Ontario Health

Best-Practice Guidance for Radiation Treatment Plan Physics Review

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Physics Community of Practice Working Group – Treatment Plan Review Quality Metrics

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Ontario Cancer Care Ontario

1. Introduction

The Physics Community of Practice under the Radiation Treatment Program at Ontario Health (Cancer Care Ontario) identified defining a list of practice guidance as a main objective to aid in the standardization of Physics plan review across the province to ensure delivery of high-quality care for patients. The secondary objective of this activity was to provide Medical Physics training and education to achieve the main objective. The tertiary objective was to advise the development of a new provincial funding model for radiation treatment (Radiation Treatment - Quality Based Procedure initiative), specific to quality metrics, on the subject of radiation treatment plan physics review.

A working group of ten medical physicists, from eight institutions across Ontario, was assembled. The group had representatives from both community cancer centres and research institutions, with expertise in external beam radiotherapy (EBRT) and brachytherapy (BT). It conducted a literature review on existing guidance and peer reviewed papers to help inform the best practice recommendations outlined in this document. In the absence of evidence, the collective clinical expertise and experience of the group members were consulted. This document should be considered for review in three years unless newly published research or guidance documents from a professional society warrants a change in plan review practice in the interim.

Radiation treatment is a complex process involving many medical personnel, equipment, software, data, and information transfer between staff and systems. Because of this complexity, there are many instances where errors can be made, with potential to propagate to patient treatment. Recently, a review of high potential severity incidents along this complex workflow lead to a systematic identification of quality control measures to mitigate the errors associated with these incidents [1]. It was found that the most sensitive measure was the pre-treatment physics plan review, otherwise known as *plan checking* or *chart checking*, with a detection rate of >60% [1].

As per the Scope of Practice defined by the Canadian Organization of Medical Physicists, radiation oncology physicists are responsible for ensuring the accuracy of the treatment delivered. This is accomplished through specific duties and responsibilities, including but not limited to: equipment selection, acceptance testing, commissioning of hardware and software, establishing quality assurance protocols and procedures, and technique development. Medical physicists are thus uniquely positioned to understand the potential errors in the entire process of treatment planning, from imaging to execution, and be able to detect them through plan review. However, a recent study found that simulated errors are detected about two out of three times only[2]. Chart checking should therefore also be treated as a means to inform local quality and safety improvement processes and as an educational opportunity.

2. Document Overview

A ***Qualified Medical Physicist*** is required to review the patient treatment plan as an integral part of the treatment planning process, and the review *must be completed prior to the start of treatment*. The results should always be within institutional policies, which in turn should be based on national and international guidelines and consensus documents, if available. Any deviation from these should be justified and documented.

In Section ***3*** of this document, the following key quality indicators (KQI) of chart checking are subdivided into five main topics. Among these topics, ***Infrastructure***, ***Combined EBRT & Brachytherapy Process***, and ***Documentation*** KQIs in ***Table 1***, ***Table 2*** and ***Table 5*** respectively, are applicable to both EBRT and BT. ***Table 3*** and ***Table 4*** contains KQIs that are EBRT or BT specific, respectively.

There are two levels of language used to refer to imperatives throughout the document:

> MUST: the term is used when the action is considered best practice and must routinely be performed, although not required by law, and is modified or removed only under extraneous circumstances.
>
> SHOULD: the term is used where the action is advisable to produce high quality review. If modification or removal of action is considered, it is recommended to do so only after careful analysis showing that quality is not degraded.

The KQIs are phrased as quality assurance activities or actions and are free of these imperatives. Section ***0*** of this document, Details and Examples, provides further explanation of the KQIs. In this section the imperatives MUST and SHOULD are used in the sense of their definitions above.

Throughout sections ***3*** and ***4***, words and phrases with specific meanings and definitions are ***bolded and italicized***. The definitions of these words and phrases as they are used in this document are provided in Section ***5***, the Glossary.

3. Quality Metrics

Table 1: Infrastructure Quality Metrics

KQI	Description	Indicator Measure
I1	A) Percentage of chart checking physicists that are ***Qualified Medical Physicist (QMP)*** or B) percentage of charts that are checked by QMPs.	0 – 100%
I2	Chart checking follows a well-defined procedure that is outlined in ***Institutional Policies***.	0 or 1
I3	A Health Canada Approved ***Treatment Planning System*** is used to generate the plan.	0 or 1
I4	The ***Treatment Planning System*** is commissioned following ***Accepted Guidance***.	0 or 1
I5	A secondary dose or monitor unit calculation is performed using software that is commissioned according to ***Accepted Guidance***.	0 or 1
I6	Standardized nomenclature is established and consistent across EBRT and Brachytherapy	0 or 1
I7	Radiation treatment centres follow well-defined procedures to ensure correct data transfer between treatment planning, record & verify, treatment delivery, and ***Secondary Dose Verification System*****.**	0 or 1
I8	A ***Feedback Learning System*** for chart checking is in place.	0 or 1

Table 2: Combined EBRT & Brachytherapy Process Quality Metrics

KQI	Description	Indicator Measure
	Patient Assessment and Treatment Prescription	
C01	The ***Patient Identifiers*** in the treatment plan are verified against the patient identifiers in the institution's Electronic Medical Record (EMR).	0 or 1
C02	Previous irradiation, pacemaker, and pregnancy status (if applicable) are identified.	0 or 1
C03	***Treatment Intent*** is documented and meets ***Institutional Policies***.	0 or 1
C04	The ***Prescription*** is assessed against ***Accepted Guidance*** *and/or* ***Institutional Policies*** or follows the study protocol**.**	0 or 1
	Simulation	
C05	The ***Primary Dataset*** is reviewed and assessed for image quality.	0 or 1
C06	Documentation on ***Patient Setup Instructions*** and supporting devices is assessed.	0 or 1
	Treatment Planning	
C07	Selection and registration of all ***Planning Image Datasets*** are reviewed.	0 or 1
C08	The ***Prescription*** in the plan is assessed against the prescription approved by the oncologist and laterality for paired sites is documented.	0 or 1
C09	Any ***ROI Structures*** that is used in the planning process is checked for nomenclature, integrity, and appropriateness according to institutional planning protocols.	0 or 1
C10	Prior radiation and its dose distribution (if applicable) are accounted for.	0 or 1
C11	***Plan Parameters*** are assessed and are appropriate.	0 or 1
C12	Spatial dose distribution and dosimetric parameters to targets and OARs are assessed and meet institutional plan quality goals as well as quality expected for the individual patient.	0 or 1
	Dose Verification	
C13	Independent dose calculation is performed.	0 or 1
C14	Patient specific QC is performed according to ***Institutional Policies*****.**	0 or 1
	Data Transfer between systems	
C15	Plan, and all ***Plan Parameters*** transferred to the record & verify system or the delivery unit are checked for accuracy.	0 or 1
C16	All plans are reviewed and approved as per ***Institutional Policies*** prior to the start of radiation delivery.	0 or 1

Table 3: EBRT-specific Process Quality Metrics

KQI	Description	Indicator Measure
	Image Guidance	
E1	***Motion Management*** instructions and parameters (gating, breath hold) are assessed for completeness and appropriateness for the planning and treatment technique.	0 or 1
E2	Image guidance instructions are assessed for completeness. ***Reference Image Transfer*** and/or transfer of DRRs is verified, if applicable.	0 or 1
E3	Potential for treatment machine collision with the patient is assessed prior to treatment.	0 or 1

Table 4: Brachytherapy-specific Process Quality Metrics

KQI	Description	Indicator Measure
B1	Review of verification images for applicator placement is performed, if applicable.	0 or 1
B2	Review of applicator/needle reconstruction is performed.	0 or 1
B3	Pre-treatment QA for HDR/LDR is performed.	0 or 1

Table 5: Documentation

KQI	Description	Indicator Measure
D1	Record of treatment details in patient chart is assessed for completeness as per ***Institutional Policies*****.**	0 or 1
D2	Record of patient-specific QA (PSQA) is assessed for completeness as per ***Institutional Policies*****.**	0 or 1
D3	Record of ***Deviations From Guidance and/or Institutional Policy*** is assessed for completeness and signed off by a physician.	0 or 1

4. Details and Specific Examples

Infrastructure

KQI	Explanation
I1	A Medical Physicist certified by the Canadian College of Physicists in Medicine (CCPM), or equivalent, is considered to be a ***Qualified Medical Physicist***[3], [4].
I2	In order to achieve uniformity in chart checking practices the Medical Physicists engaged in chart checking MUST develop a chart review protocol or check list[5, Sec. VI C.3].
I3	A ***Treatment Planning System*** is considered a ***Class III Medical Devices***. A non-Health Canada approved treatment planning system component is only to be used when no suitable alternative is available and the anticipated benefit outweighs the potential harm[6], [7]. An exception is usually made for clinical markup plans, where the treatment fields are determined at treatment time. In this case, only a secondary monitor unit calculation is performed.
I4	***Treatment Planning System*** Commissioning and on-going quality assurance MUST follow ***Accepted Guidance***[5], [8] and MUST meet the following criteria: • The commissioning was overseen and approved by a ***Qualified Medical Physicist***. • The commissioning work follows current practice guidance[9]. • Users have received the necessary training to perform their tasks in the planning system. • Documentation of the software and of the commissioning process is readily accessible. • There is on-going, documented QA of the treatment planning system.
I5	The ***Secondary Dose Verification System*** MUST be commissioned according to ***Accepted Guidance***[5], [10]. The secondary dose verification system is not considered ***Software as a Medical Device*** and does not require Health Canada Approval[11].
I6	The preferred guidance for ***ROI Structures*** nomenclature are the recommendations from AAPM Task Group 263[12], [13] and the relevant ICRU reports[14], [15]. Other standards are acceptable provided they are well documented[4].
I7	Well-defined procedures MUST be in place and followed to ensure correct ***Data Transfer*** between treatment planning, record & verify, treatment delivery, and ***Secondary Dose Verification Systems***[16].
I8	A review of rejected plans, and a discussion on ***Deviations From Guidance and/or Institutional Policy*** that are outside the usually accepted variances SHOULD be conducted periodically with all QMPs that are involved in treatment plan review. This is a continuous improvement activity and serves as an excellent educational opportunity to maintain high standards for chart checking.

Combined EBRT & Brachytherapy Process

C01	The ***Patient Identifiers*** in the treatment plan MUST be consistent with the information in the hospital's medical record.
C02	The presence of previous irradiation, ***Cardiac Implantable Electronic Devices***, and pregnancy status MUST be identified and taken into consideration for planning.
C03	***Treatment Intent*** is the physician's goal in prescribing the treatment and is usually one of "Radical", "Palliative", "Adjuvant", or some subcategory or variation of these primary intent categories.
C04	The ***Prescription*** for the given site and intent SHOULD be assessed against institutional policy, or study protocol, if applicable.
C05	Review of the ***Primary Dataset*** needs to ensure that image quality is adequate and appropriate for planning and treatment. The ***Qualified Medical Physicist*** must be aware of the factors that affect image quality as well as the effect of image distortions on treatment planning[5], for ultrasound systems, see[17]. For brachytherapy, if images are acquired to verify intracavitary, intraluminal, and interstitial implants, they SHOULD be acquired with the patient in treatment position[5], [18]–[20]. The chart checking activity SHOULD include the review of: • The appropriate use of image modality. • The coordinate systems and ***Patient Orientation*** of each image set.

- The appropriate mapping of image data to physical properties used for the dose calculation. For example: The planning system uses the correct ***CT Density Table***.
- The assessment of a sufficient field-of-view (FOV) for its purpose in the planning process. For example, for external beam planning, the patient surface SHOULD not be clipped/truncated by the FOV where fields may be entering.
- The assessment of the imaging parameters for all image sets such as slice thickness, and image resolution.
- The MRI sequences and appropriate CT reconstruction filters.
- The use of sufficient image contrast for its intended purpose.

C06 ***Patient Identifiers*** SHOULD be adequate for the reproduction of patient setup and immobilization at treatment[5], [18], [21], [22]. A case scenario for wrong documentation of couch shifts is described in[23]. Examples of setup instructions for EBRT: Position of tattoos, ***Patient Orientation***, couch shifts to isocenter, and ***Immobilization Devices***.
Brachytherapy examples include set-up notes for multi-fraction skin lesions, leg position and probe angle for LDR prostate, leg position and perineal bar measurements for gynae treatments using an intra-vaginal applicator.

C07 For EBRT, different datasets may routinely be acquired in the context of motion management (helical CT, or selected phases of a 4D-CT). The one dataset from this set that is selected for planning (the ***Primary Dataset***) SHOULD be consistent with the motion management technique for treatment according to ***Institutional Policies***. See also KQI E1.
Besides the ***Primary Dataset*** used for the dose calculation, other image datasets (e.g. CT, MRI, PET, CBCT, US), are often used for the segmentation of target and organs-at-risk or to verify brachytherapy implants. Image registration between the primary dataset and these ***Secondary Datasets*** SHOULD be reviewed and the quality of image registration verified[24].

C08 The physics check of the ***Prescription*** involves confirming consistency between the approved prescription and its application in the various components of the treatment plan[22], [25]–[28]. In particular, the location of prescription points and plan normalization and/or plan scaling MUST be assessed.
The prescription information should be non-volatile, i.e. once completed and approved, it SHOULD not be possible for it to be modified. Alternatively, institutional policies SHOULD describe a well-documented protocol for prescription changes and the physics check SHOULD include verification that this protocol was followed.

C09 The ***ROI Structures*** used in treatment planning SHOULD be assessed for the following:

- All ROI structures required for planning are present[14], [15].
- Nomenclature (see KQI I6) follows ***Accepted Guidance***
- Contour integrity (skipped slices, contour artifacts, disjoint parts of contours)
- Appropriate use of interpolation, expansion (as per protocol), combination of contours (e.g. to create ITV), etc.
- Correct use of density override
- Presence/absence of accessory structure (e.g. tabletop) as per protocol

C10 If a patient has received previous radiotherapy treatment, verification is needed that the treatment records have been obtained and reviewed, and that there is documentation of the review (usually by the physician). In case of dose distribution overlap with previous treatment, the previous treatment area is visualized in the current plan or a composite dose distribution is generated and reviewed. Examples of taking into account prior radiation dose are re-planning and retreatment scenarios, adaptive radiotherapy and in gynae brachytherapy.

C11 The purpose of ***Plan Parameters*** assessment is to ensure that they are within limits of commissioning and that the dose distribution in the treatment plan accurately reflects intended delivery. The specific parameters to be recorded in the patient's record SHOULD be defined in institutional policies and the physicist is expected to verify these parameters against the full electronic plan data.

- Examples of plan parameters for EBRT: isocentre position, technique, beam geometry, beam apertures (in particular for forward-planned treatment plans), beam segments, beam energy, machine model, use of beam-modifying devices such as bolus, wedges, or beam spoilers, use of additional shielding devices (e.g. eye or testicular shields), dose grid, total monitor units[5], [29], [30].

- Examples of plan parameters for Brachytherapy: needles, applicator type and size, etc. afterloader, seed/source type, seed/source description (line vs point), commissioned dose calculation algorithm, and total reference air kerma (TRAK)[5], [18], [27], [28].

C12 When compromises between target coverage and OAR doses are necessary, ensure that reasonable steps in plan design and optimization have been taken to achieve a high-quality plan for that patient in the context of the necessary trade-offs and in-line with physician instructions.

C13 Independent dose calculation verifies that the ***Treatment Planning System*** calculates dose as expected[10], [25], [30].
EBRT: A tolerance of 5% may be expected[30].
Brachytherapy: It is also common to use other methods (nomograms, tables, TRAK, etc.) as a check of the plan consistency or reasonableness[27], [28], but the ***Qualified Medical Physicist*** has to be aware that this does not constitute an independent dose calculation.

C14 ***Patient-Specific Quality Assurance (PSQA)*** ensures ***Plan Deliverability***. For external beam treatment plans, fluence maps or accelerator log files can be inspected or the plan can be delivered to a detector phantom. Refer to the document "Best Practice Guidance for Patient-specific Quality Assurance for IMRT and VMAT Plan Delivery Verification" and references therein. Additional references include[31], [32].
For HDR brachytherapy, performing patient specific pre-treatment measurements similar to EBRT is not common or feasible. Other brachytherapy procedures may have patient-specific QA activities such as needle loading verification for LDR prostate[30], eye plaque QA, etc.

C15 The physics check of ***Data Transfer*** can be automated, if applicable, or limited to verifying the critical components of the treatment data[16]. Appropriate checks and tools may be site specific. Tools for ***Data Transfer*** verification can be vendor supplied (e.g. check sum), Third party (e.g. Migration Check Tool[33]) or an in-house developed method. Warnings issued by the planning system at time of ***Data Transfer*** MUST be reviewed as it may impact ***Plan Deliverability***.
For brachytherapy, this activity can also be performed as part of patient-specific pre-treatment QA, as described in KQI B3 and reference[34].

C16 The treatment plan review by a ***Qualified Medical Physicist*** is considered an integral part of the treatment planning process, and the review MUST be completed prior to start of treatment.
For time-sensitive treatments, separate aspects of the treatment plan may be reviewed at different time stages; however, these parts may be transient.

EBRT-specific Process

E1 The use of a particular motion management system is selected in order to achieve the appropriate image quality for in-room guidance[35]. The particular motion management technique (e.g. if patient is to be treated in breath hold, the ***Primary Dataset*** is the scan acquired in breath hold) and relevant parameters (e.g. amplitude, phase, duty cycle, etc.) SHOULD be documented in the setup notes.

E2 IGRT technique and parameters (e.g. ***Shift Instructions***, ***Matching Structures***, ***Imaging Frequency***, pre-sets, filters, etc.) are specified and match institutional policy for the treatment[36].
Ensure that the isocenter coordinates, reference CT and/or DRRs, if applicable, are correctly transferred to the R&V system to allow image guidance and patient setup[36].
If DRRs are used for image guidance, verify that the DRR field outline in R&V matches the open field in the treatment plan.

E3 The collision potential impacts ***Plan Deliverability*** from a machine-patient interaction point of view. A trial setup[30] is an effective way to assess the collision potential.

Brachytherapy-specific Process

B1 This includes projection images for applicator placement/size verification for non-image based planning. Examples are single or multi-channel cylinder standard plans in gynae brachytherapy.

B2 Verify that applicator and needle reconstruction are correct[18]:

- Needle/catheter numbering in plan matches implant template (if applicable)
- Needle/catheter orientation with respect to patient

- Appropriate applicator and fiducials
- Indexer length specific to the applicator/needle type (if applicable)
- Offset (if applicable)
- Step size (if applicable)
- Activation or seed spacing as per institutional policy
- Correct channel numbering of the template

B3 Details of various pre-treatment procedures can be found in the references[18, sections B.3. and C.3.], [34, Table 1]. For LDR, details are in reference[19].

Documentation

D1 All ***Treatment Information*** necessary to correctly deliver the treatment and to retrospectively determine the radiation doses received by the patient MUST be included in the record. Warnings issued by the planning system MUST be carefully reviewed.

D2 The ***Qualified Medical Physicist*** SHOULD document that patient-specific QA has been completed and results are acceptable for treatment.
For more information on the documenting the results of such measurements for external beam treatment plans, refer to the CCO document "Best Practice Guidance for Patient-specific Quality Assurance for IMRT and VMAT Plan Delivery Verification, and in particular their KQI E1 to E4 and section 7. If measurements are replaced by software, the justification SHOULD be well documented[37].
For Brachytherapy: activities for permanent-seed implants and eye-plaques mentioned in KQI C14 must be documented according to ***Institutional Policies***. See also references [18], [19], [34].

D3 The most common ***Deviations From Guidance and/or Institutional Policy*** may be in dose constraints or dose conformality, but can also apply to ***Prescription***, ***ROI Structures***, treatment technique, radiation modality, or beam energy. Deviations are usually arising from practical limitations of the patient anatomy, software, and delivery method. They MUST be acknowledged by a physician.

5. Glossary

***Accepted Guidance*:** Processes and procedures, tolerances and limits put forward by various professional organizations such as the American Association of Physicists in Medicine (AAPM), Canadian Partnership for Quality Radiotherapy (CPQR), The Joint Groupe Européen de Curiethérapie (GEC) /European Society for Radiotherapy & Oncology (GEC-ESTRO), International Atomic Energy Agency (IAEA), etc. A study protocol is an approved, usually ethics-board-approved, set of procedures that may differ from the accepted guidance.

***Cardiac Implantable Electronic Devices*:** general term for pacemakers and implantable cardioverter defibrillator. If present in a patient, such devices have strict dose limits that are usually specified in institutional policies. For a recent review, see[38].

***Class III Medical Devices*:** According to Health Canada, software intended to *directly influence* the performance of a device intended to emit ionizing radiation is classified as Class III. If the device is intended to be used in "radiographic mode", the related software is classified as Class II. Any other Medical Device software is classified as Class I[6], [39]. Modern day treatment planning systems that send plan instructions, such as MLC patterns and MUs directly to a linac would fall into the Class III category. Software used with a linac for OBI acquisition and matching would qualify as class II devices. Treatment Planning Software that requires the operator to manually enter parameters, or perform treatment related actions (e.g. Software for calculations used in orthovoltage or LDR treatments) would be class I devices. As noted in glossary entry "Software as a Medical Device", software used to perform QA on a linac or TPS is not considered a medical device.

CT Density Table: The CT number to density (or electron density) conversion table.

***Data Transfer*:** An exchange of treatment plan related data between components of the Data Management System. In the context of this document, this primarily applies to centres with a multi-vendor environment.

***Deviations From Guidance and/or Institutional Policy*:** A component of a plan that does not conform to institutional policy. The deviations can be intentional (prescribed by the RO due to the unique nature of the particular case) or a compromise (where the guidance cannot be achieved for reasons beyond physicist and physician's control).

***Feedback Learning System*:** A set of procedures and tools used to record, evaluate, and track information for the purpose of improving quality. A feedback learning system is much less formal than an incident learning system[40], [41].

Imaging Frequency: The frequency with which in-room image guidance is performed.

Immobilization Devices: The accessories used to immobilize patients during treatment for reproducible setup.

***Institutional Policies*:** Processes and procedures, tolerances and limits defined by the local institution. They are usually present in the case of absence of an accepted guideline, or as supplemental or additional information to an accepted guideline to further improve quality.

Matching Structures: The structures used to localize a patient, or to define the treatment area for which the image registration has to be focused.

***Motion Management*:** Procedures and instructions in which internal motion of organs and/or regions of interest is managed during radiotherapy, imaging, or another therapeutic or imaging procedure. This management can be implicit in the procedure (e.g. 4D-CT), or added to any procedure (e.g. breath hold). The motion can be due to respiration, circulation, peristalsis, swallowing, etc. Both procedures to prevent motion (e.g. breath-hold) and/or deal with motion (e.g. gating) are part of this class of concepts. Not included under motion management are procedures meant to deal with the overall motion of the patient (e.g. immobilization).

***Patient Identifiers*:** The information necessary to uniquely identify the patient, typically: name, birth date, photograph and patient hospital ID. Other patient information may be present, but is not required.

Patient Orientation: The orientation of the patient on the table top: typically one of Head First Supine (HFS), Head First Prone (HFP), Feet First Supine (FFS), and Feet First Prone (FFP).

Patient Setup Instructions: All information required to reproduce the patient setup and immobilization from the time the planning images were acquired. Any additional information required to reflect differences between the patient setup for image acquisition and treatment delivery. This may also be necessary for multi-fraction brachytherapy treatments like skin. It is not relevant for all treatment sites (e.g. prostate), so it may be "as needed" for brachytherapy patients.

***Patient-Specific Quality Assurance (PSQA)*:** A specific set of independent measurements using the delivery settings of a given treatment plan with the goal of verifying plan deliverability and dosimetric accuracy. The procedure usually involves a dose measurement, an independent calculation or some combination of the two. The procedure used may vary with treatment modality, technique and disease. The physics check may include the performance of the dose verification procedure or just a confirmation that the results of the procedure meet predetermined criteria.

***Prescription*:** A description, signed by the oncologist, of the desired dosage and intended area for treatment[4], [14]. The information required for a prescription includes[22], [25], [27], [28]:

- Patient identifier
- Target volume, including site and laterality.
- Dose and fractionation, including timing of fractions
- Dose rate, where appropriate
- Target volumetric dose coverage
- OAR dose constraints
- Treatment technique and energy
- Physician Approval

In many cases, not all of the above information will be explicitly included in a prescription. For example, the target volume may be implied by the oncologist through the specification of certain plan parameters, such as field shapes or beam geometry, instead of a contoured ROI structure.

***Plan Deliverability*:** The ability of a particular treatment machine to deliver the radiation treatment accurately as planned. Factors affecting this ability include:

- Limits to the motion range, speed and resolution of the various components
- Potential collisions resulting from the combined motion required by the plan.
- Limits to the resolution of the dose rate(e.g. monitor units, dwell time)

***Planning Image Datasets*:** consist typically of one primary dataset and several secondary datasets.

***Plan Parameters*:** Subset of the treatment information (glossary), that contains the technical information necessary to deliver the treatment as planned. Modern radiation treatment plans are too complex for such information to be easily summarized, so the electronic plan signed by the oncologist should be treated as a part of the patient's medical record. In practice, a sub-set of the plan parameters is usually included in the patient's record in a human-readable format.

***Primary Dataset*:** An image dataset used to contour the anatomical and auxiliary ROI structures and on which the dose distribution is computed. CT is the most common modality, but many other image modalities can be used.

***Qualified Medical Physicist*:** An individual who is competent to independently provide clinical professional services in Radiation Oncology Physics; A Medical Physicist certified by the Canadian College of Physicists in Medicine (CCPM) or equivalent is considered to be a Qualified Medical Physicist[3, Sec. IV], [4].

Quality Assurance (QA): The procedures and processes followed to ensure maintenance of quality[42].

Reference Image Transfer: The transfer of the primary dataset from the treatment planning system to the Record and Verify system or the treatment unit used for in-room image guidance. This may not be applicable in some vendor environments since the database is integrated.

ROI Structures**:** Digital representations of the anatomical and non-anatomical regions of interest (targets, organs at risk, auxiliary, etc.) in the treatment planning software. They are usually defined as a set of contours, but may also be a set of voxels or triangular or tetrahedral mesh representation.

Secondary Dataset**:** An image set that augments the primary dataset for the planning process. The secondary dataset may be used to assist in the delineation of tumor volumes and/or normal tissues. Other uses for secondary image sets include: assisting with patient positioning and the evaluation of treatment response.

Secondary Dose Verification System**:** A software package or process used to check dose, monitor unit or time calculations performed by the primary Treatment Planning System[5], [10]. These tools are not considered medical devices because they do not directly affect clinical decision making[11].

Shift Instructions: Documentation of performing a table movement to shift from

a) The CT setup point to the treatment isocentre at the time of patient setup or
b) Documented process for image registration during in-room image guidance including shift tolerances (tolerance of the table top movement performed after an image registration above which an action must be taken).

Software as a Medical Device**:** Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device[11]. A spreadsheet or a simple in-house code (e.g. EQD2 spreadsheet for cervix) that assists with making a decision DOES NOT qualify, as the user is in principle able to reach the same decision without using these explicit tools. However, extreme caution is recommended when utilizing these tools, and scrutiny of performance similar to commissioning process should be undertaken prior to clinical implementation. Periodic review of spreadsheet/software performance is also recommended.

Treatment Information: The information necessary to correctly deliver the treatment to the intended patient and to retrospectively determine the radiation doses received by the patient. The treatment information typically contains the following components:

External Beam Radiotherapy[25]:

- Patient identifiers
- Diagnosis
- Prescription
- Primary dataset(s)
- Secondary dataset(s)
- Plan parameters (see glossary)
- Patient Setup instructions, and supporting devices (i.e. couch tops, and accessories for immobilization and comfort)
- Special physics consultations (e.g., non-routine field abutment, dose to critical organs, etc.).
- Image guidance requirements
- Dose Distribution(s)
- Approval Record(s)
- Treatment Record(s)
- Images acquired for image guidance and verification purposes
- Positional and/or plan modifications resulting from image guidance
- In-vivo dosimetry results (if any)

Brachytherapy[18], [25]

- Patient identifiers

- Diagnosis
- Prescription
- Primary dataset(s)
- Secondary dataset(s)
- Patient Setup instructions where appropriate
- Description of the applicator(s) or catheters used (type, size, reference positions, reconstruction)
- Description of the sources.
- Plan parameters (see glossary), such as description of technique, implant geometry, step size between dwell positions, source locations and dwell time at each location.
- Date, time and duration of dose delivery.
- The total reference air kerma (TRAK) over the time of dose delivery.

***Treatment Planning System*:** A software package or collection of software packages used either directly or indirectly in the generation of the final treatment plan. This includes image registration, contouring, dose calculation, and all other components used as aids in the clinical decision making process. These are considered Class III medical devices as they are used in a critical state of healthcare, are used to drive clinical management, and an erroneous result could lead to immediate danger to the patient[11]. Software that is not Health Canada Approved may not be imported, advertised or sold. A non-Health Canada approved treatment planning system component should only be used when no suitable alternative is available and the anticipated benefit outweighs the potential harm[6], [7].

***Treatment Intent*:** The physician's goal in prescribing the treatment. One of: Radical, Palliative, Adjuvant, or some sub category of these primary intent categories.

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