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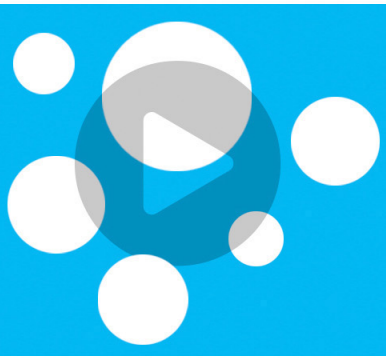

Consensus recommendations for incident learning database structures in radiation oncology

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Purpose: Incident learning plays a key role in improving quality and safety in a wide range of industries and medical disciplines. However, implementing an effective incident learning system is complex, especially in radiation oncology. One current barrier is the lack of technical standards to guide users or developers. This report, the product of an initiative by the Work Group on Prevention of Errors in Radiation Oncology of the American Association of Physicists in Medicine, provides technical recommendations for the content and structure of incident learning databases in radiation oncology.
Methods: A panel of experts was assembled and tasked with developing consensus recommendations in five key areas: definitions, process maps, severity scales, causality taxonomy, and data elements. Experts included representatives from all major North American radiation oncology organizations as well as users and developers of public and in-house reporting systems with over two decades of collective experience. Recommendations were developed that take into account existing incident learning systems as well as the requirements of outside agencies.
Results: Consensus recommendations are provided for the five major topic areas. In the process mapping task, 91 common steps were identified for external beam radiation therapy and 88 in brachytherapy. A novel feature of the process maps is the identification of "safety barriers," also known as critical control points, which are any process steps whose primary function is to prevent errors or mistakes from occurring or propagating through the radiotherapy workflow. Other recommendations include a ten-level medical severity scale designed to reflect the observed or estimated harm to a patient, a radiation oncology-specific root causes table to facilitate and regularize root-cause analyses, and recommendations for data elements and structures to aid in development of electronic databases. Also presented is a list of key functional requirements of any reporting system.
Conclusions: Incident learning is recognized as an invaluable tool for improving the quality and safety of treatments. The consensus recommendations in this report are intended to facilitate the implementation of such systems within individual clinics as well as on broader national and international scales. © *2012 American Association of Physicists in Medicine*. [http://dx.doi.org/10.1118/1.4764914]

Key words: patient safety, radiation therapy, brachytherapy, incident learning

I. INTRODUCTION

A heightened public and professional awareness of the risks patients unknowingly accept when entering medical systems has developed over the last decade.[1–3] The magnitude of the patient safety issue in radiotherapy specifically is, however, unclear. On the one hand, *Towards Safer Radiotherapy* states that in the UK experience "around 3 per 100 000 courses of radiotherapy were likely to have a clinically significant adverse outcome."[2] In contrast, Ford and Terezakis[4] have estimated the rate of errors in radiotherapy at 1 in 600 per patient, which appears to agree with other recent findings.[5] Determining the actual error rate is challenging, given the paucity of data and also disagreement on the relevant clinical endpoints and even terminology. Whatever the actual error rate, it would appear that safety performance in radiotherapy is worse than in some other areas of medicine such as modern anesthesiology.[6] A major initiative is now underway in radiation oncology to

improve this situation, with several conferences and sessions at professional meetings dedicated to this topic over the last several years.[7]

Of the many approaches to improving patient safety and treatmet quality, incident learning is recognized as playing a key role and is employed across a wide range of high-reliability industries. Incident learning refers to the entire feedback loop of reporting an incident and then analyzing it for salient detail and developing interventions to prevent it from happening again.[8,9] For example, the Commercial Aviation Safety Team (CAST) approach has reduced the risk of fatal accidents by 73% in 10 years by carrying out systematic investigations of airline crashes and near misses.[10,11] Incident learning is also a basic feature of nuclear power operations, where both in-plant and international incident learning systems are in wide use.[12]

It must be recognized that implementing incident reporting and learning on a wide scale within radiation oncology represents a considerable challenge. It will require additional clinical resources as well as a change in mindset and culture with an increased emphasis on incident learning to uncover latent error pathways. While the challenges are significant, the impact of this initiative cannot be overstated. For further discussion and motivation the reader is referred to a number of recent articles in the radiation oncology literature.[3,9,13–16] Lest the challenges be thought to be insurmountable, it must be remembered that incident learning systems have already been successfully used for a number of years in several radiation oncology clinics.[9,13–15,17] On a broader scale, ASTRO has called for a national incident reporting/learning system as part of its six-point "target safely" plan to improve patient safety in radiation therapy.[18] The American Association of Physicists in Medicine (AAPM) has supported this concept.[7] Even more broadly, the Radiation Oncology Safety Information System, ROSIS, is a voluntary international reporting system which has been in online use for 8 years.[19] A similar effort is now underway under the auspices of the International Atomic Energy Agency (IAEA) called Safety in Radiation Oncology, SAFRON.[20]

There is clearly an interest in pursuing incident learning as a means of improving patient safety and treatment quality. In the context of radiation oncology, however, two needs become immediately apparent: (1) the reporting/learning system must be specifically designed for the discipline of radiation oncology and (2) standards must be established that describe the structure and function of incident learning systems. Though it is possible to use a generic hospital reporting system which may also provide for comparative statistics, the complexity of the processes involved in radiation oncology and the need to guide the user in collecting relevant information call for a discipline-specific system. Secondly, without harmonization based on commonly accepted standards it will be impossible for systems, and indeed people, to effectively communicate with one another and hence maximize learning opportunities by sharing information. Both of the above issues are important for incident learning systems employed within individual clinics as well as for distributed systems, national or otherwise. The need for a well-organized system is particularly important when a large number of incident reports are expected. The volume of reports can become quite large in a clinic which is serious about quality improvement through incident learning. Mutic *et al.* have observed an incident report rate of 1 per 1.6 patients treated[13] which would translate into approximately 26 reports per month for a clinic treating 500 patients per year (this includes both incidents that reach the patient and near-miss incidents that are intercepted before reaching the patient). From the literature it is clear that the number of reports per patient varies hugely across institutions, presumably reflecting local culture, reporting criteria (e.g., operational and/or patient safety), the ease of reporting, and a host of other factors. However, it is worth noting that the overall goal of any system should be to collect a large number of incidents including near misses with very limited direct clinical impact. Such an approach facilitates continuous proactive improvement which can lead to the correction of small and/or latent system weaknesses before they result in much more severe events.

In summary, discipline-specific incident learning systems would significantly improve the practice of radiation oncology and yet no consensus exists as yet on the structure and design of such systems. To fill this unmet need, the AAPM Work Group on the Prevention of Errors (WGPE) undertook an initiative in June 2010 to provide consensus recommendations for incident reporting systems. These recommendations are technical in nature and also include a list of what are thought to be key functional features of a reporting system (Table I). This document summarizes this work, and should aid in the development of incident learning systems whose purpose is to improve the safety and quality of care by supporting the systematic learning from errors. This document has been reviewed and approved by AAPM, the American Society of Therapeutic Radiation and Oncology (ASTRO), and the Society of Radiation Oncology Administrators (SROA).

II. MATERIALS AND METHODS

The overall process of implementing and using an incident learning system consists of first developing the reporting and analysis system. The central thrust of the present paper is to facilitate this implementation by providing recommendations for the necessary elements of an incident learning database. Our recommendations are detailed in Secs. II and III and the five appendices. Once the incident learning system is in place, clinical staff uses it to file reports of incidents that occur in the course of clinical operations (see Fig. 1 for an example report). These reports are then investigated and analyzed. Though a detailed discussion of the operations of incident learning systems is beyond the scope of this report, salient recommendations are provided in Sec. IV.

Terminology is further clarified in Appendix A, but throughout this report we refer to "incidents" (vs "errors," "mistakes," or "adverse events") mainly to highlight the fact that all deviations are potentially of interest even those that do not necessarily impact the patient. Other terms could be used equally well such as "variance," "event," or "condition." Incidents also include deviations or variations to expected

TABLE I. Important features of incident reporting systems in radiation oncology.

Requirement	Notes
Electronic	Ease of use; data mining; interconnectivity
Ease of use	Especially for front-line reporters
Provide feedback	Feedback to both the clinic and to the person reporting
Compliant with standard	Supports extra-institutional data sharing
Validated with test-case scenarios	Test cases are also useful for training users
Support statistical analysis and filtering	Filtering by process map steps, causes, and other fields
Support for near-miss incidents	
Tools for incident investigation	Examples: root-cause-analysis structures, severity tagging
Support semi-anonymous reporting	See text for a discussion of this issue
Corrective action tracking	Management system for tracking incident follow-up
Multisite support	Support for analysis, etc.
Workflow tools	Examples include alerts to managers, pages, etc.
Secure communication tools	Tools for communicating between users (e.g., blogging)
Clear definition of reporting threshold	Ensure consistency in what is considered reportable

workflow, conditions that would impede the smooth completion of a task without a workaround of the standard process. We also refer to "incident learning" to underscore the fact that "incident reporting" is not sufficient. That is, a rigorous system of learning, feedback, and action are required for this approach to have a meaningful impact on patient care. "Learning" also has the implication that the learning might be assessed in the way that student learning is assessed with tests.

Five focus areas were identified for this effort:

- Definitions: Common terminology for incident reporting specific to radiation oncology.
- Process maps: Workflow maps representing the essential generic steps for any radiation oncology practice. Incidents are codified to this map, greatly aiding analysis and triage.
- Severity metrics: A scale for harm that is specific to radiation oncology.
- Causal taxonomies: A structure to guide the user in identifying the root causes and contributory factors of an incident.
- Data elements: Key data and data structures required for reporting and meaningful analysis.

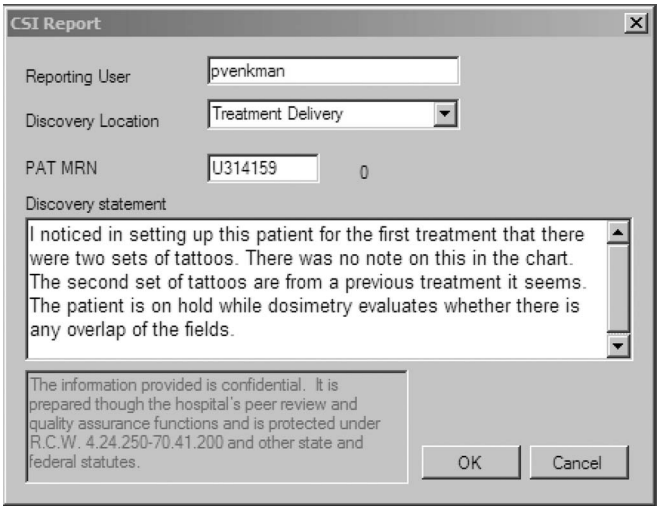

FIG. 1. An example incident report form, showing the interface through which clinical staff input the initial report information. The incident learning system consists of other levels beyond this, through which reports are further analyzed and followed up.

It was recognized throughout the project that input from other organizations would be not only valuable but essential if consensus recommendations were to be generated and accepted. This input was obtained by inviting participation in the development of the recommendations by representatives from the following groups: American Society for Radiation Oncology (ASTRO), American College of Radiology (ACR), National Institutes of Health (NIH), Conference of Radiation Control Program Directors (CRCPD), American Association of Medical Dosimetrists (AAMD), American Society of Radiological Technologists (ASRT), Canadian Organization of Medical Physicists (COMP), and Dr. Ola Holmberg, a core developer of the ROSIS and SAFRON systems. While the Working Group on the Prevention of Errors acknowledged the innovative nature of both ROSIS and SAFRON it felt that a database structure more closely reflective of North American practices would gain wider acceptance across the continent. However, the need for compatibility with international databases was also recognized and hence the participation in the group deliberations of a key architect of both ROSIS and SAFRON.

The participants listed above attended a workshop on April 14–15, 2011 in Washington DC to finalize the recommendations. Draft recommendations were discussed extensively at the workshop by preassigned smaller groups selected from all participants and then by the group as a whole. These discussions, based as they were on extensive preworkshop preparation, led to recommended structural components which garnered broad consensus from the group. Throughout the entire process there was a concerted effort to make the recommended structures consistent with those being developed for the National Radiation Oncology Registry (NROR) (Ref. 21) and those recommended by the Agency for Healthcare Research and Quality (AHRQ).[22] At the conclusion of the workshop all the key decisions had been made with only

minor modifications remaining. The process was completed in June 2011.

The organizers of the workshop realized that testing of the consensus structural recommendations developed would be an essential component of the overall project. Approximately one quarter of the workshop time was devoted to pilot testing. The pilot testing was focused on determining the usability of the proposed structure, for example the severity scales and the database elements and structure. A prototype electronic database was quickly implemented at the workshop based on the discussions and recommendations. Three hypothetical error scenarios were then logged into this database to confirm that the proposed structure could accommodate a range of situations. This exercise identified a few issues and several minor adjustments were made to the recommendations based on this experience. The three scenarios used in the pilot testing exercise were:

1. An incorrect lateral treatment due to image reversal caused by feet-first MR scanning as described by the IAEA.[23]
2. A situation in which an incorrect plan is transferred from the treatment planning system to the record and verify system.
3. Radiation overdose due to a pattern of open MLCs during IMRT treatment, as described in detail in numerous recent forums.[7]

To describe the pilot testing exercise in more detail we consider the first example scenario listed above of a wrong laterality treatment which occurred on October 24, 2007. This example was chosen because a good deal of information is available in the public realm through the IAEA report[23] and the description in NRC report #08-03. We started from the incident description outlined in the NRC report, briefly reviewing the events in which a patient being treated with radiosurgery using the Gamma Knife (Elekta Inc., Stockholm, Sweden) was scanned in the MRI unit in "caudal" mode (feet first) rather than "cranial" mode resulting in a right-to-left reversal of images in the treatment planning system and a subsequent treatment to the wrong location. The details of the incident were entered into the prototype database. Certain information was not available, for example the number of staff present at the time of the incident (Appendix E, element 2.32) or where the error was discovered (Appendix E, element 1.10). However, it was found that all of the database elements flagged as "required" (Appendix E) could be satisfactorily answered with the information available and approximately half of the other elements could be completed as well. It was even possible to assign a medical severity grade, since the NRC report included an evaluation by an independent medical consultant. The assignment of a root cause was somewhat more challenging. Multiple options on the causality table (Appendix D) could be appropriate but given the detail of the information available, it was not possible to definitively assign root causes. This pilot testing exercise underscored the need to have rapid and detailed follow-up of incidents by a person performing an evaluation. It was felt that the recommended data elements for the evaluator (Sec. 2 of Appendix E) would provide a good template to ensure that all of this information is obtained at the time of review.

III. RESULTS

The resulting consensus recommendations are presented in Appendices A–E.

III.A. Appendix A—Definitions

Though relatively straightforward, the challenge with the definitions project was to generate the briefest list which would minimize ambiguity in communication. In reviewing recent published studies reporting error rates, such as those referenced in the Introduction,[2,4] we encountered interpretation difficulties arising from the use of some terms. While complete removal of ambiguity is probably an unachievable aspiration, Appendix A presents, as a consensus view, a minimum set of useful definitions for use in incident learning. Many definitions have been drawn from the National Patient Safety Foundation website.[24] This website provides multiple definitions for many of the terms listed, which underscores the ambiguity issue.

III.B. Appendix B—Process maps

Process maps facilitate the development of learning systems and provide a means of codifying each incident in terms of its origin along the radiotherapy workflow path. It is important to distinguish the fact that a process map is useful for addressing the point at which an incident originates or is detected, but it cannot answer the question of how or why the incident occurred. The latter question is more directly addressed with the narrative descriptions of the incident and with the causality table outlined in Appendix D.

Several radiation-oncology specific process maps have appeared in the literature.[2,3,25,26] Section 1 of Appendix B shows our consensus recommendation for high level process maps of external beam radiotherapy (left) and brachytherapy (right). It was necessary to consider these two treatment modalities separately since they are different in their details, though certain aspects are the same. Sections 2 and 3 of Appendix B list the detailed process steps for external beam radiotherapy (EBRT) and brachytherapy, respectively. The reader is referred to the appendices for details, but broadly the process steps are: patient assessment, imaging for treatment planning, treatment planning, pretreatment plan review and verification, patient setup verification, treatment delivery, On-treatment quality management, posttreatment completion, and equipment and software quality management. For the purposes of this work, we defined radiation therapy process as beginning at the time of the patient consult in the radiation oncology department and extending into posttreatment follow-up. There are 91 process steps in EBRT and 88 in brachytherapy. The group felt that it was essential to describe the radiotherapy workflow at this level of detail in order to support the accurate codification of incidents and to facilitate root-cause analysis by pinpointing the process step(s) that failed. Note that the "other" category listed in

Secs. 2 and 3 of Appendix B is meant to support the use of drop-down lists by a reporting database. The process steps outlined in Appendix B serve as input to the following data elements in Appendix E: 1.9 (where the incident was found) and 2.42 (where the incident originated).

One novel additional feature of the process maps developed here is the identification of "safety barriers" ("SB" in Secs. 2 and 3 of Appendix B). We define a safety barrier, sometimes known as a critical control point, as any process step whose primary function is to prevent an error or mistake from occurring or propagating through the radiotherapy workflow. There are 35 identified possible safety barriers in the EBRT workflow (out of a total 91 steps) and 32 in brachytherapy (of 88 steps). These same safety barriers are referenced in the Causal Taxonomies, Appendix D, and Data Elements, Appendix E (data element 3.3), providing links between three of the structural components of an incident learning database.

We note that a somewhat different process tree specific to IMRT is presented in AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*, part 2). The two process outlines cover very similar content, although specifics differ. The most notable difference is the inclusion of safety barriers in the present report. These were deliberately excluded from TG100 because in the failure mode and effects analysis (FMEA) formalism failure modes are assessed without reference to the barriers that might prevent them. In FMEA the effect of barriers is included in the use of an undetectability score.

III.C. Appendix C—Severity metrics

Appendix C presents recommendations for two complementary severity scales. We recommend assigning severities to both actual and near miss incidents as both provide rich learning opportunities. In item 1.5 of Sec. 1 of Appendix E, Data Elements, the reporter distinguishes between actual and near miss incidents early on in the reporting process.

The reader is referred to the appendix for full details, but severities are defined which span a range from premature death (10), to permanent major disability (or grade 3/4 toxicity), to temporary side effect with intervention indicated (2).

The assignment of a severity to an actual or potential (near miss) incident is difficult and the issue has not been satisfactorily resolved. While an attempt has been made to develop objective quantitative measures of at least the dosimetric impact of generic inappropriate treatments,[27] it is clear that such an approach may require additional physics resources which may not always be available. Alternatively severity metrics can be based on regulatory requirements as described in Towards Safer Radiotherapy.[2] The French nuclear regulatory agency has developed a rating scale for radiotherapy[28] and the Cancer Therapy Evaluation Program of the National Cancer Institute has proposed a disease specific scheme within a generic framework.[29] The medical severity table in Sec. 1 of Appendix C is a consensus recommendation drawing on these various sources. The table is also compatible with the harm index scale advocated by AHRQ.[22]

The severity scale presented here differs from that proposed by AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*, Table I). The differences are largely due to the different intended uses. TG100's aim is to demonstrate the use of FMEA in crafting a QM program and much of the TG100 terminology is more qualitative and descriptive. The intention of the present document is to provide a standard for intra- and interinstitutional database reporting purposes that will permit subsequent data mining. We deliberately separate dosimetric and clinical severities; for a reporting system which may be mined for in-depth information, we must distinguish between failures with large dosimetric but minor clinical consequences, failures with modest dosimetric but serious clinical consequences and failures where both dosimetric and clinical consequences are of commensurate severity. TG100 reasoned along generic lines, arguing that dosimetric errors with minor consequences for a particular incident could become serious in a future case. TG100 also specifically recognized failures which disrupt clinical workflow (e.g., lost immobilization, tardy volume delineation) even though these may not impact patient safety directly. Finally, the TG100 scores all start at 1 rather than zero to avoid zero for the calculated risk priority numbers.

The medical severity score assigned using Sec. 1 of Appendix C will likely depend on whether one is considering late vs early toxicities. This issue is at least partly accommodated by the recommended data element 2.39 in Appendix E, namely the time point at which the severity is assessed or estimated. It must be noted that the tracking of late toxicities can be challenging. Also in Appendix E is an accommodation for the severity assessment type, i.e., based on an actual observation vs estimation (element 2.38). The latter may be useful for near-miss incidents. Rating severity for near-miss incidents may be especially difficult since one has to estimate the harm that would have reached the patient several steps down the chain of events.

The second, and complementary, scaling system is listed in Sec. 2 of Appendix C, namely the deviation of the delivered dose from that intended. The reader is referred to the Appendix for full details, but the range spans from 100% dose deviation from the intended dose to any structure (10), down to <5% deviation (level 1–2). Radiotherapy has the advantage of being quantitative as far as dose deviations are concerned, at least to a point in or around the target. However, a simple metric of dose deviation clearly may not capture all of the information about an incident. A treatment may be inappropriate for example due to a deviation in the other component of the physician's directive, viz. the volume(s).[30] In the specific case of a geographic miss, we propose that the dosimetric severity of an incident be rated in comparison with a deviation in dose in terms of isoeffect, recognizing the difficulties involved in such calculations. In many cases, including geographic misses or contouring errors, it is clear that rating the medical severity of the incident will require the exercise of judgment based on clinical training and experience. That judgment will have to include the likely severity of late reactions or compromised disease control. It is important to note

that the two scales in Appendix C, one for medical severity and one for dosimetric deviation, are separate and should not be intermixed. Clearly in some situations large dosimetric deviations may have only a small medical impact, while the reverse may be true in another case. It is also the case that some incidents will have no dosimetric component in which case the correct choice for Sec. 2 of Appendix C would be "not applicable." Examples include contrast reaction, Tandem and Ovoid HDR skin burn, and equipment failure not leading to radiation dose errors. In analyzing a radiation therapy incident it is recommended that both a medical and dosimetric severity score be assigned.

Related to the concept of severity of harm is a term that we refer to as "clinical action scale" rated on a scale of A-D (see Sec. 3 of Appendix E data element #3.1). The clinical action scale guides the follow-up to a reported incident and is established locally reflecting local organizational structure and administrative processes. This has been found to be useful in incident reporting because it is not always straightforward to precisely judge the clinical significance or harm of an individual incident, especially a near-miss incident, and because some relatively low-harm incidents may deserve more extensive preventative actions, such as in the case of recurrent problems that may later manifest themselves as large errors. To take an example, consider an incident in which the wrong patient medical record number is entered into the radiation oncology information system (OIS). Though this may receive a low potential-severity score by itself, it may be given a high clinical action score due to potential for future error (e.g., import of the wrong pathology report into the OIS due to a patient identification number mismatch). Each clinic should determine the meaning of the scale (A vs B vs C) and the corresponding course of action, but we recommend that A be standardized as high-priority with priority decreasing in B, C, and D levels.

III.D. Appendix D—Causal taxonomies

The goal of the causal table is to facilitate the identification of all root causes and contributory factors that underlie an incident and to improve consistency of interpretation amongst different users. The reader is referred to the Appendix for the full causal table, but the table includes listing such as "organizational management," "technical issues," and "human behavior involving staff." These levels are further divided into more specific causes. For example, under staff behavior, relevant causes include acting outside one's scope of practice, a slip, or poor judgment.

The taxonomy outlined in Appendix D is designed to encompass the conceivable basic causes of, and contributory factors to, errors that can occur in radiation oncology. The lists are organized into a hierarchy so that similar causes are grouped together. The utility of this taxonomy depends on several factors including:

1. Ease of use: so that the classifier can quickly find the causes he or she is looking for.
2. Appropriateness: so that poorly conceived causes are not listed.
3. Robustness: so that different classifiers looking at the same situation are likely to select the same causes from the list.
4. Mappability: so that the taxonomy elements in a list can be identified with the taxonomy elements in the lists used by other organizations.

When implementing a clinical reporting system, the design should encourage the user to enter all root-cause/contributory factor choices that are applicable, since it is a rare situation in which only one single cause is at work. It is also desirable that the causes be grouped into major contributing causes and minor contributing causes. In the implementation and use of a clinical reporting system it must be established which cases will require a full root-cause analysis (which is time consuming) and which can be more quickly categorized. For quick categorization and trending some clinics have found it useful to employ a list of "apparent causes," that is a relatively compact list of commonly known error pathways. An example might be "unclear physician directive at the time of simulation." A list of apparent causes is beyond the scope of these recommendations.

Several considerations went into the creation of the causality table in Appendix D. First, the causal list must be robust when used by individuals with different levels of expertise, cultural backgrounds, professional perspectives, and training in root-cause analysis. The goal is to have multiple users looking at the same incident identify the same causes. This will improve the quality of statistical causal data and thus clarify trends in the data. To promote this, the hierarchy was kept to three levels with each node having from four to eight subnodes. The descriptions were kept reasonably short and are consistently stated in the negative. In spite of these efforts, some aspects of the causality table will likely require guidance or training in order to be used consistently. Section 6 (Procedural Issues) is an example; it contains concepts such as event detection, interpretation, rule selection, response approach, and response execution which will likely require explanation for the frontline user.

A final consideration is the prevention of incomplete or inappropriate root cause or apparent cause selections. There are many excellent, though at times conflicting, methods for how to perform root-cause analysis, but it is worth pointing out some of the wrong directions which one should avoid in root-cause analysis. A common inappropriate use of root-cause analysis is to affix blame to an individual or group as the only root cause, which may lead to corrective actions that fail to address an underlying cause.[1,8] This is not to say that personal accountability is not relevant or important, but rather that an individual's actions must be viewed in the context in which they act when performing root-cause analysis. Another inappropriate use is to focus primarily on staffing levels. Certainly staffing issues may be key component of some incidents, but root-cause analysis should also examine inappropriate division of work and inadequate training, as well as insufficient training, training materials and/or onsite training by vendors. A third inappropriate use is to focus too heavily on the role of policies and procedures, which in isolation have weak

influence on behavior,[7] though it should be noted that incident reports may aid in correcting unclear or contradictory policies and procedures. The root-cause taxonomy, by itself, cannot address these issues and, as with other aspects of incident learning, awareness and training will be required in order for the system to be used consistently.

We note a "human factors" table is also presented in AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*). The TG100 table is less detailed form of the table presented here, and all of the information there is also included here.

III.E. Appendix E—Data elements

Appendix E presents a summary of the key data elements for a radiation oncology incident learning system and the associated structures for each. This may be thought of as a common standard for patient safety similar to the use of DICOM-RT as standard for software requirements in radiation therapy. Appendix E identifies and distinguishes between those data elements that are considered "required" from those that are "recommended" or purely "optional." These terms are meant to indicate which fields should be implemented in a clinical database, but may not necessarily represent which data are logged in an actual incident report. Some "recommended" data elements are clearly irrelevant for some error scenarios (e.g., treatment unit and treatment planning system information are irrelevant to a situation where a patient has an allergic reaction to contrast at the time of CT simulation).

Data elements are structured in Appendix E to support the use of a relational database design, i.e., linked tables for "pull-down menus" that will support fast and effective queries. In an actual database implementation, the working group noted that logic functions would be useful. For example, if the user selects electron treatment modality (1.14) then the treatment techniques (2.17) would not, for example, include modulated arc therapy. We note that some elements outlined in Appendix E already exist in other parts of the department or hospital oncology information system, for example, attending physician, diagnosis, prescription, etc. In implementation of a clinical system, these data should be pulled from such systems or, if they are not, data integrity checks need to be in place.

Appendix E recommends that the system be structured into three levels, a design which is intended to improve the ease of use of the system. The first level, a reporter's form, is intended to be used by the person initially logging the report, and includes only the most essential information (see Fig. 1 for an example). We note that it is essential to keep the reporter's form as simple as possible to facilitate use in a busy clinical environment. Further benchmarking is required to determine the time required to enter an incident report. A reasonable design goal is less than 1 min. If further streamlining is needed, some of the elements in Sec. 1 of Appendix E may need to be moved up to the analyst's level. As is standard in other industries, the person initiating the report does not perform any analysis but simply enters a brief description of the incident.

The second level (Sec. 2 of Appendix E) is the analyst's form which includes much more information and is intended to be completed by a second person or persons investigating the incident in more detail. The analyst likely should check back with the reporter to make sure the analysis is correct. The third level is for response to the incident and may be completed by the person performing the analysis or by someone different as dictated by the departmental quality management program. This structure represents a consensus of people at the workshop and of those who have experience using such reporting systems. There was some debate as to how elements should be grouped among levels. Some participants, for example, advocated the inclusion of a causality table at both the reporter's level and at the evaluator's level. Appendix E was constructed to minimize the detail at the reporter's level based on the experience of people using reporting systems in clinical operation.

It remains to be determined which of the data elements in Appendix E are needed for a distributed national or international system. We recommend that all of the elements in Appendix E be supported in the design of a distributed system. We believe that the "required" elements listed in Appendix E will need to be present in every report, while the "recommended" and "optional" elements may be less strictly enforced. Appendix E also lists the elements that likely would need to be stripped or encrypted if data will be shared between organizations in a distributed system. The database design may facilitate this process by organizing all of these elements into a single table. Hiding or encrypting this single table would then, in principle, make the data anonymous.

Several specific elements deserve further discussion. First, the facilities profile (element 2.2) is intended to be a set of data that describes the operations, workload and services of the clinic. The exact information included in the profile remains to be determined but would likely include such descriptors as geographic location, number of staff, number and types of equipment, number of patients on-treatment for each service, and so on. Next, element number 2.4 (patient's race) is a field that is required by AHRQ for the purposes of disparities research. The options listed in Appendix E are those outlined by AHRQ as applicable for North America. Internationally an expanded and altered list may be necessary. Finally of note is the fact that data element 3.3 (safety barriers) refers to the process steps in Appendix B (process maps) which are identified as functioning primarily as safety barriers. The relevant data to be collected for element 3.3 are which safety barrier(s) prevented the error from reaching the patient and which safety barrier(s) could have prevented the error from propagating as far as it did.

IV. DISCUSSION

The data in Appendices A–E represent the consensus recommendations from a wide range of experts on an incident learning database structure specific to radiation oncology. These recommendations are intended to be complete to the extent that a database programmer could use this document in a straightforward manner to develop a system. This was

demonstrated by the fact that during the April 2011 workshop, a prototype database was developed in a matter of a few hours based on these recommendations. To the extent possible the recommendations were made compatible with the "common formats" for patient safety reporting promulgated by the Agency on Healthcare Research and Quality (http://www.ahrq.gov), and a concerted effort was made to make them compatible with other standards and systems in use such as ROSIS and SAFRON. Within the constraints of this project validation of the recommendations has been performed. Both longer term application of the recommended structure and the changing radiotherapy clinic environment will almost certainly suggest further development of this structure. In implementing these recommendations within an electronic database the prudent developer will incorporate the necessary flexibility to permit future changes.

Several general features of an incident learning system will impact its utility. Table I summarizes key functional, as opposed to structural, requirements of a useful system as identified at the WGPE April 2011 workshop. These are ranked roughly in order of priority. Two of the most important features are that the system be electronic and be easy to use. These are particularly crucial if a busy health care provider is expected to use the system to log reports.

Another series of features is related to the effective use of the system. These include: feedback, tools for incident investigation, corrective action tracking, and workflow tools. Though detailed recommendations on these aspects are beyond the scope of the present work, several points can be made. First, the need for follow-up and feedback has been found to be an essential element of incident learning. That is, both individual reporters and participating institutions need to know the resolution of their particular report and the improvements that come about because of reporting in general. Workflow tools that support this are therefore considered essential. These might include alerts to the appropriate manager or person responsible for QA oversight and the ability to track and close-out reports. Also if the follow-up to a particular incident involves corrective, preventive or learning actions (see data elements #3.4, 3.5, and 3.6) then there must be some mechanism to assess whether these actions were completed[8] and whether they were effective. The need for action levels and workflow tools becomes especially acute when large numbers of incident reports are expected.

Each clinic should also determine the course of follow-up action for each incident. Some reports will require a comprehensive root-cause analysis and intervention while others may be best handled by tracking to assess for long-term trends or recurrent issues. It must be recognized that the medical severity scale may not be the most appropriate metric to use in establishing the priority level for action. Some clinics with experience using incident learning systems have found it more useful to directly assign each incident a score called a clinical action score (see data element #3.1). This score then dictates, by established policy, the follow-up that will occur.

We recommend that the overall structure of the incident learning system consist of three levels: (1) report, (2) analysis, and (3) follow-up. The report level may involve a simple entry form to be used by front-line providers, an example of which is shown in Fig. 1. Unanswered questions remain as to which staff should be responsible for levels 2 and 3, especially in smaller clinics where the majority of patients are treated. For workflow efficiency, it may be advisable to have a cross-disciplinary group of approximately three people investigating incidents as part of a periodic review. The issue of independence and anonymity is important as well and lessons may be taken from the nuclear power industry where in-plant incident reporting is required in the US by the Nuclear Regulatory Commission and is accomplished successfully with in-house investigational teams.

In a distributed system on the national or international level a parallel three-level structure would exist wherein a separate analyst investigates the incident and completes the data sections outlined in Secs. 2 and 3 of Appendix E. Part of the response should include both validation and quality control of the data, which are essential elements of a good database.

In the course of developing these recommendations several other important issues have been raised. One that generated considerable discussion was whether or not anonymous reporting should be supported within an institution. Anonymous reporting may address the issue of reprisal against the person reporting. We therefore recommend that the system provide an option to register anonymous reports. However, the safety culture in any department should be such that the anonymous reporting option is rarely used. This is similar to the practice in the nuclear power industry where anonymous event reporting is allowed, but the number of such reports is tracked as an indicator of safety climate. For a discussion of safety culture within radiation oncology we refer the reader to Marks *et al.*[31] Not only is the necessity for anonymous reporting possibly a reflection of a negative safety culture, but anonymity can also impede the ability to perform further investigation and follow-up into root causes since it may not be clear which staff to query for further information. Furthermore, it must be acknowledged that in a smaller clinic truly anonymous reporting may not be possible as it may be obvious who the reporter is. We also recommend that reports be made visible only to the person logging that report and to the person responsible for oversight and follow-up. This approach would protect confidentiality and promote the use of the system. Redacted reports may be made more widely available for learning purposes.

Looking beyond a single institution, the need for anonymity and protection becomes more complex and will likely need to be supported by the mechanism of a Patient Safety Organization (PSO). This mechanism established by the US Congress as part of the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) provides medical-legal protection to encourage confidential reporting. PSOs are widely used in other areas of medicine. An attempt has been made in Appendix E to outline which data elements might need to be either stripped or encrypted in order to provide confidentiality within such a system.

Another important issue in the operation and evaluation of an incident learning system is metrics to quantify effectiveness. Ongoing evaluation of the incident learning system and

updating the system is recommended. The choice of evaluation metrics is a difficult challenge with little research to inform it. The total number of reports will likely not be a very useful indicator; it is highly variable over time and subject to reporting bias. A somewhat better indicator may be the number of a certain type of event (e.g., high-severity) divided by the total number of reported events in the same time period (see, e.g., Clarke *et al.* 2006). Theoretically, one should see the pattern of events shift to less severe as the system is used. It may also be possible to develop metrics related to follow-up of events, for example, the number of reports that resulted in some type of intervention and the time to completion of these interventions. Finally it may be useful to consider recurrences as a measure of effectiveness. In other words, a better functioning learning environment will show fewer repeats of the same type of event. During the development of the database, designers should consider the methods for collecting data to measure the impact of the system and should, when feasible, design into the database upfront, data elements that facilitate this.

While it is hoped that the recommendations presented here will facilitate the development and adoption of compatible incident learning databases it has been the experience of users of currently available systems that effective implementation is considerably more involved than just getting the system online. It is important to consider the specifics of clinical operation of an incident learning system. As a starting point, we can rely on recommendations from other industries such as the nuclear power or airline industries. Specific recommendations for radiation oncology can be found in Clark *et al.* (2006). We recommend that clinical operations be established according to a written policy. One person should be identified who is responsible for the initial review of reports. The strategy for response, investigation and follow-up should be prioritized based on the initial clinical action score. For the most serious incidents senior management, supervisor, and the physician should be notified immediately (as well as relevant authorities), while for less serious incidents and near-misses only the supervisor need be notified. For minor incidents or near-misses an initial investigation should be completed within ten working days and should involve the individual involved and the supervisor. For more serious incidents an initial investigation should be completed by the next business day and should involve the individual involved, other domain members, the supervisor, and senior management. Further follow-up and implementation of interventions should also follow an established policy. Ultimately, very specific recommendations will be developed over time as the system is used and collective knowledge is shared via the professional societies and Patient Safety Organization that deploys the event reporting system. The way in which the system is rolled-out is also important in order to maximize the buy-in from all clinical staff.[8] Careful consideration must be given to these issues in order to maximize the improvement in patient care.

As with any other process change, training is essential to maximize the benefit of an incident learning system. The resources needed for appropriate training in terms of staff time should not be underestimated. Just as inadequate training has been recognized as contributing to accidents in radiotherapy[2,3,7] so also will inadequate training on the use of incident learning systems limit the impact on quality improvement.

A final consideration is the staff time and resources necessary for implementing and managing an incident learning system. The technical realization of a computer interface may be relatively straightforward as witnessed by the fact that a basic relational database was constructed for pilot testing at the April 2011 workshop in a matter of a few hours by a physicist with little specialized IT training. Ultimately commercial solutions may become available, though to our knowledge no such systems exist yet and so it is not possible to estimate the cost of such a system. Operational management resources must be considered as well; the act of logging an incident report may take no more than a few minutes (cf. example in Fig. 1), but the subsequent management and follow-up can be resource intensive. This must be recognized, and a clear institutional commitment must be present if incident learning is to positively impact patient care.

Realistically, not every institution will adopt every recommended element of the structures developed and described here. By defining and implementing the required elements in this consensus report, such customization need only have a minor impact on our ability to share information if we can map from one system onto another. In the development of these recommendations we made a concerted effort to ensure compatibility among the systems known to be in use.

V. CONCLUSIONS

Incident learning is recognized as an invaluable tool for improving quality and safety across a wide range of industries and medical disciplines. However, developing an incident reporting system is time consuming and difficult. In addition, clinical or engineering groups working in isolation without any recommendations on the basic structure are likely to leave out one or more essential elements. The difficulties are especially acute in a field as complex and specialized as radiation oncology. It is the hope that the consensus recommendations in this report will facilitate the design and implementation of incident learning systems within individual clinics as well as on broader national and international scales.

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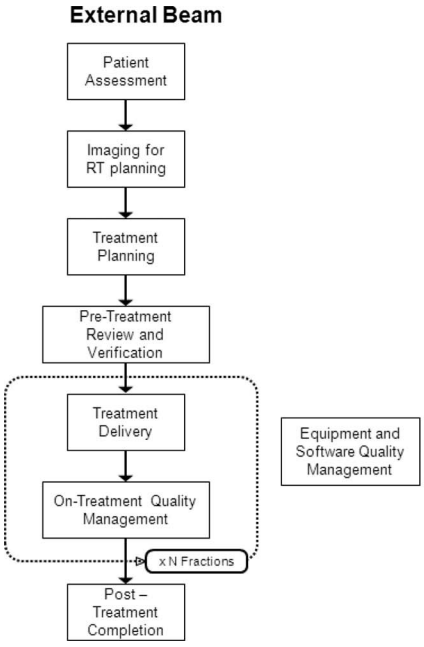
APPENDIX A: DEFINITIONS

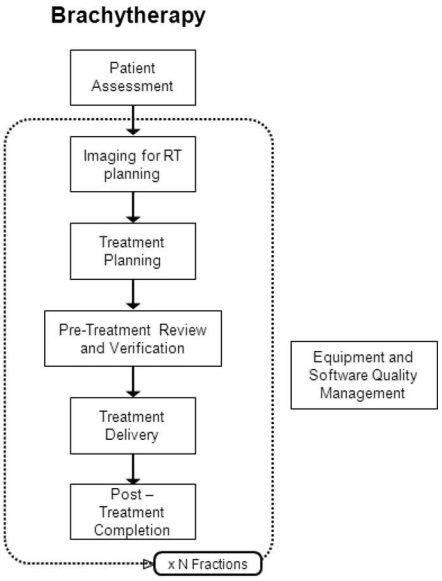
Term	Definition
Adverse event	An incident that occurs during the process of providing health care that results in suboptimal clinical outcome including unintended injury or complication leading to disability, death, or prolonged hospital stay for the patient
Cause	A situation, condition, action, or omission that leads to an incident
Calibration of dose	The determination of the relationship between the absorbed dose of radiation at a point under specified reference conditions in a medium and the user set parameter which limits the emission, such as monitor units or time
Clinical dosimetry	The process of measuring radiation dose in a clinical setting. Accomplished and/or supervised by a qualified medical physicist
Clinical Infrastructure	Hardware, software, protocols, beam, and equipment data used in activities for all or a subset of patients
Clinical Processes	A series of activities which use the Clinical Infrastructure to prepare and deliver the prescribed treatment
Commissioning	Characterization and preparation for clinical use of any component of clinical infrastructure or clinical process, according to applicable published guidelines
Contributing factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident
Delivery	All the activities carried out during a visit for treatment and necessary for the safe and effective administration of therapeutic radiation
Dosimetric treatment planning	The process of translating a physician's prescription into a corresponding plan-of-treatment and the concomitant determination of the user determined settings on the treatment unit. Normally accomplished by a qualified dosimetrist or qualified medical physicist. Also known as treatment planning
Equipment and software QM	A comprehensive program that monitors, evaluates, and optimizes the hardware and software used in radiation treatment planning and delivery
Error	Failure to complete a planned action as intended or the use of an incorrect plan of action to achieve a given aim
Failure mode	A state arrived at when a process and result deviate from intent
Failure modes and effects analysis	A prospective assessment that identifies and analyzes states arrived at when a process and result deviate from intent. Thus facilitating development of control measures to reduce the likelihood that the failure modes would occur, or reduce the severity or improve the detectability
Human factors	The study of the interrelationships between individuals, the tools they use, and the environment in which they live and work
Incident	An unwanted or unexpected change from a normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment
Infrastructure processes	Activities to prepare and maintain the Clinical Infrastructure at the level required for safe and effective treatment
Inter-treatment review and verification	Processes that confirm that the treatment is being delivered in accordance with the physician's prescription
Latent condition	Underlying inadequacies in the design organization, training, or maintenance that have the potential to lead to operator errors
Medical dosimetrist	A member of the radiation oncology team, who has knowledge of the overall characteristics and clinical relevance of radiation oncology treatment and planning equipment, is cognizant of procedures commonly used in brachytherapy and external beam radiotherapy, and has the education and expertise necessary to generate radiation dose distributions and dose calculations under the direction of the qualified medical physicist
Medical physicist	A physical scientist who is responsible for the measurement and calculation of radiation doses from treatment units and in the design of appropriate quality assurance measures for clinical processes (see also qualified medical physicist)
Mistake	Implementation of a plan unlikely to achieve its intended outcome even if executed correctly. Blunder, wrong judgment, wrong action or statement from faulty judgment; inadequate knowledge or inattention
Near miss	An event or situation that could have resulted in an accident, injury, or illness but did not either by chance or through timely intervention. Also known as a close call, good catch or near hit
Patient assessment	Acquisition and analysis of the patient's medical information that indicates and permits the initiation of the radiotherapy process
Preparation	All the clinical processes carried out prior to and necessary for the safe and effective treatment of a patient with radiation
Prescription	In Radiation Oncology, a radiation oncologist's directive for treatment including but not limited to volume (site) to be treated, description of portals [anteroposterior (AP), posteroanterior (PA), lateral, etc.], radiation modality, energy, dose per fraction, number of fractions per day, number of fractions per week, total number of fractions, total tumor dose, and prescription point, or isodose volume

Term	Definition
Pre-treatment review and verification	Confirmation that the instructions to the treatment delivery system will result in a treatment in compliance with the physician's directive
Post-treatment review	Retrospective evaluation of the treatment course and assessment of the patient outcome
Qualified medical physicist	For the purpose of providing clinical professional services, a qualified medical physicist (QMP) is an individual who is competent to independently provide clinical professional services in one or more of the subfields (Ref. 1) of medical physics, specifically for this report, therapeutic medical physics
Quality assurance	All those planned and systematic actions necessary to provide adequate confidence that a product or service fulfills the requirement for quality
Quality control	The operational techniques that are used to evaluate and correct conditions or settings to achieve the desired quality
Quality of care	Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge
Quality management	Framework to guide an organization towards improved performance. Quality management includes quality planning, quality control, quality assurance and quality improvement. Resources are acquired and administered to achieve the desired level of quality
Radiation oncologist	A medical doctor who has completed a residency in radiation oncology or has been certified by the ABR in radiation oncology
Radiation safety	A set of policies and processes implemented to insure that the public, staff and patient exposures to radiation are kept to within regulatory limits and further are kept As Low As Reasonably Achievable
Radiation therapist R.T.(T)/registered technologist in therapy	An individual educated in the delivery of ionizing radiation for the treatment and control of disease, primarily cancer, and certified depending on local standards
Random	Having no discernable pattern or cause-and-effect relationship with any known variable.
Risk	The estimated probability of an event's occurring and the severity should it occur
Safety barrier	Any process step whose *primary* function is to prevent an error or mistake from occurring or propagating through the radiotherapy workflow
Root-cause analysis	A process for identifying the contributing factors that underlie variations in performance associated with incidents
Severity	The extent to which an action causes harm
Sporadic	Occurs in an unpredictable fashion
Systematic	Occurs predictably under similar circumstances
Treatment delivery	The process of administering radiation to the patient in accordance with a radiation oncologist's prescription
Treatment planning	In the context of radiation oncology, treatment planning refers to the process of translating the physician's prescription into instructions for the treatment delivery device
Uncertainty	The range within which the value of a measurable quantity is known to fall at a stated confidence level

APPENDIX B: PROCESS MAPS

*Note that these process trees differ somewhat from those specific to IMRT as presented in AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*, part 2) (see text for full description of the differences).





1. Process map, EBRT

"SB" indicates a process step that serves primarily as a safety barrier. The symbol ☺ indicates processes in which the patient is physically present during at least some part of the process.

1. Patient assessment ☺		
SB	1.1	Verification of patient ID by two methods
	1.2	Diagnosis definition including imaging and outside records
SB	1.3	Review and verification of pathology report
	1.4	Physical exam
	1.5	Clinical staging
	1.6	Evaluation of patient medical conditions
	1.7	Evaluation of special needs for radiotherapy (e.g., pacemakers)
	1.8	Evaluation of previous radiotherapy treatments (including treatment port images and planning records)
	1.9	Evaluation of other treatment modalities (i.e., chemo, surgery)
	1.10	Decision to treat
	1.11	Entering patient information into radiation oncology information system
	1.12	Selection of clinical protocol
	1.13	Selection of clinical trial (if any)
	1.14	Patient consent
	1.15	Patient education
	1.16	Insurance evaluation
SB	1.17	Peer review of treatment decision (e.g., tumor board)
	1.18	Fiducial placement
SB	1.19	Evaluation/ordering of workup for IV contrast
	1.20	Social work and nutritional assessment
	1.21	Other
2. Imaging for RT planning ☺		
SB	2.1	Verification of patient ID
	2.2	Imaging decision (type and technique)
	2.3	Physician directive for imaging technique and immobilization
	2.4	Patient positioning
	2.5	Construction of immobilization and ancillary devices
	2.6	Documentation of patient positioning and immobilization and ancillary devices
	2.7	Contrast administration
	2.8	Primary image acquisition (CT)
	2.9	Marking reference point on patient and/or localization device and in software
	2.10	Utilization of other imaging modalities (i.e., MRI, US, PET)
	2.11	Transfer of images to treatment planning system
	2.12	Transfer of images to archiving system
	2.13	Other
3.Treatment planning		
	3.1	Registration of image sets
	3.2	Delineation of target(s)
	3.3	Delineation of organs-at-risk
	3.4	Preliminary prescription parameters, constraints & technique (i.e., physician intent)
SB	3.5	Physics consult
	3.6	Isocenter definition
	3.7	Dose distribution optimization
	3.8	Dose distribution calculation
SB	3.9	Preliminary evaluation of treatment plan by physicist
SB	3.10	Preliminary evaluation of treatment plan by physician
	3.11	Iteration of treatment plan
	3.12	Set up for image-guidance/motion management
	3.13	Final plan and prescription approval by physician
	3.14	Plan information transfer to radiation oncology information system
	3.15	Scheduling treatment session(s)
	3.16	Archiving of the treatment plan (images, RT dose and RT structures)
	3.17	Other
4. Pretreatment review and verification		
SB	4.1	Physics plan review
SB	4.2	Independent dose calculation
	4.3	Plan data transfer to treatment unit
SB	4.4	Verification of parameters at treatment unit
SB	4.5	Pretreatment patient specific plan measurement (e.g., IMRT QA)
SB	4.6	Physics verification/approval
SB	4.7	Physician plan peer review (e.g., chart rounds)
SB	4.8	Therapists chart check
	4.9	Other
5. Treatment delivery ☺		
SB	5.1	Verification of patient ID
SB	5.2	Time-out (e.g., verification of clinical parameters, treatment consent, etc.)
	5.3	Prepare patient for treatment (medications, IV, anesthesia, sedation, etc.)
	5.4	Selection of intended course/session
	5.5	Plan information transfer to treatment unit
	5.6	Selection of intended field
	5.7	Patient positioning and immobilization
	5.8	Setting treatment accessories and treatment unit parameters
SB	5.9	Validation of treatment accessories and treatment unit parameters
SB	5.10	Image-guided verification
	5.11	Utilization of motion management system
SB	5.12	Physician verification before treatment
SB	5.13	*In vivo* dosimetry
	5.14	Treatment delivery
SB	5.15	Intratreatment monitoring
	5.16	Record of treatment delivery
	5.17	Monitor evaluation of special needs (e.g., pacemaker protocol)
	5.18	Other
6. On-treatment quality management ☺		
SB	6.1	Initial physics check
SB	6.2	Review of portal images
SB	6.3	Review of localization images (including CBCT)
	6.4	Adaptive replanning
SB	6.5	Weekly physics chart check,
SB	6.6	Weekly physician management visit, social work, nutrition and nursing
SB	6.7	Weekly therapist chart check
	6.8	Other
7. Post-treatment completion ☺		
SB	7.1	Verification of patient ID
SB	7.2	Final chart check
	7.3	End of treatment summary to patient and referring providers

	7.4	Follow up imaging for treatment evaluation
	7.5	Follow up lab work
	7.6	Follow up patient management visit
	7.7	Other
8. Equipment and software quality management		
SB	8.1	Acceptance testing
SB	8.2	Commissioning
	8.3	Application/system training
SB	8.4	Ongoing quality management (e.g., daily, monthly, annual QA, etc.)
SB	8.5	Preventive maintenance (PM)
	8.6	Equipment repair and software changes/updates
SB	8.7	Post-repair/changes verification
	8.8	Documentation of quality management
	8.9	Respond to medical device alerts
	8.10	Other

2. Process map, Brachytherapy

"SB" indicates a process step that serves primarily as a safety barrier. The symbol ☺ indicates processes in which the patient is physically present during at least some part of the process.

1. Patient Assessment ☺		
SB	1.1	Verification of patient ID
	1.2	Diagnosis definition including imaging and outside records
SB	1.3	Review and verification of pathology report
	1.4	Physical exam
	1.5	Clinical staging
	1.6	Evaluation of patient medical conditions
	1.7	Evaluation of special needs for radiotherapy (e.g., pacemakers)
	1.8	Evaluation of previous radiotherapy treatments (including treatment port images and planning records)
	1.9	Evaluation of other treatment modalities (i.e., chemo, surgery)
	1.10	Decision to treat
	1.11	Entering patient information into radiation oncology information system
	1.12	Selection of clinical protocol
	1.13	Selection of clinical trial (if any)
	1.14	Patient consent
	1.15	Patient education
	1.16	Insurance evaluation
SB	1.17	Peer review of treatment decision (e.g., tumor board)
	1.18	Fiducial placement
SB	1.19	Evaluation/Ordering of workup for IV contrast
	1.20	Social work and nutritional assessment
	1.21	Other
2. Imaging for RT planning ☺		
SB	2.1	Verification of patient ID
	2.2	Imaging decision (type and technique)
	2.3	Physician directive for imaging technique and immobilization
	2.4	Patient Positioning
	2.5	Construction of immobilization and ancillary devices
	2.6	Documentation of patient positioning and immobilization and ancillary devices
	2.7	Contrast administration
	2.8	Primary image acquisition
	2.9	Utilization of other imaging modalities (i.e., MRI, US, PET)
	2.10	Transfer of images to treatment planning system
	2.11	Transfer of images to archiving system
	2.12	Other
3. Treatment planning		
	3.1	Registration of image sets
	3.2	Delineation of Target(s)
	3.3	Delineation of organs-at-risk
	3.4	Preliminary prescription parameters, constraints & technique (i.e., physician intent)
	3.5	Selection of applicator
	3.6	Selection of source
	3.7	Selection of template or other auxiliary instruments
	3.8	Source ordering
SB	3.9	Physics consult
	3.10	Dose distribution optimization
	3.11	Dose distribution calculation
SB	3.12	Preliminary evaluation of treatment plan by physicist
SB	3.13	Preliminary evaluation of treatment plan by physician
	3.14	Iteration of treatment plan
	3.15	Final plan approval and prescription by physician
	3.16	Plan information transfer to radiation oncology information system
	3.17	Other
4. Pre-treatment review and verification		
SB	4.1	Physics plan review
SB	4.2	Independent dose calculation
SB	4.3	Independent source assay
SB	4.4	Source and/or dwell verification
	4.5	Plan data transfer to treatment unit
SB	4.6	Verification of parameters at treatment unit (if appropriate)
SB	4.7	Physics verification/approval
SB	4.8	Physician verification and approval of plan/written directive
SB	4.9	Physician plan peer review (e.g., chart rounds)
	4.10	Other
5. Treatment delivery ☺		
SB	5.1	Verification of patient ID
SB	5.2	Time-out (e.g., verification of clinical parameters, treatment consent, etc.)
	5.3	Prepare patient for treatment (medications, IV, anesthesia, sedation, etc.)
	5.4	Selection of intended course/session
	5.5	Patient positioning
	5.6	Source preparation
SB	5.7	Validation of proper applicator
	5.8	Applicator placement
SB	5.9	Validation of proper source
SB	5.10	Image-guided verification
SB	5.11	*In vivo* dosimetry
	5.12	Treatment delivery/Source placement
	5.13	Verification of source removal time
	5.14	Source removal

SB	5.15	Postradiation survey/release criteria
	5.16	Management of non-utilized or return sources
	5.17	Record of treatment delivery
	5.18	Weekly on-treatment visit by attending, NP, etc.
	5.19	Other
6. Post-treatment completion ☺		
SB	6.1	Verification of patient ID
	6.2	Follow up imaging for treatment evaluation
SB	6.3	Post-treatment dosimetry and review
SB	6.4	Review of written directive
SB	6.5	Final chart check
	6.6	End of treatment summary to patient and referring providers
	6.7	Follow up lab work
	6.8	Follow up patient management visit
	6.9	Other
7. Equipment and software quality management		
SB	7.1	Acceptance testing
SB	7.2	Commissioning
	7.3	Application/system training
SB	7.4	Ongoing quality management (e.g., daily, monthly, annual QA, etc.)
SB	7.5	Preventive maintenance (PM)
	7.6	Equipment repair and software changes/updates
SB	7.7	Post repair/changes verification.
	7.8	Documentation of quality management
	7.9	Respond to medical device alerts
	7.10	Other

APPENDIX C: SEVERITY SCALES

1. Medical severity scale

Score	Consequences (actual or predicted)
10	Premature death
8/9	Life threatening—intervention essential. Possible recurrence due to underdose.
7	Permanent major disability (or grade 3/4 permanent toxicity)
5/6	Permanent minor disability (or grade 1/2 permanent toxicity)
3/4	Temporary side effects—major treatment/hospitalization
2	Temporary side effects—intervention indicated
1	Temporary side effects-–intervention not indicated
0	No harm
. . .	Unknown

Note: Near-miss incidents should be assigned the estimated harm that would have occurred had the incident reached the patient. Consequences may arise from underdosing a target structure as well (with a recommended score of 9 in the above table). This recommendation may change over time based on developing quantitative knowledge of tumor control probabilities. Some of the words and notions in the table are taken from the common terminology criteria for adverse events (CTCAE) grading system.[29] *Note that this scale differs from the one presented in AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*) (see text for full description).

2. Dosimetric scale

Score	Dose deviation per course
9/10	>100% absolute dose deviation from the total prescription for any structure
7/8	>25%–100% absolute dose deviation from the total prescription for any structure
5/6	>10%–25% absolute dose deviation from the total prescription for any structure
3/4	>5%–10% absolute dose deviation from the total prescription for any structure
1/2	<5% absolute dose deviation from the total prescription for any structure
. . .	Not applicable

Note: A geographic miss or treatment delay is given the score that describes a similar expected dosimetric outcome as an absolute dose deviation for a geometrically correct delivery at the correct time. *Note that this severity scale differs from the one presented in AAPM Task Group 100 (TG100, "Application of Risk Analysis Methods to Radiation Therapy Quality Management" Huq *et al.*) (see text for full description).

APPENDIX D: CAUSALITY

1. Organizational management
    a. Planning for program maintenance or expansion
        i. Inadequate human resources
            1. Staffing not consistent with professional clinical recommendations
            2. Staffing not consistent with vendor specs, or
            3. Staffing not consistent with regulations
            4. No provision for incremental increases in activities (reports, additional duties, committee participation)
        ii. Inadequate capital resources
            1. Inadequate budget for equipment
            2. Inadequate support/service contracts
            3. Inadequate training support
            4. Insufficient educational budgets
            5. Insufficient IT infrastructure
            6. Inappropriate or inadequate equipment
        iii. Admin/contractor negotiations for support or staff
    b. Policies, procedures, regulations
        i. Relevant policy nonexistent
        ii. Policy not implemented
        iii. Policy inadequate
        iv. Policy not followed
        v. External regulation not followed
        vi. Conflicting policies

- c. Training; acquiring, and transmitting knowledge and skills
  - i. Appropriate skills not acquired from facility training
  - ii. Appropriate skills not acquired from vendor provided training
  - iii. Inadequate periodic assessment of staff competencies
  - iv. Lack of continuing education
- d. Communication
  - i. Poor, incomplete, unclear or missing documentation
  - ii. Inadequate communication patterns designed
  - iii. Inappropriate or misdirected communication
  - iv. Failure to request needed information
  - v. Outside medical records old/incorrect/incomplete/absent
  - vi. Lack of timeliness
  - vii. External factors
  - viii. Verbal instructions not supported by written documentation
- e. Physical environment
  - i. Physical environment inadequate (poor lighting, excessive sound etc.)
  - ii. Distracting environment
  - iii. Interruptions
- f. Leadership and external issues
  - i. Inadequate safety culture
  - ii. Failure to remedy past known shortcomings
  - iii. Environment not conducive to safety
  - iv. Hostile work environment
  - v. Inadequate supervision
  - vi. Lack of peer review
  - vii. Leaders not fluent in the discipline
  - viii. Outdated practices

2. Technical
   - a. Proper acceptance testing and commissioning of new equipment
     - i. Not following explicit referral to best-practice documents (AAPM TG reports, ASTRO, ACR, IPEM, COMP, etc)
     - ii. Lack of independent review
     - iii. Lack of review of preexisting reports
     - iv. Lack of effective documentation (vendor or self)
   - b. Equipment design and construction issues
     - i. Inadequate policies and procedures for quality assurance and quality control
     - ii. Poor human factors engineering
     - iii. Interoperability problems
     - iv. Networking problems (IT)
     - v. Software operation failure
     - vi. Hardware failure
     - vii. Poor construction (physical)
   - c. Equipment maintenance issues
     - i. Failure to report problems to vendor
     - ii. Failure to follow vendor notices (field change orders)
     - iii. Failure to provide adequate preventive maintenance
     - iv. Failure on the vendor's part to share failure/safety issues in a timely manner
     - v. Unavailability of local and field support as needed
   - d. Environment (within the facility)
     - i. Ergonomics (room layout and equipment setup)
     - ii. Machine collision issues (room specific)
     - iii. Environment (water, HVAC, electrical, gas)
     - iv. IT infrastructure and networking issues (including compliance to expected security and capacity standards)
     - v. Delay in corrective actions for facility problems
3. Human behavior involving staff
   - a. Acting outside one's scope of practice
   - b. Slip causing physical error (failure in performance of highly developed skills as intended or maintained)
   - c. Poor judgment (e.g., failure to carry out quality control on a patient due to time limitation)
   - d. Language and comprehension issues
   - e. Intentional rules violations (sabotage/criminal acts, criminal intent, intentional violation)
   - f. Negligence (risky behavior, poor judgment in failure to address issues or extreme demands, lack of vigilance; recklessness)
4. Patient-related circumstances
   - a. Misleading representation
   - b. Cognitive performance issues
   - c. Non-compliance
   - d. Language issues and comprehension
   - e. Patient medical condition (inability to be positioned or remain still)
5. External factors (beyond facility control)
   - a. Natural environment
   - b. Hazards
6. Procedural issues
   - a. Failure to detect a developing problem
     - i. Environmental masking
     - ii. Distraction
     - iii. Loss of attention
     - iv. Lack of information
   - b. Failure to interpret the nature of the developing problem
     - i. Inadequate search
     - ii. Missing information
     - iii. Incorrect information
     - iv. Expectation bias
   - c. Failure to select the correct rule to address problem
     - i. Incomplete or faulty rule
     - ii. Old or invalid rule
     - iii. Misapplication of a rule
       1. Similarity bias/stereotype fixation
       2. Familiar pattern not recognized
       3. Familiar association short-cut
   - d. Failure to develop an effective plan
     - i. Information not seen or sought
     - ii. Inappropriate assumptions
     - iii. Information misinterpreted
     - iv. Side effects not adequately considered
     - v. Mistaken options
   - e. Failure to execute the planned action
     - i. Stereotype take-over/faulty triggering
     - ii. Plan forgotten in progress
     - iii. Plan misinterpreted
     - iv. Plan too complicated (bounded reality)
7. Other

APPENDIX E: DATA ELEMENTS

Data elements are organized into a trilevel system:

(1) Report. To be completed by the person initially reporting the incident.
(2) Analysis. To be completed by the person performing follow-up analysis.
(3) Response. To be completed as part of the response to the incident.

1. Reporter's form

#	Data element	Level	Format	Encrypt	Definition
1.1	Date of incident(s)	Required	YYYY-MM-DD	N	The date that the incident occurred. If the incident occurred on more than one date, this is the date of the first occurrence
1.2	Time of incident(s)	Optional	HH:mm 24-hr format UTC	N	The time of day that the incident occurred. If the incident occurred on more than one time this is the time of the first occurrence
1.3	Date of report	Recommend	YYYY-MM-DD	N	The date that the report is logged
1.4	Date of discovery	Optional	YYYY-MM-DD	N	The date that the incident was first discovered
1.5	Incident type	Required	Pulldown	N	Near miss or actual event
	Options: 1: actual incident 2: near-miss; no-one affected				
1.6	Person affected	Required	Pulldown	N	The person(s) affected in the incident
	Options: 0: no one affected 1: one patient affected 2: several patients affected (give number) 3: staff 4: other (specify) 5: unknown				
1.7	Number of fractions delivered incorrectly	Required	Integer	N	The number of radiation treatment fractions delivered incorrectly
1.8	Incident description	Required	Text	N	Description of the incident provided by the person reporting. This should be a detailed description that can be read and understood by any radiation therapy professional in any clinic
1.9	Where found	Recommend	Pulldown	N	The point in the workflow where the incident was initially discovered
	Options: refer to detailed process maps (Secs. 2 and 3 of Appendix B, WGPE process maps)				
1.10	How discovered	Recommend	Text	N	A brief description of how the event was discovered
1.11	Patient's first name	Recommend	Text	Y	The first name of the patient affected. "Multiple" if multiple patients were affected
1.12	Patient's last name	Recommend	Text	Y	The last name of the patient affected. "Multiple" if multiple patients were affected
1.13	Patient's medical record number	Recommend	Text	Y	The medical record number of the patient affected. "Multiple" if multiple patients were affected
1.14	Treatment modality	Recommend	Pulldown	N	The radiation therapy modality used or planning to be used at the time of the incident
	Options: 1: photons 2: electrons 3: particles 4: brachytherapy 5: radioisotope 6: other (specify) 7: not applicable				
1.15	Person reporting first name	Optional	Text	Strip	The first name of the person filing the initial report
1.16	Person reporting last name	Optional	Text	Strip	The last name of the person filing the initial report
1.17	Person reporting 's role	Optional	Pulldown	Strip	The departmental role of the person filing the initial report
	Options: 1: attending radiation oncologist 2: resident radiation oncologist 3: other physician 4: radiation therapist 5: dosimetrist 6: physicist 7: nurse, NP or PA 8: administrator 9: patient 10: other (specify)				
1.18	Action taken by reporter	Optional	Text	N	The immediate response of the person reporting. This information is provided so the evaluator has it up front for follow up

2. Analyst's form

#	Data Element	Level	Format	Encrypt	Definition
2.1	Location	Recommend	Text	Y	City and state/province where the incident occurred
2.2	Facility profile	Recommend	TBD	Y	Information about the facility where the incident occurred including number of linacs, patients on treatment, etc.
2.3	Patient's age at the time of the incident	Recommend	Integer	Y	The age of the patient when the incident occurred
2.4	Patient's race	Recommend	Pulldown	N	The ethnic race of the patient.
	Options: 1: American Indian or Alaska Native 2: Asian 3: Black or African American 4: Hispanic 5: Native Hawaiian or Other Pacific Islander 6: White 7: Some other race 8: More than one race 9: Unknown 10: not applicable				
2.5	Gender	Recommend	M/F/unknown	N	The sex of the patient
2.6	Patient notification	Recommend	Y/N/unknown	N	Were patient, patient's family or guardian notified?

#	Data Element	Level	Format	Encrypt	Definition
2.7	Treating radiation oncologist	Recommend	Pulldown	Y	The radiation oncologist of record at the time of the incident
	Options: for individual clinic systems the pulldown consists of a list of physician provides for a national system the list would derived from a database of provider IDs				
2.8	Treating radiation oncologist notified	Recommend	Y/N/unknown	N	Was treating radiation oncologist notified?
2.9	Referring physician(s) notified	Recommend	Y/N/unknown	N	Was referring physician(s) notified?
2.10	Disease being treated	Recommend	Text	N	The primary disease being treated. Use ICD-9 code if available
2.11	Disease stage	Optional	Text	N	The stage of the disease at the time of the incident. Use TNM staging descriptors
2.12	Intended treatment site	Recommend	Text	N	Intended anatomical site of treatment. For multiple sites indicate the most appropriate site
2.13	Treatment intent	Optional	Pulldown	N	Immediate intent of radiation treatment
	Options: 1: curative 2: palliative 3: unknown 4: not applicable				
2.14	Total prescribed dose	Recommend	Real number	N	Total prescribed radiation dose for the full treatment being delivered at the time of the incident in units of Gy
2.15	Dose per fraction	Recommend	Real number	N	Total prescribed radiation dose per fraction at the time of the incident in units of Gy
2.16	Course	Recommend	Pulldown	N	Radiation course at the time of the incident
	Options: 1: primary phase 2: boost phase 3: modification during treatment 4: other (specify) 5: not applicable				
2.17	Treatment technique	Recommend	Pulldown	N	The radiation therapy technique used or planning to be used at the time of the incident
	Options (select all that apply): 1: simple 2: 3D conformal 3: IMRT 4: SRT/SRS cranial 5: SBRT 6: modulated arc therapy 7: intracranial, intraluminal, intravascular or surface 8: interstitial 9: LDR, PDR 10: HDR 11: temporary implant 12: permanent implant 13: orthovoltage 14: other (specify) 15: not applicable				
2.18	Image guidance	Optional	Pulldown	N	The image-guidance technique(s) used or planning to be used at the time of the incident
	Options (select all that apply): 1: kV or MV radiographs 2: IGRT: kV cone-beam CT 3: IGRT: MV cone-beam CT 4: MV CT 6: stereo camera tracking 7: other (specify) 8: none 9: not applicable				
2.19	Person discovering first name	Optional	Text	Strip	The first name of the person who initially discovered the incident
2.20	Person discovering last name	Optional	Text	Strip	The last name of the person who initially discovered the incident
2.21	Person discovering 's role	Optional	Pulldown	Strip	The departmental role of the person who initially discovered the incident. Note may be different than the person reporting (element 1.15, 1.16, and 1.17)
	Options: 1: attending radiation oncologist 2: resident radiation oncologist 3: other physician 4: radiation therapist 5: dosimetrist 6: physicist 7: nurse, NP or PA 8: administrator 9: patient 10: other (specify)				
2.22	Treatment unit manufacturer(s)	Recommend	Pulldown	N	The manufacturer of the hardware used to deliver treatment in the incident
2.23	Treatment unit model(s)	Recommend	Pulldown	N	The model of the hardware used to deliver treatment in the incident
2.24	Treatment planning system manufacturer	Recommend	Pulldown	N	The manufacturer of the software used to plan treatment in the incident
2.25	Treatment planning system model	Recommend	Pulldown	N	The model of the software used to plan treatment in the incident
2.26	Record and verify system manufacturer	Recommend	Pulldown	N	The manufacturer of the record and verify system in the incident
2.27	Record and verify system model	Recommend	Pulldown	N	The model of the record and verify system in the incident
2.28	Third-party ancillary device manufacturer	Recommend	Pulldown	N	The manufacturer of any third-party ancilliary devices being used or planned for use in the incident.
2.29	Third-party ancillary device model	Recommend	Pulldown	N	The model of any third-party ancilliary devices being used or planned for use in the incident
2.30	Number of patients on-treatment	Optional	Integer	N	The number of patients being treated on the day of the incident on the treatment unit where the incident occurred
2.31	Number of radiation therapists present	Optional	Integer	N	The number of RTTs present at the time when the incident occurred. Leave blank if incident did not occur on treatment unit

#	Data Element	Level	Format	Encrypt	Definition
2.32	Number of other staff present	Optional	Integer	N	The number of other staff present at the time when the incident occurred. Leave blank if incident did not occur on treatment unit
2.33	Staff involved	Optional	Pulldown	Y	Names and roles of staff present when the incident occurred
2.34	Error type	Optional	Pulldown	N	The type of error that occurred or potentially could occur
	Options (select all that apply): 1: wrong patient or potentially wrong patient 2: wrong anatomical site or potentially wrong site 3: wrong laterality or potentially wrong laterality 4: wrong dose to all or part of the tumor or normal tissue or potentially wrong dose 5: wrong modality or energy or potentially wrong modality or energy 6: other (specify) 7: not applicable				
2.35	Dosimetric severity	Optional	Pulldown	N	See Appendix C
	Options: refer to Appendix C, WGPE severity scales				
2.36	Reportable event	Optional	Y/N/unknown	N	Was the event reportable to the relevant regulatory agency (state, NRC)?
2.37	Medical severity	Required	Pulldown	N	See Appendix C. For potential incidents (near-misses) assume a worst-case scenario if the incident were actually to occur
	Options: refer to Appendix C, WGPE severity scales				
2.38	Severity assessment type	Required	Pulldown	N	The method used for assessing the severity of harm
	Options: 1: estimated severity 2: actual observed severity 3: not applicable				
2.39	When severity assessed	Recommend	Pulldown	N	The time after the incident at which the severity of harm was observed or at which it is estimated to occur
	Options: 1: before 24 hours 2: after 24 hours but before 3 days 3: three days or later 4: unknown				
2.40	Summary title	Optional	Text	N	A very brief title phrase describing the incident
2.41	Incident analysis (from evaluator)	Optional	Text	N	Description of the incident provided by the person evaluating the incident in the clinic. This should provide very detailed information from which one can infer root causes
2.42	Where originated	Recommend	Pulldown	N	The point in the workflow where the incident originated
	Options: refer to detailed process maps (Secs. 2 and 3 of Appendix B, WGPE process maps)				
2.43	Attached files	Optional	File	N	Files (e.g., screenshots, pdf reports, etc.) that may help clarify the details of the incident
2.44	Causes	Required	Pulldown	N	List all the causes and contributing factors at work in the incident. For potential incidents assume a worst-case scenario if the incident had actually occurred. See Appendix D
	Options (select all that apply): Refer to Appendix D, WGPE causality table				

3. Responder's form

#	Data Element	Level	Format	Encrypt	Definition
3.1	Clinical action scale	Optional	Pulldown	N	Priority scale to guide the follow-up actions of the clinic
	Options: A,B, C, D (exact meaning of each to be determined by the individual clinic)				
3.2	Intervention	Recommend	Pulldown	N	Was any intervention attempted in order to "rescue" the patient (i.e., to prevent, minimize or reverse harm)?
	Options (select all that apply): 1: treatment stopped 2: treatment modified 3: added additional treatment fractions 4: patient's stay in hospital extended 5: intervention pending 6: no intervention 7: unknown 8: other (specify) 9: not applicable				
3.3	Safety barriers	Recommend	Pulldown	N	The safety barriers or quality control measures in place which prevented or could prevent the incident
	Options: (select all that apply). Refer to detailed process maps (Secs. 2 and 3 of Appendix B, WGPE process maps)				
3.4	Corrective action	Optional	Text	N	Corrective action(s) taken to mitigate the harm for this particular patient
3.5	Preventive action	Optional	Text	N	Preventive action taken to insure that a similar incident will not happen to a patient in the future
3.6	Learning actions	Optional	Text	N	The learning activities that were undertaken in response to the incident, for example, presentation at rounds, etc.
3.7	Incident closed	Optional	Y/N	N	Has the incident been closed by the evaluator responsible for incident handling? This includes the implementation and evaluation of corrective, preventive and learning actions. Quality control of the data should also be performed

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