there may still be time for medical measures that can partly mitigate possible harm. One example reported into RO-ILS was a case where two sites were intended to be treated. One of these sites received treatment, but the second site was never planned because no prescription was written for the second site. Table S1.C.iii presents an example checklist for EOT chart review. These items were developed from the high-RPN failure modes and frequency of use data from the survey.

There may be challenges in accomplishing continued chart review for hypofractionated treatments delivered over less than six days. One problem is that a hypofractionated course may not have an associated weekly chart review or it may receive a weekly chart review only after a substantial fraction of the prescription has been delivered. This is not ideal and approaches should be developed to address this. The Task Group recommends that each clinic develop a policy and procedure around on-treatment physics chart review for hypofractionated treatments. For example, centers with a relatively small number of hypofractionated treatments might elect to review each chart after the first treatment delivery, while centers with a higher number of hypofractionated treatments may find some other solution for ensuring early review.

5.C. Proton radiotherapy initial plan/chart review

Table S2.A.i provides a list of risk (RPN)-ranked failure modes for proton initial plan/chart review. Table S2.A.ii provides an example checklist of important proton chart checks and their corresponding failure modes. The percentage of use for each check by the physicists who participated in the survey is also listed.

There were 24 proton-specific failure modes and 71 causes. Interestingly, the highest *RPN* ranked failure mode was caused by "Waiting for insurance clearance", which reflects the current concern that insurance issue may cause a delay in starting a patient's treatment resulting in a possible increase in tumor size from that which was simulated. In such cases a target volume increase could be caught during early repeat CT/CBCT imaging studies for adaptive radiotherapy. However, only 42.6% of physicists surveyed indicated that adaptive radiotherapy process was performed in their clinic (Table S2.A.ii).

The list of proton therapy-specific failure modes is dominated by CT image metal artifacts and various potential causes for proton range uncertainties. Seventeen percent of causes are from one single failure mode- inaccurate proton range estimation, which highlighted a major concern in current proton therapy. Various mitigations have been proposed, which include (1) careful beam angle selection, (2) including definition of all materials in the proton beam path, and (3) robustness evaluation to assess the impact of setup error and range uncertainties etc.

5.D. HDR gynecology brachytherapy plan/chart review

The physics plan review for HDR brachytherapy was previously discussed in TG-59[10]. The task group recommended a check of 13 primarily technical items while also emphasizing the clinical appropriateness, reasonableness, and self-consistency of the treatment plan. While some of the technical items appear outdated as a result of the move from two-dimensional to 3D based planning, the basic framework of the TG-59 recommendations remains true. The strength of the current analysis is that it adds further detail and context to this framework based on the collection of failure modes specific to the HDR-GYN process.

Table S3.A.i provides a list of risk (RPN)-ranked failure modes for HDR initial plan/chart review. Using the results of the FMEA, a checklist was devised to help guide the initial plan/chart review for HDR-GYN (Table S3.A.iii). The checks are generalized to cover a variety of failure modes which are detailed more explicitly through notes and examples. The checklist is ordered such that the items towards the top of the list address the highest priority failure modes as determined by the FMEA. In many instances, a single type of check covers a wide variety of failure modes. Particularly, the first five checks cover 30 different failure modes including the eight highest as ranked by *RPN*. While three of the five checks are related to technical aspects, the remaining two concerning contouring and implant quality are clinical in nature. The intent of these checks is not to focus on the more subjective aspects of the subprocess but instead look for discernable errors which a QMP could identify. Examples include contours with incorrect names (e.g. bladder labeled as rectum) or implants with gross deviations such as shielded cylinders with the shield reversed. Also of note, many of the

recommended checks may not be adequately performed through a review of documentation alone. Depending on the level of detail provided in such documentation, it may be necessary to review items directly within the treatment planning system and/or within the treatment control station.

Ideally, the person performing the plan review should be different than the person involved in the planning process. This may be difficult to arrange when physics is also tasked with the creation of the treatment plan. Nevertheless, planning often occurs on a short timeframe where the interval between simulation and treatment is on the order of a few hours. In this high stress environment it is easy for slips and lapses to occur, both of which were identified through FMEA as causes of high-RPN failure modes. A plan review performed by the treatment planner is less likely to successfully find such errors due to inherent bias. Additionally, if the error was caused by an underlying misunderstanding of technique, the planner will continue to follow the same error pathway during the plan review. In the absence of a truly independent second check, a method of delayed self-verification should be instituted whereby the plan review is performed after a time delay. This method has been shown to improve error detection rates in comparison to reviews performed immediately after the completion of a task[52].

In addition to failure modes related to the initial plan review, Table S3.A.i also includes those related to the EOT chart review. The failure modes happen in the postprocedure steps and mostly pertain to recordkeeping and therefore were subsequently given lower scores, particularly in regard to severity. While the overall *RPN* values were low, these failure modes represent latent errors which can lead to future problems if not addressed. Such problems could relate to the current patient, future patients, or possibly with regulatory or accrediting bodies who require specific documentation for brachytherapy procedures. Overall, the review of these items represents good practice and should be included in an EOT chart review.

5.E. Suggestions to software vendors

Software systems play a central role in physics plan and chart review. While software systems can contribute to errors in radiation oncology[53] they can also play a central role in the identification of errors during plan and chart review. There are several key software-related suggestions that can be drawn from the work of this Task Group. These suggestions apply to all software systems but particularly to the OIS and to treatment planning systems.

First is the need to automate the physics plan and chart review. Currently the process for physics plan and chart review relies heavily on manual human inspection which is time-intensive and is known to be prone to error[4]. While automation cannot replace human decision making in various clinical situations, it can improve efficiency and effectiveness and allow physicists to focus more attention on the review tasks that require human judgment. Table S1.A.ii indicates the photon/electron EBRT checks which might be automated. A further discussion of automation can be found in Section 2.D. Some examples of potential automatic checks include the following: (a) Approval of the prescription by a physician. This could be easily automated in the OIS. (b) Verification of field parameters in the OIS vs the treatment planning system. This is possible but might involve coordination of multiple software systems. (c) Presence of patient consent, consult note or other crucial documents. While it might not be possible to verify that the information in these documents is correct, it should be possible to verify that the documents are present. (d) Verification of the treatment site. A site verification check might be automated but would require a standard nomenclature such as that proposed in AAPM TG-263.[54] Standardization is a common theme for automation, that is, that standards need to be in place for automation to be possible, as illustrated by some of the checks in Table S1.A.ii (e.g. technique, regimen, contour density overrides, motion management, all of which require standardization). (e) Checking values of various parameters (or collections of parameters) against historical data. For example, in proton radiotherapy, range checking could be performed to evaluate whether values exceed previously defined tolerance. Section 2.D provides an overview of previous studies which have pursued approaches to automatic checking.

Another recommendation of this Task Group is that the OIS and other software systems present review information in a way that is presentable and easily "digestible" to a busy clinical medical physicist. Current systems often place critical information in various locations which is accessible only through multiple clicks and/or opening multiple instances of the software. The review task would be greatly improved by streamlining the system so that required information is presented in a single interface in an intuitive format. One specific case for this is the physics weekly review. Software interfaces should make it obvious to the user what has changed since the previous check, for example prescription, table, and field parameter changes. This will greatly improve the reliability and efficiency of weekly checks.

Software systems should highlight items that are difficult to check and review. An example is the margins used for the PTV. This shows up as a relatively high-risk failure mode for EBRT planning (e.g. Table S1.A.i) and yet is often very challenging to review given the information that is routinely accessible in physics plan and chart review. Such a check might be partially automated or, if a standard automated margin is used, this information could be displayed for review. Some treatment planning systems do track and display the status of derivative structures. These systems and others should also be capable of displaying how derivative structures were generated (e.g. margins used or the Boolean operators, etc.).

This Task Group recommends that workflow tools be provided to assist in the communication and enforcements of review. For example, if a medical physicist reviews the presence of an implanted cardiac electrical device at the time of simulation, the information from that review should be clearly presented for others downstream in the radiation oncology workflow. This represents the communication and

verification aspect of review. Systems should also be designed to lock-out some functionality depending on which checks have or have not been completed. For example, some systems make it possible to lock-out treatment until it has met physics plan check criteria (e.g. until it is verified that a medical physicist has reviewed the prescription and confirmed that it matches the treatment plan and parameters).

In all software design the user interface should be explicitly considered with input from clinical partners. The user experience aspects should be developed relying on best principles for designing safe systems[55]. This is related to the current movement toward usability in software (i.e., the "UX" or user experience). Solutions should be made flexible since it must be recognized that clinical processes, procedures and workflow will vary between institutions.

6. LIMITATIONS OF THIS REPORT

Though this report is intended to be comprehensive, the reader should be aware of several limitations. First the risk profile and review practice (survey) were determined from sampling of clinics mostly in the United States. The results, therefore, are biased toward the workflow, equipment, staffing and training currently in use in these clinics. The risk profile and review practices may be quite different in other settings and they are also expected to change over time. For example, in the clinics sampled here it is relatively rare to manually record and transfer data. Instead, DICOM-RT and other data transfer standards are more commonly used. Manual recording and transfer of data is high-risk and is strongly discouraged by this Task Group as highlighted in the key recommendations section. The risk profiles outlined here will change depending on manual recording and transfer of data and other practices. It is the hope of this Task Group that this report and the data in it will be revisited as technologies and practices evolve.

Another limitation relates to the FMEA risk-assessment tool employed here. Although the Task Group did attempt to validate results with outside data sources, it must be recognized that the FMEA method has limitations (see TG-100 for further discussion). FMEA results from the Task Group represent an averaging across the various clinical systems and experiences of the Task Group's members. This should be considered when interpreting the results. For example, a failure mode that would be scored very high based on one system may score very low based on another system. The overall score would be an average of the two and may not stand out as a priority. Another limitation is in the linking of failure modes with corresponding check review items. It was not always possible to determine with sufficient granularity how each specific check functioned and if it fully addressed a particular failure mode. These limitations underscore the importance of the recommendation that each clinic evaluate its own procedures.

A final limitation is that the impact of these recommendations has not been carefully studied, since this is beyond the scope of the charges of the Task Group. One concern is that the recommendations may present a higher workload for medical physicists which may be difficult to accommodate in some centers depending on staffing levels. It is important to remember that plan and chart reviews are only one of the many responsibilities of the medical physicist. Though the issue of workload deserves a more careful examination, several observations can be made. First, there is value to improved plan and chart reviews as suggested by data on current performance. Second, the effort is not unreasonable. This task group has pilot tested the EBRT initial plan/chart review recommendations in a handful of centers (Section 5.A) and they were found to be useable, consistent with their current practices, and not overly burdensome. Since the EBRT initial plan/chart review recommendations are arguably the most extensive recommendations in this report, this test provides some indication that the workload associated with these recommendations is reasonable. Third, it may be possible to shift some of the responsibilities for specific aspects of plan and chart review to other members of the team. For example, some of the checks outlined in Table S1.A.iii could be reviewed by therapists, physicians, or nurses (see Section 5). To date, this has been difficult to accomplish given the lack of concrete recommendations. Now, with the publication of this report, it may become possible. The Task Group recommends that if this path is pursued it should be done under the supervision of a Qualified Medical Physicist (see Recommendations below). A second concern with this report is that very detailed lists of recommended checks might create medical physicists who function on "checklist autopilot", i.e. someone who follows a detailed formula for a task without applying critical thinking skills. Physicists and others need to remain capable of assessing the many subtle and complex issues not reflected in a simple list. This report discusses many ways to address this including automating routine checks, reassigning responsibilities as appropriate, and moving some checks earlier in the workflow.

7. KEY RECOMMENDATIONS

- Physics plan/chart review should be based on risk analysis methods as advocated by TG-100 recommendations such as process maps and FMEA (Section 4).
- Physics plan/chart review procedures should aim to identify failure modes which are high-risk and/or high potential severity. This report identifies numerous such failure modes in the following areas:
    - a Photon/electron EBRT. Initial plan/chart review (Table S1.A.ii), weekly review (Table S1.B.iii), and end-of-treatment review (Table S1.C.iii). Particular importance should be placed on the priority review items marked with as "++".
    - b Proton therapy EBRT. (Table S2.A.ii).
    - c Brachytherapy, HDR gynecological. (Tables S3.A.i and S3.A.iii).
- Each clinic should develop standardized policies and procedures for physics plan/chart review (Section 5).
    - a Each practice should assess local processes in light of this report and identify key high-risk failure modes.

b Policies for on-treatment physics chart review should include consideration for hypofractionated and HDR brachytherapy treatments where a relatively small number of treatments might necessitate a different review process..
c The clinic should maintain a periodic ongoing review to evaluate the efficacy of newly implemented methods and to stay current with practice changes. The assessment should include a review of the practice's incident learning experience.
d Ongoing incident learning should be conducted to identify error pathways as they arise and incorporate into the plan/chart review process as necessary.

- Staff responsible for plan/chart should be provided with the tools and environment for success. This includes sufficient time for completing the plan/chart review, a quiet environment, and adequate training (Section 5).
- Failure modes that are out of the scope of medical physics practice should be considered by other professional groups at the departmental and national/international levels (e.g. Table S1.B.i part 2).
- Practices should work to incorporate physics reviews as early in the workflow as possible and not rely solely on review at the end-of-treatment planning (Section 5).
- The initial physics plan/chart review should be performed prior to the first treatment fraction. Approval requirements should be enforced with treatment lockout functions (Section 5.A).
- Physics plan/chart review should be performed by a QMP or, if the review is performed by someone who is not a QMP then, at a minimum, this work should be supervised by a QMP (Section 5).
- Tools such as checklists (e.g. Table S1.A.iii) and standardization should be used to enhance the performance of physics plan and chart review. They may also serve as communication tools. Forcing functions should also be used when they are available, e.g. an interlock in the OIS to prevent treatment until physics approval is complete, which is available in some systems and is configurable (Section 5).
- Software vendors should aim for the following goals (Sections 2.D and 5.E).

a Employ design features and forcing functions where possible to prevent error.
b Develop automated tools to assist with physics plan and chart review tasks. But also maintain an awareness of the limits of automation.
c Present information in a way that is easily reviewed by the clinical medical physicist and consider human-computer interface elements to minimize error. For further discussion see Section 5.E. This section also presents an example of weekly review where required information could be presented in a single interface in an intuitive format.
d Develop workflow tools to assist in the communication and enforcement of review

- Manual transcription and entry of data should be avoided, especially the manual transcription of plan and field information between a planning system and a treatment management system/treatment control system (TMS/TCS). In clinics or clinical situations where manual entry is necessary (e.g. emergency treatments with clinical setups, TBI treatments, etc.) caution must be used. Vendors and clinics are encouraged to develop solutions to eliminate the need for manual entry.

8. CONCLUSIONS

TG-275 provides specific recommendations for physics plan and chart review based on a formal risk assessment and, in the case of photon/electron EBRT, a survey of AAPM member practices. Numerous high-risk failure modes were identified. In many cases these failure modes had a corresponding check which may identify such errors. In some cases these checks are widely used but in others they are not, representing an area for improvement. Example checklists are provided as guidance for physics reviews. These include checklists for photon/electron EBRT initial, weekly and EOT reviews, proton radiotherapy and HDR-GYN. Some failure modes lie outside the purview of medical physicists and represent an area of improvement for other medical professionals. The review process could be greatly enhanced with the following key software improvements: automating checks where possible, presenting information in a logical way to aid review, and providing workflow tools for communication and interlock functionality.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1.A.i: Photon/electron external beam radiotherapy high-risk failure modes for initial plan/chart review.
Table S1.A.ii: Photon/electron external beam radiotherapy initial plan/chart review checks.
Table S1.A.iii: Example checklist for photon/electron external beam radiotherapy initial plan/chart review.
Table S1.B.i: High-risk failure modes for photon/electron external beam radiotherapy weekly chart review.
Table S1.B.i (part 2): Failure modes for photon/electron external beam radiotherapy for weekly chart checks by other personnel within the RO department; RTT and/or MD.
Table S1.C.i: High-risk failure modes for photon/electron external beam radiotherapy for end-of-treatment chart review.
Table S1.B.iii: Example checklist for photon/electron external beam radiotherapy for weekly chart review.
Table S1.C.iii: Example checklist for photon/electron external beam radiotherapy end-of-treatment chart review.
Table S2.A.i: Failure modes for proton radiotherapy.
Table S2.A.ii: Proton therapy initial plan/chart review checks.
Table S3.A.i: Failure modes for high-dose rate gynecological brachytherapy.
Table S3.A.iii: Example checklist for high-dose rate gynecological brachytherapy initial plan/chart review.
Supinfo 2. Digital versions of the Tables in this report.

Table S1.A.i. Photon/electron EBRT high-risk failure modes for initial plan/chart review. Failure modes (FMs) with *RPN*>100 are listed in order of decreasing RPN. For each FM the number of checks is listed, i.e. the number of different checks from Table C1.i which might identify this failure mode.

FM#	Process step	Failure mode	Cause	# checks	RPN	S	O	D
1	Tx plan	"Wrong" or inaccurate MD contours	Workflow/communication Issue, for example, attending MD does not review resident contours, MD does not clearly identify dose levels, incorrect CT dataset, fusion incorrect or with wrong image set, target motion not considered, wrong set of contours imported	7	261.3	7.4	4.9	7.2
2	Pt assmnt	Miscommunication about prior dose, pacemaker, pregnancy	Information not communicated or available information incorrect	4	214.1	7.4	5.5	5.3
3	Tx plan	Improper margins for PTV	Structural issues, for example, policies and procedures inadequate or non-existent, margins not provided	2	198.0	5.5	6.0	6.0
4	Tx plan	Unintentional re-irradiation of a previously treated area	Technical issue: Inadequate medical records in hospital data base, re-creation of prior plan incorrect, missing previous RT dose structure, no records available (foreign country, distant past, lost)	3	181.2	7.7	3.8	6.2
5	Pt Assmnt	Incorrect or missing pathology	Pathology report incorrect or not read by MD	3	180.3	6.8	3.6	7.3
6	Tx plan	Dose in plan does not match intended	Wrong Rx provided to planner, for example, why: MD wrote wrong Rx (typo, e.g. 220x30 vs. 200x33) maybe via email, MD unintentionally writes Rx to max dose, wrong Rx signed off in chart or Rx not signed	7	175.3	6.4	5.8	4.8
7	Tx plan	"Wrong" or inaccurate dosimetrist contours	Human performance issue by dosimetrist or other, e.g. distraction or interruption, inattention, slip, lack of training, mistakes CTV for PTV, forgets to expand CTV to PTV, full structure not contoured (e.g. partial cord in Tx region)	5	175.2	6.2	5.5	5.2
8	Pt assmnt	Sub-optimal treatment plan or approach related to communication or coordination with multidisciplinary care	Lack of coordination or miscommunication with e.g. surgeons, med onc, etc.	4	160.2	4.9	4.3	7.6
9	Pt assmnt	Plan does not reflect intent: target extent (e.g., prostate/SVs vs prostate/SVs & nodes)	Incomplete or incorrect treatment planning note or prescription	2	159.1	6.5	4.4	5.6
10	Pt assmnt	Unable to assess potential overlap of prior and current treatment fields	Missing or inadequate prior radiation records	3	155.9	6.5	4.8	5.0
11	Pt assmnt	Additional Imaging (e.g., 4D, PET) not performed	MD did not request	2	153.2	4.6	5.5	6.1

(Continues)

Table S1.A.i. Continued.

FM#	Process step	Failure mode	Cause	# checks	RPN	S	O	D
12	Tx plan	Wrong normal tissue or critical structure dose	Miscommunication or slip. For example, special OAR tolerances not provided to planner (e.g. prior Tx), missing info on previous dose, MISSING planning note, OAR dose-volume exceeded/not reviewed, missing or incorrect contours	8	150.3	6.2	5.4	4.5
13	Pt assmnt	Wrong preliminary prescription (e.g. wrong energy, dose/# fx, bolus, type of image guidance)	Either diagnosis confused or MD confused/misinformed leading to wrong Rx	12	144.5	5.0	5.7	5.1
14	Tx plan	Poor registration between different imaging studies	Lack of training; sub-optimal images registered; incorrect images registered; registration not reviewed by MD; poor choice of studies (e.g. PET emission only vs planning CT scan); inadequate registration tools	3	144.2	4.9	5.5	5.3
15	Tx plan	Plan does not reflect intent: Incorrect fractionation scheme	Missing or incorrect treatment planning note or standardized prescriptions (e.g. treatment regimen) without which review is difficult.	7	143.2	5.4	4.7	5.7
16	Pre-Tx rev	Plan reviewed incorrectly by attending MD	Covering MD (not familiar with case details), MD rushed	0	138.9	4.5	4.2	7.5
17	Tx plan	Wrong target dose	Wrong Rx due to causes other than a mismatch in intent vs. planned. For example, MD changes mind, typo in Rx, Rx not provided so planner uses a placeholder Rx	8	137.9	6.3	4.7	4.7
18	Tx plan	Missing MD or dosimetry contours	Lack of standard procedures, inadequate training, relevant structures not populated	4	135.0	5.8	5.4	4.3
19	Sim	Patient pregnancy status not assessed	Sim therapist forgets to ask or no standard policy	2	134.0	6.3	3.1	6.9
20	Tx plan	Plan does not reflect intent: Boost/no boost	Missing or incorrect treatment planning note	6	131.9	5.8	4.5	5.1
21	Sim	Inappropriate abdominal compression used	Too little compression (does not limit motion enough)	4	131.5	4.3	4.5	6.9
22	Sim	Dosimetrist or physicist not informed about an outside image (e.g. MRI/PET)	No MD order	2	130.7	3.9	4.5	7.4
23	Pt assmnt	Insufficient patient screening during CONSULT	MD did not screen patient for cardiac device	3	125.7	5.5	4.5	5.0
24	Sim	wrong setup instructions (e.g. wrong breast board settings, bolus, etc.)	Therapist inattention to workflow; wrong Setup photos; typo by therapists; setup changes during simulation and changes not noted; plan changed in treatment planning and setup notes no longer reflect intended	8	124.4	3.7	6.2	5.5
25	Sim	Wrong scan used for planning	Patient with multiple CT scans or outside images and no clear direction as to which one to use	3	122.8	4.8	4.3	6.1
26	Pt assmnt	Very (dangerously) wrong preliminary prescription	MD confused or misinformed	3	122.5	8.2	2.6	5.7
27	Sim	Wires for site demarcation not in the correct place	Wires shift after mask is placed	2	120.5	4.9	3.6	6.8
28	Pt assmnt	Treatment strategy not standard of care (Suboptimal)	MD confused or misinformed, MD inattention, inadequate oversight of resident by attending MD	3	120.3	4.3	4.5	6.2
29	Tx plan	Incorrect images registered	Incorrectly labeled (ex. wrong date) image sequence	2	119.6	4.3	4.4	6.3
30	Sim	Wrong special prep ordered (e.g. contrast in allergic patient is worst case)	MD confusion and/or therapist confusion	1	115.7	3.8	4.6	6.6
31	Pt assmnt	Incorrect laterality	Missing or incorrect treatment planning note	6	114.8	7.3	3.5	4.5
32	Sim	Incorrect CT dataset (e.g. 4D/non-4D) imported into patient's plan	Human error by simulation therapists, dosimetrist or physicist	4	113.8	4.7	4.5	5.4
33	Tx plan	Treatment devices omitted (such as bolus)	Miscommunication; not included in sim documentation; not included in treatment planning note; not specified by physician	6	112.7	4.2	5.5	4.9
34	Pt assmnt	Treatment strategy not standard of care (grossly deviates)	MD confused or misinformed, MD inattention, inadequate oversight of resident by attending MD	3	110.0	6.4	3.2	5.5
35	Tx plan	Suboptimal plan	Beam or arc arrangement suboptimal, not enough flash, field matching incorrect, optimization objectives missing or wrong, suboptimal field weighting	8	108.3	3.8	6.4	4.5

(Continues)

Table S1.A.i. Continued.

FM#	Process step	Failure mode	Cause	# checks	RPN	S	O	D
36	Tx plan	Dose calculation error	Slip, for example, dose calc done for wrong SSD, wrong separation, staff unfamiliar (e.g. trainee or weekend staff coverage)	1	108.2	5.3	4.4	4.7
37	Tx plan	Wrong MU for electron hand calculation	Wrong SSD, wrong energy, wrong depth, wrong factors from tables, wrong Rx line for calc, wrong thickness in bolus, physical measurements not taken for small cutout, typo entering parameters in R&V,	7	107.6	5.2	5.0	4.2
38	Tx plan	Shifts not communicated	Dosimetry did not notice shifts were erroneously made during planning, or shifts were correct but dosimetry did not document shifts	4	107.3	4.5	5.6	4.3
39	Sim	Isocenter incorrectly or inconveniently set	MD identifies wrong target or MD confusion	1	107.0	5.5	3.5	5.5
40	Pre-Tx rev	Physician peer review (chart rounds) not performed or inadequate	Standard procedure not followed (did not make it on list), not reviewed due to high-volume at chart rounds, policy for review is lacking	2	106.2	3.9	4.8	5.6
41	Sim	For cases where MD designs apertures at simulation (e.g. electron boosts, simple treatments): wrong apertures	Inattention or lack of training of MD	7	105.2	4.4	4.0	6.0
42	Tx plan	Incorrect isocenter in cone-beam CT reference data	CBCT isocenter coordinates changed in IGRT system (e.g., ± polarity typo in OIS)	2	105.2	6.4	3.3	4.9
43	Tx plan	Incorrect field parameters	Typo entry in R&V, TPS default energy (e.g. 6X) not changed by planner , FS changed not executed, collimator angle change but leaf positions not updated, collimator angle not changed after xfer to new unit, gap wrong after adjacent fields were modified.	29	105.1	5.6	4.4	4.3
44	Tx plan	Plan performed on wrong CT scan	Free-breathing scan used instead of breath-hold. Similar to #32 but patient scanned both ways and unclear communication/documentation.	6	104.9	4.4	4.8	5.0
45	Pt assmnt	Miscommunication on treatment strategy from the physician to the rest of the team. Includes: intent (curative vs. palliative), image-guidance, respiratory management, etc.	Information not communicated at all (physician forgets, team overlooks a note, etc) or information is present but does not match intent. e.g. a typo from the physician, typed in information from a wrong patient	12	104.0	3.6	6.2	4.6
46	Tx deliv	Pacemaker/defibrillator patient not monitored adequately during treatment	Monitoring not requested and/or presence of device not communicated	2	100.3	5.4	3.6	5.2

Table S1.A.ii. Photon/electron EBRT initial plan/chart review checks. Review check data are drawn from the AAPM all-member survey. For each check the number of corresponding failure modes (FM) is listed as well as the highest *RPN* of the corresponding FM. FMs that were not included in the final ten-point FMEA are listed as "N/A". Status indications are: ++ priority check (*RPN*>100 and use>60%), + physics check target for improvement (*RPN*>100 and use<60%), and "OP" other professional priority check (i.e. *RPN*>100 but outside the physics domain). The column "Auto. target" indicates checks that are targets for automation. "F" full automation, that is, can potentially be fully automated. "P" partial automation, i.e. can potentially automate whether particular information is present (e.g. a document exists) but not whether the information in it is correct.

Physics check item		Corresponding failure modes	# FM	Highest RPN	Use Freq	Status	Auto. target
Patient assessment							
PA-Q1-1	Prescription (with respect to standard of care or institutional clinical guidelines)	6,9,13,15,17,20,26,28,34,67	10	175.3	86%	++	
PA-Q1-2	Prescription approval by attending radiation oncologist	6,17,74,87	4	175.3	92%		F
PA-Q1-3	Diagnosis definition including imaging and outside records	5,8,13,31,45,48	6	180.3	37%	OP	
PA-Q1-4	Pathology Report	5	1	180.3	18%	OP	
PA-Q1-5	Medical Chart to confirm laterality, site, etc.	5,31,48	3	180.3	57%	+	
PA-Q1-6	Special Considerations for radiotherapy (e.g. pacemakers, ICDs, pumps, etc.)	2,19,23,46,68,73,83,91,107,110	10	214.1	89%	++	P
PA-Q1-7	Previous radiotherapy treatments	2,4,10,12,23,58	6	214.1	87%	++	P
PA-Q1-8	Utilization of other treatment modalities (i.e. chemo, surgery)	8,76	2	160.2	24%	OP	

(Continues)

Table S1.A.ii. Continued.

Physics check item		Corresponding failure modes	# FM	Highest RPN	Use Freq	Status	Auto. target
PA-Q1-9	Patient Information entered into the radiation oncology information system	71	1	82.3	64%		F
PA-Q1-10	Plan conforms to clinical trial (as applicable)	8,28,34	3	160.2	55%	+	F
PA-Q1-11	Patient Consent	None		N/A	29%		P
PA-Q1-12	Peer review of treatment decision (e.g. tumor board, peer-to-peer evaluation, etc.)	8,13,26,28,34,40,77	7	160.2	17%	OP	P
PA-Q1-13	Consult Note	2,10,19,23,46,68,73,83	8	214.1	35%	OP	P
PA-Q1-14	Insurance Approval	None		N/A	11%		P
PA-Q1-15	Other				13%		
Simulation							
Sim-Q1-1	Physician directive for imaging technique, setup and immobilization (this may include: contrast, scanning orientation, immobilization device, etc.)	21,22,25,30,33,44,45,51,52, 53,108,109	12	131.5	73%	++	P
Sim-Q1-2	Description of target location on physician planning directive (e.g. RUL Lung, H&N, L1-L4)	9,27,31,48,65,90	6	159.1	86%	++	P
Sim-Q1-3	Utilization of immobilization and ancillary devices	21,24,33,47,51,52,59	7	131.5	70%	++	
Sim-Q1-4	Construction of immobilization and ancillary devices	21,24,33,51,59	5	131.5	38%	OP	
Sim-Q1-5	Written or photographic documentation of patient positioning, immobilization and ancillary devices	24,33,47,52,59	5	124.4	70%	++	P
Sim-Q1-6	Isocenter placement	27,39,47,63,78,80	6	120.5	84%	++	
Sim-Q1-7	Isocenter consistency between patient marking and setup instructions	47,63,78,80	4	98.4	74%		
Sim-Q1-8	Patient set up and positioning	24,47,51,52	4	124.4	75%	++	P
Sim-Q1-9	Set up note	24,47,52	3	124.4	69%	++	P
Sim-Q1-10	CT Scanner technique (e.g. kV, filter, etc.)	109	1	33.4	19%		
Sim-Q1-11	CT scan artifacts	85	1	73.6	59%		
Sim-Q1-12	CT scanning range (i.e. superior – inferior range includes entire target and Organs-at-Risk)	108,109	2	35.2	57%		
Sim-Q1-13	CT scan field of view and clipping of anatomy	50,108,109	3	95.6	66%		
Sim-Q1-14	Use of contrast and corresponding effects on HU number	50,85	2	95.6	59%		
Sim-Q1-15	Consistency between orientation of image on the CT scan and treatment plan	48,64	2	97.9	72%		F
Sim-Q1-16	Transfer of image set(s) to treatment planning system	14,25,32,44,54,55,71,89	8	144.2	57%	+	F
Sim-Q1-17	Transfer of images to archiving system	None		N/A	15%		F
Sim-Q1-18	Other:				4%		
	2) Items Reviewed that are part of the Motion Management Techniques Process:						
Sim-Q2-1	4D CT parameters and data set	11,32,44,45,54,86	6	153.2	63%	++	
Sim-Q2-2	Breath-hold parameters and data set	11,32,44,45,54,86,109	7	153.2	41%	+	
Sim-Q2-3	Gating parameters	44,45,54,109	4	104.9	23%	+	
Sim-Q2-4	Other				7%		
Treatment planning							
	Contouring checks	**Yes: 77%**					
	items reviewed during contour checks:						
TP-Q1a-1	Target(s)	1,3,7,18	4	261.3	65%	++	P
TP-Q1a-2	Organs-at-Risk (OAR's)	1,7,18	3	261.3	69%	++	P
TP-Q1a-3	Body/External contour (if required/applicable)	1,7	2	261.3	57%	+	P
TP-Q1a-4	PTV and OAR Margin	3,7,18	3	198	59%	+	F
TP-Q1a-5	Structures used during optimization	35	1	108.3	39%	+	F
TP-Q1a-6	High-Z material, contrast, artifacts	50,85	2	95.6	66%		
TP-Q1a-7	Contours density override	50,85	2	95.6	65%		F
TP-Q1a-8	Approval of contours by MD	None		N/A	29%		F
TP-Q1a-9	Supporting structures (i.e. couch, immobilization and ancillary devices, etc.)	None		N/A	59%		F

(Continues)

Table S1.A.ii. Continued.

Physics check item		Corresponding failure modes	# FM	Highest RPN	Use Freq	Status	Auto. target
TP-Q1a-10	Other				5%		
	Prescription checks (physician intent/Rx vs. treatment plan)	**Yes: 97%**					
	Items reviewed for prescription checks:						
TP-Q2a-1	Site	31,56,77	3	114.8	94%	++	F
TP-Q2a-2	Laterality	31,48,90,100	5	114.8	75%	++	F
TP-Q2a-3	Total dose	6,13,17,20,26,61,81	7	175.3	96%	++	F
TP-Q2a-4	Energy	13,37,43,60,104	5	144.5	91%	++	F
TP-Q2a-5	Bolus	24,33,37,52,53,59,61	7	124.4	90%	++	F
TP-Q2a-6	Dose/fraction	6,15,17,81	4	175.3	96%	++	F
TP-Q2a-7	Number of fractions	6,15,17,20,81	5	175.3	96%	++	F
TP-Q2a-8	Fractionation pattern Note: this should also include check of dose charted in a secondary EMR (e.g. EPIC) for communication with other providers and as a backup.	6,15,20,67	4	175.3	85%	++	F
TP-Q2a-9	Additional shielding	41,58,70	3	105.2	61%	++	
TP-Q2a-10	Prescription vs consult note	4,15,17,31,68,77	6	181.2	39%	+	
TP-Q2a-11	Modality (e.g. electrons, photons, protons, etc.)	None		N/A	92%		F
TP-Q2a-12	Technique (e.g. 3D, IMRT, VMAT, SBRT, etc.)	None		N/A	92%		F
TP-Q2a-13	Regimen (e.g. BID, Quad Shot, etc.)	15,67	2	143.2	78%	++	F
TP-Q2a-14	Other				6%		
	Isocenter checks (documentation of isocenter location, e.g. shifts, multiple isocenters)	**Yes: 95%**					
	Items reviewed for isocenter checks:						
TP-Q3a-1	Additional shifts	38,49,65,78,80,92,96	7	107.3	87%	++	F
TP-Q3a-2	Multiple isocenters	56,65,77,92	4	91.3	82%		F
TP-Q3a-3	Others				9%		
	Optimization or calc parameters checks (target and OAR objectives, algorithms, grid size, etc.)	**Yes: 82%**					
TP-Q4a-1	Target planning objectives	35	1	108.3	58%	+	F
TP-Q4a-2	Organs-at-risk planning objectives	12,35	2	150.3	57%	+	F
TP-Q4a-3	Normalization	50,82	2	95.6	70%		F
TP-Q4a-4	Calculation algorithm	50	1	95.6	69%		F
TP-Q4a-5	Calculation grid size	None		N/A	69%		F
TP-Q4a-6	Density override	50,85	2	95.6	71%		F
TP-Q4a-7	Electron density-HU table	None		N/A	38%		F
TP-Q4a-8	Other				5%		
	Dose distribution and overall quality of the plan						
TP-Q5-1	DVH statistics	12	1	150.3	96%	++	F
TP-Q5-2	Target coverage	17,35,82	3	137.9	94%	++	F
TP-Q5-3	Sparing of OARs	7,12,18,35	4	175.2	91%	++	F
TP-Q5-4	Dose distribution	35,50,60,82	4	108.3	92%	++	
TP-Q5-5	Hot spots	35	1	108.3	92%	++	F
TP-Q5-6	Prior radiation	2,4,10,12,58,108	6	214.1	87%	++	P
TP-Q5-7	Plan sum (e.g. original plus boost plans)	12,20,61	3	150.3	93%	++	
TP-Q5-8	Other				5%		
	Standard operating procedures of practice followed or correctly used						
TP-Q6-1	Beam arrangement	35	1	108.3	85%	++	F
TP-Q6-2	Beam deliverability	None		N/A	74%		F
TP-Q6-3	Treatment technique (e.g. 3D, IMRT, VMAT, SBRT, etc.)	45	1	104	94%	++	F
TP-Q6-4	Field ID or name	None		N/A	87%		F
TP-Q6-5	Course and plan ID	56,98,103	3	91.3	82%		F

(Continues)

Table S1.A.ii. Continued.

Physics check item		Corresponding failure modes	# FM	Highest RPN	Use Freq	Status	Auto. target
TP-Q6-6	Setup note	24,47,52,59	4	124.4	71%	++	P
TP-Q6-7	Delivery system (e.g. linac or other specialized unit)	None		N/A	73%		F
TP-Q6-8	Beam modifiers (e.g. wedges, electron and photon blocks, tray, etc.)	53,88,105,111	4	95.2	92%		F
TP-Q6-9	MU	37,53,72	3	107.6	96%	++	F
TP-Q6-10	Energy	13,37,43,60,73,104	6	144.5	96%	++	F
TP-Q6-11	Dose rate	None		N/A	79%		F
TP-Q6-12	Field size	43,58,72	3	105.1	86%	++	F
TP-Q6-13	Field aperture	41,43,58,70,72	5	105.2	78%	++	
TP-Q6-14	Tolerance table	None		N/A	81%		F
TP-Q6-15	Field delivery times	None		N/A	55%		
TP-Q6-16	Bolus utilization	13,24,33,37,52,53,59,61	8	144.5	91%	++	F
TP-Q6-17	Collision	None		N/A	56%		F
TP-Q6-18	Setup shifts	38,49,80	3	107.3	83%	++	
TP-Q6-19	Treatment couch model	None		N/A	56%		F
TP-Q6-20	Reference points	49,63,80	3	96.1	78%		F
TP-Q6-21	Dose tracking	112	1	30	78%		F
TP-Q6-22	Dose breakpoints	None		N/A	47%		F
TP-Q6-23	Treatment plan warnings/errors	None		N/A	74%		P
TP-Q6-24	Other				4%		
	Data transfer from TPS to a 3rd party OIS (e.g. Eclipse to MOSAIQ, Pinnacle to ARIA, etc.)	**Yes: 66%**					
TP-Q7a-1	Field ID or name	43,94	2	105.1	63%	++	F
TP-Q7a-2	Dose/fraction	43,81,94	3	105.1	67%	++	F
TP-Q7a-3	Number of fractions	81,94	2	76.7	66%		F
TP-Q7a-4	Fractionation pattern	43,67,81	3	105.1	59%	+	F
TP-Q7a-5	Treatment regimen	43,67,81,94	5	105.1	49%	+	F
TP-Q7a-6	Treatment technique	43,94	2	105.1	62%	++	F
TP-Q7a-7	Treatment machine	43,94	2	105.1	64%	++	F
TP-Q7a-8	Beam arrangement	43,94,112	3	105.1	61%	++	F
TP-Q7a-9	Energy	43,94	2	105.1	67%	++	F
TP-Q7a-10	MU	37,43,81,94	4	107.6	68%	++	F
TP-Q7a-11	Dose rate	43,94	2	105.1	54%	+	F
TP-Q7a-12	Gantry	41,43,94	3	105.2	65%	++	F
TP-Q7a-13	Collimator	41,43,94	3	105.2	64%	++	F
TP-Q7a-14	Field size	41,43,94	3	105.2	63%	++	F
TP-Q7a-15	Field aperture	41,43,94	3	105.2	56%	+	F
TP-Q7a-16	MLC control points	43,81,94	3	105.1	43%	+	F
TP-Q7a-17	Beam modifiers (e.g. wedges, electron and photon blocks, tray, etc.)	43,52,53,88,94,105	6	105.1	64%	++	F
TP-Q7a-18	Field delivery times (if applicable/needed)	43,81	2	105.1	37%	+	F
TP-Q7a-19	Couch parameters	43,78,94	3	105.1	48%	+	□
TP-Q7a-20	Tolerance table	43,78,94	3	105.1	53%	+	F
TP-Q7a-21	Setup note	38,43,52,53,59,61,78,94	8	107.3	45%	+	□
TP-Q7a-22	DRRs	43,64,78,92,93,94	6	105.1	59%	+	F
TP-Q7a-23	Isocenter	38,42,43,64,78,93,94	7	107.3	60%	++	F
TP-Q7a-24	Imaging sequence	43,64,94	3	105.1	30%	+	□
TP-Q7a-25	Dose tracking	43,94,112	3	105.1	50%	+	F
TP-Q7a-26	Dose breakpoints	43,94	2	105.1	30%	+	F
TP-Q7a-27	Warnings/errors	None		N/A	45%		F
TP-Q7a-28	Other				3%		
Setup for image-guidance							
TP-Q8-1	Matching instructions (e.g. 2D/2D, 3D, etc.)	13,45,64	3	144.5	72%	++	

(Continues)

Table S1.A.ii. Continued.

Physics check item		Corresponding failure modes	# FM	Highest RPN	Use Freq	Status	Auto. target
TP-Q8-2	Reference CT	42. 64	2	105.2	68%		F
TP-Q8-3	DRR association	92	1	68.1	79%		F
TP-Q8-4	Reference image (2D or 3D) isocenter	42,93	2	105.2	71%	++	F
TP-Q8-5	Imaging technique	13,45,64	3	144.5	67%	++	
TP-Q8-6	DRR image quality	None		N/A	65%		
TP-Q8-7	Matching structures	13,45,64	3	144.5	56%	+	P
TP-Q8-8	Imaging regimen (e.g. daily, weekly, daily followed by weekly, etc.)	13,45,64	3	144.5	67%	++	F
TP-Q8-9	Other				3%		
	During a patient's treatment course, verify that the original plan and corresponding dosimetry (i.e. DVH, target coverage, OAR sparing, etc...) is still meeting the treatment intent by using the original plan on a new simulation CT set	**Yes: 63%**					
TP-Q9a-1	Old/new CT registration	14,29	2	144.2	61%	++	
TP-Q9a-2	Isocenter placement	49,80	2	96.1	57%		
TP-Q9a-3	Deformed or new contours	1	1	261.3	49%	+	
TP-Q9a-4	DVH comparison	12,17	2	150.3	57%	+	F
TP-Q9a-5	CTV/PTV coverage	17	1	137.9	61%	++	F
TP-Q9a-6	Organs at risk dose limits	12	1	150.3	60%	++	F
TP-Q9a-7	Other				4%		
	If the original plan on the new simulation CT set does not meet the treatment intent, is a new plan created in order to meet the treatment intent?	69	1	83.5			
TP-Q9b-1	Always				59%		
TP-Q9b-2	Usually				31%		
TP-Q9b-3	Sometimes				9%		
TP-Q9b-4	Rarely				1%		
	If a new plan is created, please specify the type of check that is done on the new plan						
TP-Q9c-1	Full plan check				99%		
TP-Q9c-2	Partial plan check				1%		
TP-Q9c-3	No plan check				0%		
	Other checks during the initial plan check process						
TP-Q10-1	Registration/fusion of image sets (CT, PET, MRI, etc.)	1,14,22,29	4	261.3	65%	++	
TP-Q10-2	Image set chosen for treatment planning	1,25,32,44,54,55,62,71,89	9	261.3	70%	++	
TP-Q10-3	Approval of physician intent/prescription	6,74,87	3	175.3	94%	++	F
TP-Q10-4	Physician designed apertures	41,58,70	3	105.2	53%	+	
TP-Q10-5	Physics consult (e.g. evaluation of dose to pacemaker, previous treatment, etc.)	None		N/A	87%		
TP-Q10-6	Parameters and setup for specialized devices (e.g. ExacTrac, VisionRT, RPM, etc.)	45	1	104	55%	+	
TP-Q10-7	Request for in-vivo dosimetry	106	1	45.9	72%		P
TP-Q10-8	Motion management instructions	1,21,44,45,54,109	6	261.3	62%	++	P
TP-Q10-9	Treatment delivery regimen (e.g. daily, BID, regular plan follow by boost, etc.)	13,15,20,67	4	144.5	86%	++	F
TP-Q10-10	Verification plan for patient specific QA measurement	75,95,99	3	80	86%		F
TP-Q10-11	Transferring of treatment plan information (e.g. images, RT dose and RT structures) to archiving system	None		N/A	39%		F
TP-Q10-12	Final plan and prescription approval by physician	6,74,87	3	175.3	91%	++	F
TP-Q10-13	Second calculation check	36,37,50	3	108.2	98%	++	F
TP-Q10-14	Instruction for re-planning	69	1	83.5	46%		
TP-Q10-15	Scheduling of tasks (e.g. weekly chart checks, MD image review, etc.)	40	1	106.2	45%	+	
TP-Q10-16	Other	None		N/A	3%		

Table S1.A.iii. Example checklist for photon/electron EBRT initial plan/chart review. These are adapted from the checks in Table A1.ii. All checks with failure modes of *RPN*>100 are included and those with use frequency >60% are indicated with an asterisk (*). This checklist is provided as an example only and is not meant as a definitive list of all the items to be checked in any given clinic.

Patient assessment and intent

- ☐ Special considerations for radiotherapy (e.g. pacemakers, ICDs, pumps, etc.)*
- ☐ Previous radiotherapy treatments*

Simulation

- ☐ Physician directive for imaging technique, setup and immobilization (this may include: contrast, scanning orientation, immobilization device, etc.) *
- ☐ Description of target location on physician planning directive (e.g. RUL Lung, H&N, L1-L4) *
- ☐ Patient set up, positioning and immobilization*: (a) Appropriate for site and/or per clinical standard procedures, (b) Written or photographic documentation of patient positioning, immobilization and ancillary devices, including setup note
- ☐ Image quality and usability: CT Scan Artifacts, Scan sup/inf Range Includes Enough Data, Scan FOV encompasses all required information, Use of Contrast
- ☐ Motion management*: (a) MD directive, (b) breath-hold parameters, (c) gating parameters, (d) 4D-CT parameters and data set
- ☐ Registration/Fusion of image sets (CT, PET, MRI, etc.)*
- ☐ Patient Orientation - CT information matches patient setup
- ☐ Transfer and selection of image set in treatment planning system*

Treatment planning

Contouring checks

- ☐ Target(s)* - e.g. discernible errors, missing slices, mislabeling, gross anatomical deviations.
- ☐ Organs-at-risk (OAR's)*
- ☐ PTV and OAR Margin* - as specified in the chart and/or per protocol
- ☐ Body/External contour*
- ☐ Density overrides applied as needed (ex. High-Z material, contrast, artifacts, etc.)
- ☐ Consideration of Supporting Structures (i.e. couch, immobilization and ancillary devices, etc.)

Prescription checks (physician intent/Rx vs. treatment plan)

- ☐ Final plan and prescription approval by physician*
- ☐ Prescription (with respect to standard of care, institutional clinical guidelines or clinical trial is applicable)*
- ☐ Site and laterality (incl. medical chart to confirm laterality)*
- ☐ Prescription vs consult note* *(e.g. physician report in EMR on plans for treatment)*
- ☐ Total dose, dose/fractionation, number of fractions*
- ☐ Fractionation pattern and regimen (e.g. daily, BID, Quad Shot, regular plan follow by boost, etc.) *
- ☐ Energy matches prescription*
- ☐ Modality (e.g. electrons, photons, protons, etc.)
- ☐ Technique (e.g. 3D, IMRT, VMAT, SBRT, etc.) matches prescription
- ☐ Bolus*
- ☐ Additional shielding* *(e.g. eye shields, testicular shields, etc. as applicable)*

Standard operating procedures of practice followed or correctly used

- ☐ Treatment technique (e.g. 3D, IMRT, VMAT, SBRT, etc.)*
- ☐ Delivery system *(e.g. standard linac, CyberKnife, Tomotherapy, etc. as applicable)*
- ☐ Beam arrangement*
- ☐ Beam deliverability
- ☐ MU, energy, dose rate*, field delivery times*
- ☐ Field size and aperture, bolus utilization, beam modifiers* (e.g. wedges, electron and photon blocks, trays, etc.)
- ☐ Treatment plan warnings/errors
- ☐ Field ID or name
- ☐ Course and plan ID
- ☐ Tolerance table
- ☐ Potential for collision
- ☐ Setup shifts use standard SOP*
- ☐ Physics consult (e.g. evaluation of dose to pacemaker, previous treatment, etc.)

Dose distribution and overall quality of the plan

- ☐ Target coverage and target planning objectives*
- ☐ Sparing of OARs and OAR planning objectives*
- ☐ Plan conforms to clinical trial (as applicable)*

(Continues)

- ☐ Structures used during optimization*
- ☐ Physician designed apertures*
- ☐ Dose distribution*
- ☐ Hot spots*
- ☐ Reference points and plan normalization
- ☐ Calculation algorithm and calculation grid size
- ☐ Prior Radiation accounted for in plan*
- ☐ Plan Sum (e.g. Original plus boost plans)*

Dose verification

- ☐ Second calculation check and/or QA performed*
- ☐ Verification plan for patient specific QA measurement
- ☐ Request for in-vivo dosimetry

Isocenter checks (documentation of isocenter location, e.g. shifts, multiple isocenters)

- ☐ Isocenter: placement and consistency between patient marking and setup instructions*
- ☐ Additional shifts*
- ☐ Multiple isocenters

Setup for image-guidance and ancillary systems

- ☐ Matching instructions (e.g. 2D/2D, 3D, etc.) and MD directive for IGRT*
- ☐ Matching structures*
- ☐ Reference CT
- ☐ Isocenter on reference image(s), 2D or 3D*
- ☐ DRR association
- ☐ DRR image quality
- ☐ Imaging technique*
- ☐ Imaging regimen (e.g. daily, weekly, daily followed by weekly, etc.)*
- ☐ Parameters and setup for specialized devices (e.g. ExacTrac, VisionRT, RPM, etc.)*
- ☐ Isocenter for specialized devices (e.g. VisionRT, ExacTrac, etc.)*

Task schedules

- ☐ Scheduling of safety-critical tasks (e.g. weekly chart checks, IMRT QA, etc.)*

Checks for a replan, adaptive plan or verification plan (i.e. original plan on new CT)

- ☐ Full plan check if new plan generated
- ☐ Old/new CT registration*
- ☐ Isocenter placement
- ☐ Deformed or new contours*
- ☐ DVH comparison*
- ☐ CTV/PTV coverage*
- ☐ Organs at risk dose limits*

Deviations

- ☐ Any unexpected deviations entered into incident learning system

THE FOLLOWING SECTION IS RELEVANT FOR SOFTWARE SYSTEMS THAT ARE NOT FULLY INTEGRATED (e.g. TPS and OIS from different vendors, or systems from a single vendor in which the databases and variable states cannot be confirmed to be identical, see reference 11)

Data transfer from TPS to a 3rd party OIS (e.g. Eclipse to MOSAIQ, Pinnacle to ARIA, etc.)

- ☐ Field ID or name*
- ☐ Dose/Fraction, fractionation pattern, treatment regimen, number of fractions*
- ☐ Dose tracking, dose breakpoints
- ☐ Treatment technique*
- ☐ Treatment machine*
- ☐ Beam arrangement*
- ☐ Energy, gantry, collimator, couch, tolerance table, beam modifiers (e.g. wedges, trays)*
- ☐ Field size and aperture, MLC control points*
- ☐ MU, Dose rate, field delivery times*
- ☐ DRRs*
- ☐ Imaging sequence to be performed (if programmed in TPS)*

Table S1.B.i. High-risk failure modes for photon/electron EBRT weekly chart review. Only those which are potentially identified by physics review are shown.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
1	Tx Deliv	Incorrect dose administered	Patient was unable to physically maintain position for treatment and one or more fields not treated and no documentation in chart	216.0	3.0	8.0	9.0
2	Tx Deliv	Proper IGRT not performed	Therapist did not follow MD imaging instructions	136.1	4.0	6.3	5.4
3	Tx Deliv	Incorrect dose administered	Chart documentation was unclear/insufficient and one or more fields not treated and no documentation	123.8	5.8	3.5	6.1
4	Tx Deliv	Incorrect dose administered	MD changes dose in prescription and not communicated to planning or treatment therapist	121.9	5.3	4.6	5.0
5	Tx Deliv	Pacemaker not monitored according to instructions	No instructions in chart for in vivo dosimetry	113.7	5.5	3.9	5.3
6	Tx Deliv	Proper IGRT not performed	MD did not review images as per policy	108.0	2.0	6.0	9.0
7	Tx Deliv	Incorrect laterality/site	**First weekly only**: Patient mismarked	103.9	7.1	2.4	6.1
8	Tx Deliv	Incorrect laterality/site	No imaging performed pre-treatment	102.1	7.4	2.3	6.0
9	Tx Deliv	Wrong treatment fields delivered to wrong site during XRT to multiple sites	Unclear/insufficient documentation	98.8	6.3	2.8	5.6
10	Tx Deliv	Fraction not delivered as intended	Treatment delivered out of clinical mode, but not charted	96.0	4.0	4.0	6.0
11	Tx Deliv	Pacemaker not monitored according to instructions	Therapist inattention for in vivo dosimetry	85.1	5.4	3.5	4.5
12	Tx Deliv	Incorrect laterality/site	**First weekly only:** Confusion due to prior treatment in system	79.5	7.5	2.0	5.3
13	Tx Deliv	Incorrect laterality/site	Therapist inattention	64.5	7.5	2.0	4.3
14	Tx Deliv	Incorrect laterality/site	Unclear/insufficient documentation e.g.: no field setup images)	54.0	7.5	2.0	3.6
15	Tx Deliv	Incorrect fields treated	Patient had incomplete prior treatment and the prior plan erroneously sent over and treated or fields were not treated	45.7	6.4	2.1	3.4
16	Tx Deliv	Not all fields administered to particular disease site	Prescription improperly written	41.3	5.0	2.5	3.3
17	Tx Deliv	Incorrect laterality/site	Therapist overrode couch position without documentation. Severity assumes this only happens once in treatment course - not the majority of fractions	33.9	5.1	1.9	3.5
18	Tx Deliv	Incorrect dose administered	Therapist intentionally overrode dose or MU at time of treatment and no documentation	24.1	5.3	1.3	3.5
19	On-Tx quality Mgt	Deviation from treatment not detected	Inadequate review of plan and/or chart e.g.: boost started early, resimulation ordered	138.2	4.8	4.5	6.4
20	On-Tx quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Inconsistent documentation e.g.: script terminated bolus and setup instructions not updated	97.8	3.5	6.5	4.3

Table S1.B.ii. Failure modes for photon/electron EBRT for weekly chart checks by other personnel within the RO department; RTT and/or MD (part 2).

FM#	Process step	Failure mode	Cause	RPN	S	O	D
1	Tx Deliv	Incorrect dose administered	Incorrect orientation of electron cutout	270.0	6.0	5.0	9.0
2	Tx Deliv	Fraction not delivered as intended	Inattention by physician during image review	196.0	4.0	7.0	7.0
3	Tx Deliv	Collision of delivery system with patient	Treatment fields not checked pre-treatment	162.0	6.0	3.0	9.0
4	Tx Deliv	Incorrect dose administered	Incorrect manual shift used	162.0	6.0	3.0	9.0
5	Tx Deliv	Suboptimal plan delivered	No peer-review prior to treatment - per department policy	162.0	4.5	4.8	7.5
6	Tx Deliv	Fraction not delivered as intended	Incomplete or unclear instructions for image registration	160.0	4.0	8.0	5.0
7	Tx Deliv	Fraction not delivered as intended	Treatment not delivered, but marked as competed	144.0	4.0	4.0	9.0
8	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Alternative bolus not appropriate (e.g. wet towel bolus not wet enough or thick enough)	144.0	2.0	8.0	9.0
9	Tx Deliv	Incorrect dose administered	Patient not properly identified and treated with another patient's fields	126.0	7.0	2.0	9.0
10	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Bolus placed incorrectly (partial field vs full field)	126.0	2.0	7.0	9.0

(Continues)

Table S1.B.ii. Continued.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
11	On-TX quality Mgt	Plan not reviewed in chart rounds	Miscommunication - per department policy	120.1	3.3	5.6	6.5
12	Tx Deliv	Incorrect dose administered	Dose delivered out of clinical and not recorded as part of patient treatment	110.0	4.9	3.3	6.8
13	Tx Deliv	Fraction not delivered as intended	Incorrect shift information	108.5	5.4	4.9	4.1
14	Tx Deliv	Fraction not delivered as intended	Beam not turned off when patient moved or unable to maintain treatment position	108.0	3.0	4.0	9.0
15	Tx Deliv	Pacemaker not monitored according to instructions	Telemetry not scheduled	106.7	5.8	4.6	4.0
16	Tx Deliv	Fraction not delivered as intended	Incorrect or inadequate setup instructions.	104.7	3.8	5.3	5.2
17	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Wrong immobilization devices selected	98.0	2.0	7.0	7.0
18	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Bolus not placed due to oversight by RTT	98.0	2.0	7.0	7.0
19	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Therapist inattention	98.0	2.0	7.0	7.0
20	On-TX quality Mgt	Wrong setup device, i.e. bolus, vaclock, etc	Wrong thickness of bolus used	96.0	2.0	6.0	8.0
21	TX delivery	Proper IGRT not performed	Incorrect anatomical site matched (e.g. incorrect vertebral body)	96.0	6.0	4.0	4.0
22	On-TX quality Mgt	Deviation in treatment caught but not relayed to responsible staff	Unclear clinical policy for how or to whom the deviation should be communicated	95.2	5.0	2.8	6.8
23	Tx Deliv	Proper IGRT not performed	Calculated shifts not noted by the planner	95.0	4.5	4.4	4.8
24	Tx Deliv	Suboptimal plan delivered	Plan not reviewed by MD prior to treatment	94.2	5.1	3.3	5.6
25	Tx Deliv	Fraction not delivered as intended	Incorrect plan loaded after replan	91.6	5.3	3.6	4.8
26	Tx Deliv	Fraction not delivered as intended	Incorrect or absent MLC aperture or control points	88.8	6.0	4.0	3.7
27	Tx Deliv	Fraction not delivered as intended	Inattention by treatment therapist during pre-treatment imaging.	80.0	5.0	8.0	2.0
28	Tx Deliv	Fraction not delivered as intended	Couch positions substantially different from plan or initial filming day.	65.4	5.5	4.1	2.9
29	Tx Deliv	Proper IGRT not performed	Considerable patient anatomy change from simulation to treatment	60.0	5.0	6.0	2.0
30	Tx Deliv	Fraction not delivered as intended	Incorrect override of machine parameter (e.g. collimator, gantry, jaw position)	45.9	5.0	2.7	3.4
31	Tx Deliv	Incorrect dose administered	Incorrect electron cutout	36.0	6.0	3.0	2.0

Table S1.B.iii. Example checklist for photon/electron EBRT for weekly chart review. Checks with a use frequency >50% in the survey are indicated with an asterisk. Checks performed on first weekly chart review or for plan revision only are indicated with ^. This checklist is provided as an example only and is not meant as a definitive list of all the items to be checked in any given clinic.

Check performed
Documentation and communication
☐ Modification of prescription or plan*
☐ Prescription matches plan (change in prescription during course of treatment and not communicated to planning or treatment therapist)*
☐ Prescription signed*
☐ IMRT QA performed, reviewed and appropriate*^
☐ Treatment history (review chart for correct site treated and old fields are "hidden" and cannot be confused with the current fields)*^
☐ Special instructions or needs (pacemakers, medications, chemo, blood counts, etc.)*
☐ Prescription appropriate for treatment (according to department standards)*^
☐ Treatment notes (documentation for overrides, patient inability to maintain treatment position, placement of bolus or other treatment aide not verified automatically)*
☐ Documentation of special procedures (e.g. SBRT, TBI, TSE, etc)*
☐ In vivo dosimetry (In vivo dosimetry not ordered, especially for cardiac devices)*
☐ Patient alerts*
☐ Weekly SSD checks*

(Continues)

Plan parameters

- ☐ MU, energy, field size, gantry, collimator, MLC, dose rate*
- ☐ Treatment modality (e.g. photons, electrons, etc.)*
- ☐ Treatment technique (e.g. IMRT, VMAT, 3D conformal, etc.)*
- ☐ Beam modifier (e.g. wedges, electron and photon blocks, tray, etc.)*
- ☐ Plan parameter override (especially dose and/or MU and no documentation)*
- ☐ Dose limit override (no documentation)*
- ☐ Couch position (vertical/lateral/longitudinal/rotational)*
- ☐ Couch position acquired at time of verification*
- ☐ Setup instructions (review for incorrect, unclear or insufficient documentation pertaining to laterality and site; multiple site cases; missing setup images; changes in script; bolus terminated)^
- ☐ Correct fields treated (especially in cases with prior treatment that was incomplete; boost started early; resimulation ordered)

Treatment progression

- ☐ Fraction treated (review all fields were treated for a given treatment site, especially in cases with prior treatment that was incomplete; boost started early; resimulation ordered)*
- ☐ Dose tracking*
- ☐ Partial treatments*
- ☐ Changes in treatment field parameters*
- ☐ Treatment sessions remaining (verify treatments delivered match treatment sessions and review notes for missed sessions)*
- ☐ Unexpected breaks in treatments*
- ☐ Treatments completed out of clinical mode*
- ☐ In vivo dosimetry (not performed, especially in the case of cardiac devices)
- ☐ Treatment sequence (e.g. first plan followed by boost, etc)*
- ☐ Treatment regimen (e.g. BID, Quad Shot, etc.)*

Image-guidance

- ☐ Images approved (as per department policy, especially pre-treatment imaging)*
- ☐ Shifts applied*
- ☐ Image technique prescribe by MD is followed (e.g. CBCT, 2D kV, 2D MV)*
- ☐ Isocenter on DRRs match plan^

Table S1.C.i. High-risk failure modes for photon/electron EBRT for end-of-treatment (EOT) chart review.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
1	TX Deliv	Incorrect dose administered	MD changes dose in prescription and not communicated to planning or treatment therapist	121.9	5.3	4.6	5.0
2	TX Deliv	Incorrect dose administered	Dose delivered out of clinical and not recorded as part of patient treatment	110.0	4.9	3.3	6.8
3	TX Deliv	Fraction not delivered as intended	Treatment delivered, but not charted	96.0	4.0	4.0	6.0
4	On-TX quality Mgt	Deviation from treatment not detected	Inadequate review of plan and/or chart	138.2	4.8	4.5	6.4

Table S1.C.ii. Example checklist for photon/electron EBRT end-of-treatment (EOT) chart review. Checks with a use frequency >50% in the survey are indicated with an asterisk. This checklist is provided as an example only and is not meant as a definitive list of all the items to be checked in any given clinic.

Check performed	
☐	End-of-Treatment Summary present*
☐	All documents approved*
☐	Course completed (Verify all treatments were delivered as prescribed) OR treatment stopped or cancelled (verify accurate documentation)*
☐	All physics tasks completed*
☐	Review any treatments delivered out of clinical mode
☐	Documented plan matches the prescription and the chart, including changes and revisions (total number of fractions and dose delivered)
☐	All images approved*

Table S2.A.i. Failure modes for proton radiotherapy. For each FM the number of formal checks which might identify this failure mode is listed.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
1	Tx plan	Tumor growth while waiting for treatment start	Waiting for insurance clearance	150.5	4.0	5.7	6.6
2	Sim	Strong, unrepairable metal artifacts	Patient has extensive or high density metal causing severe CT scan artifacts	148.5	3.1	7.5	6.5
3	Tx plan	Over-dosing normal structures	Prior radiation was not considered carefully	133.4	6.3	3.3	6.3
4	Tx plan	Inaccurate proton range calculation	Failure to consider organ motion or setup uncertainties in the beam path	117.9	3.2	5.5	6.7
5	On-TX quality Mgt	Adaptive plan was not created	Failed to review or detect any substantial/meaningful changes in patient''s anatomy in the beam path due to inadequate staff training or no well-established guideline etc.	111.6	3.4	4.9	6.7
6	Tx plan	Inaccurate proton range calculation	Inappropriate manual override of CT numbers (for artifacts or metal objects etc.)	106.1	3.4	4.8	6.5
7	Tx plan	Over-dosing normal structures	Inadequate treatment robustness evaluation	102.9	3.5	4.9	6.0
8	Pre-Tx Rev	Patient specific devices were not manufactured	Wrong plan sent to machine shop	101.6	4.0	3.6	7.0
9	Tx plan	Over-dosing normal structures	Inadequate range uncertainty estimation	101.5	4.0	4.3	5.9
10	Tx plan	Inaccurate proton dose calculation	Inaccurate modeling of proton beams	99.7	3.6	3.9	7.1
11	Tx plan	Inaccurate proton dose calculation	Failure to select the correct beam modifying devices or device settings (range shifter, compensator drill bit sizes, aperture thickness)	98.9	4.0	4.0	6.2
12	Tx plan	Inaccurate proton range calculation	Inappropriate "body contour" delineation that exclude a portion of the immobilization device or human tissue in the proton beam path	97.4	3.6	4.1	6.6
13	Sim	Wrong CT imaging condition was used for proton planning (wrong kV, filter settings, contrast CT only etc)	Wrong CT imaging parameters were used that might alter the CT number calibration for proton stopping power calibration	96.6	3.3	4.5	6.6
14	Pre-Tx Rev	Non-ideal proton plans used for patient treatment	Inadequate review of plan robustness	96.5	2.8	5.3	6.5
15	Tx plan	Inaccurate proton range calculation	Failure to delineate or model couch support device in the beam path	96.3	3.1	4.9	6.3
16	Tx plan	Incorrect or inadequate documentation of setup, treatment devices, or composite plans	Failure to communicate patient setup position, treatment devices needed, or immobilization devices	95.0	3.5	4.6	5.9
17	Pre-Tx Rev	Non-ideal proton plans used for patient treatment	Inadequate consideration of setup error and organ motion	93.5	2.9	5.2	6.2
18	Tx plan	Inaccurate proton dose calculation	Wrong CT data set was used for proton dose calculation	93.3	4.4	3.2	6.7
19	Tx Deliv	Patient treatment devices were incorrectly selected	Mismatch in device IDs or human errors in manual selection of accessory devices (compensators, apertures, etc.)	89.8	3.8	3.6	6.7
20	Tx Deliv	Inaccurate beam delivery	Patient has "accessory" added or removed from beam path: i.e. port placed after treatment starts, surgery drain removed, a patient specific range shifter/bolus was not placed or incorrect etc.	88.6	3.8	4.4	5.3
21	Tx Deliv	Failure to deliver the proton beam	Machine problems	88.1	1.6	8.6	6.4
22	Tx plan	Inaccurate proton range calculation	Image artifacts reduced the accuracy of CT numbers	87.8	1.9	6.9	6.7
23	Sim	Entire body or immobilization devices were not scanned into the planning CT for accurate proton range calculation	Inappropriate FOV or patient body position selection that causes missing tissues in the planning CT	87.8	2.7	5.4	6.0
24	Tx plan	Inaccurate proton dose calculation	Non-robust spot spacing or layer change parameters	86.8	2.6	5.3	6.3
25	Tx Deliv	Collision	Indexing was incorrect; patient setup position conflicts; conflicting couch position with cone-beam CT scanning	85.3	2.5	5.5	6.2
26	Pre-Tx Rev	Incorrect treatment devices were selected	Correct plan but incorrect devices selected	85.2	4.2	3.6	5.7
27	Tx plan	Inadequate target dose coverage	Inadequate range uncertainty estimation	83.8	2.9	5.4	5.3
28	Pre-Tx Rev	Patient plan was not uploaded or incorrectly updated	Human error in manual processes involved in uploading proton plans	83.0	2.7	4.4	7.0
29	Tx plan	Over-dosing normal structures	Inadequate margin for setup	82.6	4.1	4.1	4.9
30	Tx Deliv	Collision	Incorrect snout position was used	81.6	2.9	4.2	6.7
31	Tx plan	Inaccurate proton range calculation	Failure to consider the movement uncertainties of immobilization devices in the beam path	81.2	3.1	5.0	5.2
32	On-TX quality Mgt	Adaptive plan was not created	Insufficient imaging (for example, in CBCT imaging or 2D kV x-rays) to review potential changes that may impact proton dose distribution	81.2	3.1	5.0	5.2

(Continues)

Table S2.A.i. Continued.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
33	Tx plan	Inaccurate proton range calculation	Wrong CT data set was used for proton dose calculation	80.9	3.4	3.4	7.0
34	Simulation	Incorrect or non-ideal immobilization device(s) were used for proton simulation	Immobilization device does not extend completely as it should (e.g., vaclock cradle) or varies (towel) for beam path	80.3	2.3	5.6	6.3
35	Tx plan	Inadequate target dose coverage	Inadequate treatment robustness evaluation	80.3	2.9	5.0	5.6
36	Pre-Tx Rev	Patient specific devices were not manufactured	Failure to communicate the construction of patient specific treatment devices (compensators, apertures etc.)	79.5	2.8	4.2	6.8
37	Tx plan	Inadequate target dose coverage	Inadequate margin for setup	79.1	2.9	4.7	5.8
38	Simulation	Inadequate slice resolution or inadequate scan range used in the simulation CT for planning non-coplanar proton beam angles	Wrong scan protocol selected	78.5	2.7	4.3	6.7
39	Pre-Tx review and verification	Non-ideal proton plans used for patient treatment	Inadequate consideration of beam angles	77.6	2.1	5.6	6.6
40	Tx Deliv	Failed to image the patient	Imaging capabilities are inadequate, for example, imaging FOV is too small	77.0	2.8	5.0	5.5
41	Pre-Tx Rev	Non-ideal proton plans used for patient treatment	Inadequate consideration of beam deliverable parameters (spot spacing, the use of range shifters, custom-devices etc.)	76.4	2.4	4.9	6.5
42	On-TX quality Mgt	Adaptive plan was not created	Miscommunication	76.3	3.1	4.1	6.0
43	On-TX quality Mgt	Adaptive plan was not created	Failed to acquire an adaptive CT scan due to CBCT limitations or CT simulation failures; or motion management device failures etc	75.6	2.5	4.2	7.2
44	Pre-Tx Rev	Incorrect treatment devices were selected	Human error in manual processes involved in uploading proton plans	75.7	3.8	3.8	5.4
45	Sim	Incorrect or non-ideal immobilization device(s) were used for proton simulation	Communication that patient may / will receive proton therapy	75.7	2.6	5.2	5.7
46	Sim	Inadequate slice resolution or inadequate scan range used in the simulation CT for planning non-coplanar proton beam angles	Proton beam angles / treatment technique not anticipated / communicated to simulation staff	75.4	2.6	4.9	5.8
47	Sim	Patient simulated position prohibits some proton beam angles (for example, arm-down in lung treatment)	Proton therapy uses fewer beam angles, beam angle availability is important	74.6	1.8	6.7	6.1
48	Tx Deliv	Patient name/ID was misentered on the scanners	Some OIS systems do not fully integrate with proton delivery systems	71.6	3.1	3.0	7.7
49	On-TX quality Mgt	Poor quality in the adaptive plan	Target or normal structure contours did not have good quality	71.3	3.0	4.1	5.8
50	Tx Deliv	Collision	Robotic couch setup was inadequately considered	70.6	2.3	5.2	5.9
51	Tx Deliv	Patient treatment devices were incorrectly selected	Incorrect gantry/couch angle used due to poor OIS communication (poorly integrated OIS)	70.1	4.0	2.7	6.6
52	Pre-Tx Rev	Non-deliverable treatment plans	Failure to deliver certain proton beam modes	68.7	2.4	3.7	7.7
53	Tx Deliv	Failed to image the patient	Unable to image due to setup position or robotic couch support device is in the way	68.0	2.4	4.3	6.4
54	Sim	Incorrect or non-ideal immobilization device(s) were used for proton simulation	Availability of devices used for proton simulation	67.6	2.2	5.1	6.1
55	Pre-Tx Rev	Treatment MU is not measured or confirmed	Insufficient time to perform patient specific QA	67.2	2.4	4.0	6.9
56	On-TX quality Mgt	Poor quality in the adaptive plan	Inadequate time to plan or review the adaptive	67.1	2.3	4.9	5.9
57	Pre-Tx Rev	Non-deliverable treatment plans	Failure to consider machine geometry causing collision issues	67.0	2.0	5.4	6.2
58	Tx Plan	Inadequate target dose coverage	Inappropriate consideration of the balance between target coverage and normal tissue sparing	66.0	2.9	4.9	4.7
59	On-TX quality Mgt	Adaptive plan did not start in time or treatment was delayed	Physicians did not approve the contours or the treatment plan in time	65.4	1.9	6.2	5.6
60	Treatment delivery	Failure to deliver the proton beam	Incorrect planning parameters used	65.4	1.7	5.8	6.8
61	Pre-Tx Rev	Patient specific devices were not manufactured as per standard	Correct plan sent to machine shop but plan is wrong	64.9	2.8	3.6	6.5

(Continues)

Table S2.A.i. Continued.

FM#	Process step	Failure mode	Cause	RPN	S	O	D
62	Pre-Tx Rev	Non-ideal proton plans used for patient treatment	Inadequate consideration of immobilization devices	64.8	2.2	4.6	6.4
63	Pre-Tx Rev	Treatment MU is not measured or confirmed	No secondary MU calculation method available	63.8	2.6	3.6	7.0
64	On-TX quality Mgt	Poor quality in the adaptive plan	Non-optimal plan	63.1	2.2	4.7	6.1
65	Pre-Tx Rev	Patient specific devices were not manufactured	Electronic data communication transfer failure	62.3	2.8	3.7	6.1
66	Pre-Tx Rev	Patient specific devices were not manufactured correctly	Some failure in creation / machining of devices	60.5	2.6	4.0	5.8
67	On-TX quality Mgt	Adaptive plan did not start in time or treatment was delayed	Inadequate time to produce or QA the adaptive plan	55.6	1.6	5.7	6.1
68	Tx plan	Inaccurate proton range calculation	Inherent uncertainties in CT number to proton stopping power conversion	55.4	1.5	6.6	5.6
69	Pre-Tx Rev	Potential for collision	Inappropriate air gap was used to set up snout position	54.7	1.6	6.0	5.7
70	Tx Deliv	Inaccurate beam delivery	Patient positioning not match beam parameters (due to couch auxiliary equipment e.g. HN couch extender)	48.2	3.4	3.0	4.8
71	On-TX quality Mgt	Poor quality in the adaptive plan	Original plan forward calculated on new evaluation CT but calculated incorrectly: i.e. beamline recalculated	46.5	3.1	3.0	5.0

Table S2.A.ii. Proton therapy initial plan/chart review checks. The corresponding failure modes and the highest *RPN* are listed for each check. These include checks specific to proton therapy and also some more general checks related to high-risk items. The frequency of the check used by proton therapy physicists is listed as the percent of total proton physicists participating in the survey.

Physics check item		Highest RPN	Use Freq
Patient assessment			
PA_Pr-Q1-1	Evaluate the impact of implantable metallic objects	148.72	98.0%
Simulation			
Sim_Pr-Q1-1	External metallic appendages (e.g. patient was scanned without rings or clips on ear, nose, brow, hair, tongue, etc.)	148.72	80.9%
Sim_Pr-Q1-2	HU-proton stopping power on CT Scanner	96.75	63.8%
Sim_Pr-Q1-3	HU- proton stopping power table on CT image recon parameters		40.4%
Sim_Pr-Q1-4	Patient hair set up (i.e. not wet, gelled, nor braided)	94.99	38.3%
Sim_Pr-Q1-5	CT Number or relative stopping power override (e.g. high-Z material, contrast, artifacts, etc.)	106.08	97.9%
Treatment planning			
Treatment planning - contouring			
TP_Pr-Q1a-1	Includes everything in the beam path	97.42	100.0%
TP_Pr-Q1a-2	Non-reproducible external objects (e.g. clothing, blankets, hair gel or wet hair, etc.)	88.62	55.3%
	Other		6.4%
Treatment planning - beamline hardware			
TP_Pr-Q2-1	Snout Position	76.44	89.4%
TP_Pr-Q2-2	Snout Size (e.g. range of modulation for the specific target size)	86.81	74.5%
TP_Pr-Q2-3	Snout Air Gap	76.44	89.4%
TP_Pr-Q2-4	Lateral Expansion of the Aperture	76.44	76.6%
TP_Pr-Q2-5	Thickness of Collimator Aperture	76.44	55.3%
TP_Pr-Q2-6	Compensator (drill bit selection, manual modification of compensator, compensator smearing radius)	101.5	78.7%
TP_Pr-Q2-7	Settings for Range Shifter or Energy Absorber	76.44	83.0%
TP_Pr-Q2-8	Custom Ridge Filter	76.44	23.4%
TP_Pr-Q2-9	Other		21.3%
Treatment planning- optimization or calculation parameters			
TP_Pr-Q3-1	Dose Calculation Volume Covers the Beam Path		89.4%
TP_Pr-Q3-2	HU-Proton Stopping Power Table		68.1%
TP_Pr-Q3-3	Dose Grid Size	65.27	83.0%
TP_Pr-Q3-4	Beam Calculation Model	99.68	80.9%
TP_Pr-Q3-5	Beam Weights	65.27	76.6%
TP_Pr-Q3-6	LET/Biological Dose Evaluation		36.2%

(Continues)

Table S2.A.ii. Continued.

Physics check item		Highest RPN	Use Freq
TP_Pr-Q3-7	Optimization Methods (e.g. SFO or MFO)		74.5%
TP_Pr-Q3-8	Other		12.8%
Treatment planning- plan robustness evaluation			
TP_Pr-Q4a	Perform a plan robustness evaluation on proton plans : Yes	102.9	72.7%
TP_Pr-Q4a-1	Individual Beam Coverage for Passive Scattering plans		50.0%
TP_Pr-Q4a-2	Individual Beam Coverage for Scanning Beam SFO plans		59.1%
TP_Pr-Q4a-3	Robust Evaluation for Scanning Beam plans		63.6%
TP_Pr-Q4a-4	Other		9.1%
Treatment planning- beam angle or direction			
TP_Pr-Q5-1	Avoiding large inhomogeneity in the path	77.62	91.5%
TP_Pr-Q5-2	Avoiding sharp gradient (e.g. treatment couch edge in the path)	77.62	95.7%
TP_Pr-Q5-3	Avoiding all beam ranging into a critical structure.	77.62	93.6%
TP_Pr-Q5-4	Avoiding poor modeling conditions (e.g. tangential to surface or bone, bowels, rectum)	77.62	89.4%
TP_Pr-Q5-5	Considering position and geometry of internal organs	117.92	89.4%
TP_Pr-Q5-6	Other		4.3%
Treatment planning- beam matching			
TP_Pr-Q6-1	Patches		53.2%
TP_Pr-Q6-2	Abutment		76.6%
TP_Pr-Q6-3	Sequence and Frequency with respect to total Rx		63.8%
TP_Pr-Q6-4	Individual dose distribution from each beam		87.2%
TP_Pr-Q6-5	Other	85.07	8.5%
Treatment planning- beam margins			
TP_Pr-Q7-1	Check proximal, distal, and lateral beam margins for proton plans	101.48	83.0%
Treatment planning- beam range			
TP_Pr-Q8-1	Review or check each beam range for proton plans	106.08	91.5%
Treatment planning- backup plan			
TP_Pr-Q9-1	Create and review a photon backup plan for a situation when your proton system is not available or down		52.2%
Treatment delivery			
CC_Pr-Q4-1	Repeat imaging (weekly CT/MRI) performed	89.55	72.3%
CC_Pr-Q4-2	Adaptive RT	81.23	42.6%
CC_Pr-Q4-3	Pre-defined order and frequency of field specific deliveries is maintained as planned	82.96	63.8%
CC_Pr-Q4-4	Instruction for re-planning and tolerance levels		59.6%
CC_Pr-Q4-5	Other	85.25	4.3%

Table S3.A.i. Failure modes for HDR gynecological brachytherapy. These failure modes were drawn from the process up to treatment (i.e. initial applicator placement, imaging and treatment planning) as well as some points in post-treatment QA. These are the issues that can be addressed in physics plan and chart review. The column 'checklist' refers to whether these were found on the checklists of the clinics surveyed (see text for detail).

Rank	Process step	Failure mode	Cause	Checklist	RPN	S	O	D
1	Planning	Wrong MD contours	Physical environment - interruptions, MD rushed, etc	Yes	131.8	4.6	4.8	6.0
2	Planning	Catheters digitized incorrectly (e.g. wrong offset, digitizing something other than the catheter)	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc.	Yes	120.8	5.0	4.6	5.3
3	Planning	Incorrect treatment length planned	Communication - MD intention not relayed properly to planner	Yes	119.0	4.9	4.3	5.7
4	Planning	Wrong distal reference length entered into TPS	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	98.3	4.9	3.8	5.4
5	Imaging	Incorrect measurement and/or documentation of channel lengths or number	Slip or lapse caused by inattention, distraction, etc. - staff misread measurement	Yes	95.3	5.1	4.4	4.3

(Continues)

Table S3.A.i. Continued.

Rank	Process step	Failure mode	Cause	Checklist	RPN	S	O	D
6	Imaging	Wrong dataset exported (e.g. 2nd scan performed after applicator adjustment but 1st scan sent for planning)	Communication - Poor, incomplete, unclear, or missing documentation - incorrect scan entered into simulation documentation	Yes	91.6	4.3	3.8	5.8
7	Planning	Channel mapping incorrect (e.g. tandem must be 3 but set to 1)	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	83.5	4.6	4.4	4.1
8	Applicator placement	Shielded cylinder inserted incorrectly	Equipment related - shielding labeling difficult to detect	No	82.0	4.4	3.8	5.0
9	Planning	BED calculated using wrong formulation	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	80.9	3.8	3.8	5.8
10	Planning	Prior treatment not taken into account	Communication - poor incomplete, unclear, or missing documentation	No	78.9	4.9	3.5	4.6
11	Applicator placement	Insufficient packing around applicator - applicator moved	Patient related- patient habitus or anatomy makes insertion and insertion verification challenging	Yes	73.7	2.9	5.0	5.1
12	Imaging	Wrong fiducials inserted into applicator or not inserted fully	Slip or lapse caused by inattention, distraction, etc. time pressure due to schedule or patient discomfort	No	71.4	3.5	5.6	3.6
13	Planning	Poor registration of secondary dataset	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	No	70.5	2.8	5.1	5.0
14	Imaging	Patient not eligible for image modality	Communication - Poor, incomplete, unclear, or missing documentation - incorrect information provided on patient compatibility	No	69.7	4.3	4.4	3.8
15	Planning	Incorrect applicator selected from library (e.g. shielded cylinder vs non-shielded vs stump)	Slip or lapse caused by inattention, distraction, etc	Yes	69.0	3.9	3.8	4.8
16	Applicator placement	Infection	Loss of sterility; not familiar with procedure	No	68.8	4.0	3.1	5.5
17	Planning	Applicator model placed incorrectly on image dataset (not correct with respect to patient anatomy)	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc.	No	68.0	4.0	4.0	4.3
18	Planning	Plan change between MD approval and export to treatment control station	Procedural issues - failure to detect a developing problem - distraction	No	59.1	3.5	3.4	5.0
19	Planning	Prescription dose changed during planning but dwell times not updated	Communication - poor incomplete, unclear, or missing documentation	No	55.1	4.5	3.5	3.5
20	Planning	DVH constraints not met and not noticed	Failure to interpret the nature of a developing problem - missing information (e.g. critical structures not contoured)	Yes	53.1	4.0	4.3	3.1
21	Planning	Incorrect selection of connector end vs tip end	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	No	53.0	4.4	3.1	3.9
22	Planning	Plan does not match prescription (e.g. wrong dose or fractionation)	Communication - Poor, incomplete, unclear or missing documentation	Yes	52.0	4.8	4.4	2.5
23	Planning	Treatment plan does not conform to recognized guidelines	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	51.9	2.9	4.4	4.1
24	Imaging	Incorrect bladder fill	Slip or lapse caused by inattention, distraction, etc. - time pressure due to schedule or patient discomfort	No	51.7	2.6	5.6	3.5
25	Applicator placement	Left and right ovoid crossed during insertion	Equipment related - left/right labeling difficult to detect	No	51.2	3.0	3.3	5.3
26	Applicator placement	Applicator not locked together correctly	Procedural - lack of imaging during applicator insertion, not checking applicator is correctly locked	Yes	50.9	2.6	3.9	5.0
27	Imaging	Scan orientation labeled incorrectly	Slip or lapse caused by inattention, distraction, etc. - time pressure due to schedule or patient discomfort	No	49.3	3.9	2.8	4.6
28	Planning	Source dwells added to catheter outside of applicator device	Slip or lapse caused by inattention, distraction, etc	Yes	48.8	3.8	4.0	3.3
29	Applicator placement	Vaginal cylinder inserted into wrong orifice	Procedural - appropriate imaging not used	Yes	48.3	5.3	2.4	3.9
30	Applicator placement	Tandem perforated cervix	Patient related- patient habitus or anatomy makes insertion and insertion verification challenging	No	47.8	4.0	5.6	2.1
31	Planning	Heterogeneity corrections applied incorrectly (TG-186 formalism)	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	No	47.6	2.5	3.6	5.3
32	Planning	Plan normalized incorrectly	Slip or lapse caused by inattention, distraction, etc	No	45.9	3.8	3.6	3.4

(Continues)

Table S3.A.i. Continued.

Rank	Process step	Failure mode	Cause	Checklist	RPN	S	O	D
33	Planning	Patient not planned per protocol	Communication - poor incomplete, unclear, or missing documentation	No	42.0	2.6	3.9	4.1
34	Applicator placement	Incorrect applicator inserted	Staff not familiar with procedure or confused - MD experience or lack of oversight of residents; applicators stored in incorrect location (shielded or stump cylinders stored in location for standard cylinders)	Yes	39.4	3.6	3.6	3.0
35	Planning	Importing of wrong dataset	Communication - poor incomplete, unclear, or missing documentation	Yes	37.4	3.6	2.8	3.8
36	Post-procedure	Treatment not recorded in record and verify or paper chart	Slip or lapse caused by inattention, distraction, etc	Yes	37.3	4.0	4.7	2.0
37	Planning	Wrong step sized entered into TPS	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	35.4	3.6	3.1	3.1
38	Applicator placement	Ring not inserted high enough into vagina	Procedural - lack of imaging during applicator insertion, not checking applicator has been inserted far enough	No	35.3	3.4	4.0	2.6
39	Imaging	Treatment applicators not compatible with image modality	Communication - Poor, incomplete, unclear, or missing documentation - incorrect information provided on applicator compatibility	No	34.5	4.1	3.4	2.4
40	Planning	Incorrect labeling of OAR	Slip or lapse caused by inattention, distraction, etc	Yes	29.1	2.5	3.9	3.0
41	Applicator placement	Flange not flush with ovoids	Poor imaging; tech not familiar with process	No	28.2	1.9	4.6	3.3
42	Applicator placement	Angled tandem inserted upside down	Procedural - appropriate imaging not used	No	28.1	3.1	3.1	2.9
43	Post-procedure	Post-procedure radiation survey not performed	Slip or lapse caused by inattention, distraction, etc	Yes	25.7	3.0	2.3	3.7
44	Planning	Incorrect source selected in treatment plan	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	25.1	4.3	2.3	2.6
45	Planning	Incorrect selection of afterloader/device	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc	Yes	23.4	2.5	3.0	3.1
46	Applicator placement	Mismatch of angles between tandem/ovoids or tandem/ring	Procedural - lack of imaging during applicator insertion, not checking correct applicator has been inserted	No	22.9	1.8	3.9	3.4
47	Imaging	Imaging does not include enough patient anatomy	Slip or lapse caused by inattention, distraction, etc. - time pressure due to schedule or patient discomfort	No	21.3	2.1	5.0	2.0
48	Applicator placement	Catheter kinked during surgery	Staff not familiar with procedure or confused - Surgeon not aware of consequences of kink; surgical staff not familiar with procedure; Stylet not used during insertion	No	20.3	2.0	3.9	2.6
49	Post-procedure	Proper signatures not obtained	Slip or lapse caused by inattention, distraction, etc	Yes	20.0	1.0	6.7	3.0
50	Post-procedure	Documentation not uploaded to record and verify or recorded in paper chart	Slip or lapse caused by inattention, distraction, etc	Yes	17.6	1.3	5.7	2.3
51	Planning	Secondary dose calculation not performed	Policies, procedures, regulations - Relevant policy nonexistent or not followed	Yes	17.4	1.1	4.0	3.9
52	Imaging	Incorrect scan parameters	Slip or lapse caused by inattention, distraction, etc. - time pressure due to schedule or patient discomfort	No	15.1	1.5	4.3	2.4
53	Post-procedure	Cumulative dose summary not completed	Slip or lapse caused by inattention, distraction, etc	No	12.0	1.7	4.3	1.7

Table S3.A.ii. Example checklist for HDR gynecological brachytherapy initial plan/chart review. This checklist is provided as an example only and is not meant as a definitive list of all the items to be checked in any given clinic.

Priority	Check	Notes/examples	RPN rank
1	Review OAR and target contours for discernable errors	Missing slices, missing contours, names match anatomy	1,39
2	Verify catheter digitization/applicator modeling	Orientation, step size, numbering, mapping, if model is used - that it matches implant and placed correctly	2,7,15,17,21,28,36
3	Verify treatment length	Length reasonable, measured length matches planned length	3,4,5
4	Verify planning and secondary datasets	Correct patient, correct orientation, proper timepoint, image registration accuracy, image includes enough anatomy and image quality is reasonable	6,13,27,35,45,48
5	Review the quality of the implant for discernable errors	Shield cylinder inserted correctly, tandem has not perforated uterus, ovoids flush with cervix, etc.	8,11,15,24,25,26,29,30,37,40,41,46
6	Verify OAR constraints have been met and that BED, if used, has been calculated correctly	Compare to published and departmental standards or via protocol	9,20,33
7	Review any special conditions	Consideration of prior treatment	10
8	Verify that the correct fiducials set was used and the fiducials were inserted fully	Based upon appearance within image dataset or physical inspection	12
9	Verify that the applicator matches the plan	Correct sized cylinder, tandem and ovoid vs tandem and ring, if model is used check for correct placement	15,34,44
10	Verify plan transfer to treatment control station	TPS matches TCS, documentation matches TCS	18
11	Verify that reference points are placed correctly and that plan is normalized properly	Location of point ICRU reference points if used, absolute dose agrees with plan normalization	19,32
12	Review integrated dose/kerma	IRAK or activity x treatment time are reasonable or that they are identical for subsequent deliveries using the same plan	19,32
13	Verify that the plan matches the prescription	Dose, fractionation, etc	22
14	Review the quality of the treatment plan	Appropriate shape of dose distribution, location of hotspots, absolute IDL covers target	23,28
15	Verify correct source, decay, and afterloader	Source strength matches decayed value, for facilities with multiple units or sources defined that correct source is applied	42,43
16	Review secondary dose calculation	Plan matches secondary dose calculation at established reference points	47