Quality Assurance of Treatment Planning Systems

Practical guideline for verification of installations and updates of treatment planning systems for external photon radiotherapy treatments

NEDERLANDSE COMMISSIE VOOR STRALINGSDOSIMETRIE

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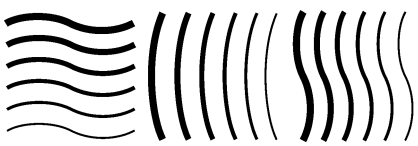

Netherlands Commission on Radiation Dosimetry

Subcommittee 'QA for TPS'

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Preface

The Nederlandse Commissie voor Stralingsdosimetrie (NCS, Netherlands Commission on Radiation Dosimetry, http://www.radiationdosimetry.org) was officially established on 3rd September, 1982 with the aim of promoting the appropriate use of dosimetry of ionising radiation both for scientific research and for practical applications. The NCS is chaired by a board of scientists, made up via recommendations from the supporting societies, including the Nederlandse Vereniging voor Radiotherapie en Oncologie (Dutch Society for Radiotherapy and Oncology), the Nederlandse Vereniging voor Nucleaire Geneeskunde (Dutch Society of Nuclear Medicine), the Nederlandse Vereniging voor Klinische Fysica (Society for Medical Physics of the Netherlands), the Nederlandse Vereniging voor Radiobiologie (Netherlands Radiobiological Society), the Nederlandse Vereniging voor Stralingshygiëne (Netherlands Society for Radiological Protection), the Nederlandse Vereniging voor Medische Beeldvorming en Radiotherapie (Dutch Society for Medical Imaging and Radiotherapy), the Nederlandse Vereniging van Klinisch Fysisch Medewerkers (Dutch Society for Medical Physics Engineers), the Nederlandse Vereniging voor Radiologie (Radiological Society of the Netherlands) and the Belgische Vereniging voor Ziekenhuisfysici/Société Belge des Physiciens des Hôpitaux (Belgian Hospital Physicists Association) and expanded with a representative from the Dutch Metrology Institute VSL. To achieve its aims, the NCS carries out the following tasks: participation in dosimetry standardisation, promotion of mutual comparisons of dosimetry, drafting of dosimetry protocols and the collection and evaluation of physical data related to dosimetry. Furthermore, the commission shall establish or maintain links with national and international organisations concerned with ionising radiation and promulgate information on new developments in the field of radiation dosimetry.

Quality assurance of Treatment Planning Systems

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Summary

In June 2018, the NCS installed a subcommittee on the quality assurance of treatment planning systems (TPS). This subcommittee had the task to update and extend a previous publication of the NCS, (Bruinvis et al., 2005) on the same subject.

The field of treatment planning has changed considerably since 2005. The current publication focusses on a department wide implementation of a TPS. New sections about education, information technology (IT) and updates/upgrades result from this wider focus.

The general parts of this report apply to all treatment modalities. The specific parts, such as beam modelling and dose reporting, are limit to photon therapy.

The introductory chapter (1) describes general subjects, such as workflow, safety and education. Chapter 2 presents guidelines about the commissioning of CT data input and the photon beam model. Chapter 3 provides tests for patient modelling and dose representation. For these tests, the NCS provides a DICOM dataset that aids in performing the tests. The optimisation and dose calculation is discussed in Chapter 4. This chapter also addresses automatic dose calculation. In chapter 5, we discuss IT integration and demands. The report concludes with a chapter (6) about the updating and upgrading of TPS.

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Abbreviations and acronyms

AAPM	American Association of Physicist in Medicine
ACR	American College of Radiology
ALARA	As Low As Reasonably Achievable
BEV	Beams Eye View
CIED	Cardiac Implantable Electronic Device
CT	Computed Tomography
DD	Dose difference
DICOM	Digital Imaging and Communications in Medicine
DTA	Distance to agreement
DVH	Dose Volume Histogram
ED	Electron Density
FFF	Flattening Filter Free
FFP	Feet First Prone
FFS	Feet First Supine
FOV	Field of View
FWHM	Full width at half maximum
GDPR	General Data Protection Regulations
GPU	Graphical Processing Unit
HFMEA	Health Failure Mode and Effect Analysis
HFP	Head First Prone
HFS	Head First Supine
IC	Ionization chamber
ICRU	International Committee Radiation Units and measurements
IT	Information Technology
IEC	International Electrotechnical Commission
IMRT	Intensity Modulated Radiation Therapy
IROC	Imaging and Radiation Oncology Core
Linac	Linear Accelerator
MAR	Metal Artifact Reduction
MDR	Medical Device Regulation
MLC	Multi-leaf Collimator

MPE	Medical physics expert
MRI	Magnetic Resonance Imaging
MU	Monitor Unit
NCS	Nederlandse Commissie voor Stralingsdosimetrie
OAR	Organ at Risk
OS	Operating System
PACS	Picture Archiving and Communication System
PDCA	Plan Do Check Act
PDD	Percentage depth dose
PET	Positron Emission Tomography
PRA	Prospective Risk Assessment
PRV	Planning risk volume
PTV	Planning Targed Volume
QA	Quality Assurance
QMS	Quality Management System
R&V	Record and Verify
ROI	Region of Interest
RTT	Radiotherapy Technologist
SBRT	Stereotactic aBlative RadioTherapy
SPECT	Single Photon Emission Computed Tomography
SRT	Stereotactic Radiotherapy
SSD	Source Surface Distance
TPS	Treatment Planning System
VMAT	Volumetric Modulated Arc Therapy

Contents

1 General overview

Treatment planning is a part of radiotherapy that constantly and quickly evolves. In this changing field, the current report aims to provide guidelines that help in the introduction, use and maintenance of treatment planning systems. Intentionally, the scope is broader than the more physics oriented topics. The practice has learned that other subjects, such as IT and education, have grown in relevance considerably. We also included a separate chapter that addresses updates and upgrades.
This report focusses on photon treatments primarily. However, the generic parts are also applicable to other treatment modalities.

1.1 Introduction

This report provides guidelines for the quality assurance of treatment planning systems and continues a series of previous publications on this topic, for example NCS-15, AAPM TG53, IAEA TRS430 (Bruinvis et al., 2005; Fraass et al., 1998; IAEA TRS 430, 2004). Whereas most of this report provides specific recommendations for validation and implementation of the treatment planning system, we add remarks concerning quality assurance of the treatment planning process in a broader perspective.
As discussed in ICRP86 (ICRP 86, 2000), errors in treatment planning originate primarily from human errors, improper training, unclear responsibilities and (IT) communication errors instead of faults or problems in properly commissioned treatment planning systems. The current chapter provides a wider perspective on quality assurance regarding the implementation and operation of the treatment planning system (TPS).
Quality management systems (QMS) as described in ISO9001 and IEC 62083 (IEC 62083, 2009; ISO 9001, 2015) include basic requirements such as the documentation of procedures and instructions of the primary process. Furthermore, these QMS recommend a clear and formal establishment of responsibilities and authorities as well as the need for a continuous improvement cycle such as Plan-Do-Check-Act (PDCA).
We provide a description of the application of the basic requirements for the treatment planning workflow, safety, education, documentation, resource planning and recommended literature.
When the TPS is commissioned, an ongoing QA program needs to be established. This involves checks after software/hardware upgrades and changes made to the related workflow, plus a continuous evaluation and improvement of the skills of the users.

1.2 Treatment planning workflow

Scope

To describe the treatment planning process.

To design a safe and efficient workflow.

To raise clarity about responsibilities for each step and the result.

Background

Treatment planning consists of many steps and each step may involve multiple disciplines. Hence defining a clear workflow and formalised responsibilities (with consensus) is an important aspect to ensure high quality.

In a linear workflow, from imaging to treatment, steps follow each other in a predefined sequence from the planning CT step to the treatment step. In a circular workflow, feedback (e.g. images) during the treatment leads to adaptations of the treatment plan. A circular workflow is more elaborate than a linear workflow and demands a higher level of communication and standardization.

Working by standards improves the clarity of the treatment planning process. For the naming of regions of interest (ROIs), use the standard defined by AAPM TG 263 (AAMP Task Group 263, 2018). For dose prescriptions and reporting, the ICRU has set standards (ICRU 83, 2010). For the naming of plans, beams and use of colours there are no international standards, but clarity improves when these are standardised within one organisation.

Standardised workflows should be used and defined in protocols. These workflows should be explicit and with clear assignment of responsibilities. Besides, there is a small group of non-standard treatments for which individual process steps may deviate from the standardised workflow steps. For these non-standard treatments, consider a multidisciplinary team (treatment planner, Radiotherapy Technologist (RTT), physician and physicist) that discusses the case ideally before making the planning CT, but certainly in between the steps of contouring and treatment planning. Preferably, members of this team should be available for (preparing) the treatment planning and (start of) the treatment to reduce errors in handing over the case.

To summarise, making this distinction between standard and special cases facilitates the scheduling (special treatments need more attention/time). In addition, a dedicated team that knows most of the case together with a limited transfer of information among colleagues improves safety for the special cases.

Recommendations

- Adhere to international standards where available.
- Define institution wide standards for ROI naming, ROI colours, naming of plans, beams etc.
- Try to standardise all common treatment plans.
- Be clear that standards must be followed to ensure quality and efficiency. If people do not comply to agreements, educate and repeat.
- Handle non-standard procedures by a small multidisciplinary team.
- Evaluate and revise standardised treatment planning procedures.
- Develop and describe the workflow in a multidisciplinary team. Include responsibilities and safety related checks. An example is included as additional material: 1- WorkFlowExample.xlsx.

Literature

- Responsibility matrix: ACR practice parameter Radiation Oncology (ACR - ASTRO, 2018)
- Field standards:
    - Dose prescription/recording/reporting: ICRU 83 (ICRU 83, 2010)
    - Dose prescription/recording/reporting stereotactic treatments: ICRU 91 (ICRU 91, 2014).
    - Naming of ROIs: AAPM TG-263 (AAMP Task Group 263, 2018)

1.3 Safety

Scope

To define sensible tests to validate the safety of the treatment planning process.

Background

The design of a validation chain starts with a Prospective Risk Analysis (European commission, 2015) (PRA). There are several methodologies to perform a PRA, a Health Failure Mode and Effect Analysis (HFMEA) is an example of a PRA methodology.

In the PRA, errors that might cause harm to patients, staff or operational management are listed and categorised in severity levels based on detectability, severity and probability of the error, based on the experience and estimates of the team. The severe risks must be mitigated by a procedure that can be performed by a human or automatically (Ford et al., 2020).

A multidisciplinary team needs to re-evaluate checks periodically and after changes that may affect the check. Therefore, checks need to be well documented. Over time practices can change, making old tests obsolete while new practices may require revised or new tests. A testing framework has the tendency to expand; this may not always add safety. In the extreme, it may lose a rational trade-off

between time investment and efficacy. Periodical discussions re-evaluating the need and efficacy of tests are therefore highly recommended. A procedure to regularly revise and update the PRA will lead to benefits in safety and efficiency.

An independent (dosimetry) audit can add valuable information about the overall quality of the treatment planning and dose delivery chain. Especially if treatment planning is also included in the audit.

When new class solutions are introduced, the first treatment plans (Mans et al., 2015; Van der Wal et al., 2013) have to be measured. When results are acceptable, new treatment plans can be checked against the class solution. If the plan is within the set limits, additional measurements can be randomly performed.

A second monitor unit (MU) check or secondary dose calculation could be considered, preferably with a 2D or 3D dose evaluation instead of on a single point (Kry et al., 2019; Zhu et al., 2021). The added value of such a routine check is disputable, but limitations of the TPS could be revealed and vice versa.

Physicists are encouraged to perform trend analyses on changes in plans (e.g. MU/cGy, number of segments, number of beams, modulation etc.). Analyses of groups of patients are useful to detect outliers in treatment plans and possible drift from the original class solution.

Recommendations

- Perform or update the PRA when new practices (introduction TPS, change of functionality in the TPS, change in workflow etc.) are introduced or current practices are changed.
- Define checks based on the PRA to mitigate risks.
- Create an overview of human and automatic checks that are performed and the purpose thereof.
- A procedure to regularly revise and update the PRA and associated tests is beneficial for the safety and efficiency of the clinical process. We advise to form a multidisciplinary team that takes responsibility for these periodic evaluations. This task should be connected to the committee handling (near) incidents.
- Participate in a dosimetry audit, preferably one also including treatment planning.
- Perform trend analysis on treatment plan metrics and use them to establish limits to detect outliers and drift from a class solution.
- Perform an independent, secondary check of all treatment plans to assess possible trends or systematic differences between planning and delivery.

1.4 Education

Scope

Description of initial and continuous education and training to use the TPS.

Background

Safe usage of a TPS requires trained staff. Whereas other reports focussed almost exclusively on technical aspects of QA, the authors of this report have chosen to include a list with suggestions concerning the training and education of all users of the TPS. The complex radiotherapy workflow leads to risks associated to human misunderstanding or improper use of systems. The importance of training is also emphasised in the MDR (European Commission, 2017) and national recommendations (Convenant (NVZ et al., 2011).)

Recommendations

- Initial education for working with the system is mandatory for all users. This education has to be documented in a training plan.
- New users must finish a training program successfully.
- Training programs should be tailored to the role each user has in treatment planning. Consider the following levels in the organisation of the educational program:
    - Background: The basic principles of the TPS optimisation and dose calculation methodology, relevant for the use and understanding of the limitations of the system.
    - Workflow: The complete workflow and explicit responsibilities.
    - Technical: describe how to create plans according to the local protocols.
    - Functional: Describe the use of buttons, tools, options and visualisations in the TPS
- Schedule an appropriate amount of time for the training of the users.
- Create an open culture where users discuss individual skills in a safe environment that stimulates learning.
- Implement a program for continuous education.
    - Regular discussions about treatment planning skills, errors and near incidents.
    - Create plans for the same case locally and outside the department and discuss results. Do not use established templates, but start from scratch to stimulate out-of-the-box plans and practice skills. Tumour site-specific (national) platforms are excellent places to conduct treatment plan comparisons.
    - Discussion of trend analysis over a given period of plan quality measures.

  - Challenge users by participation in treatment planning innovations.
  - With the increasing use of automated treatment planning, create a method to keep up the basic treatment planning skills of (a subset of the) users. Not only in case of failure of the automatic system for a specific case, but also to be able to critically evaluate the results of the automatic method.
  - Register the training activities completed by the individual users to enforce proper and updated skills in the department.
- Attend user meetings, exchange experiences with colleagues from other institutes.

1.5 Documentation

Scope

Provide suggestions concerning the documentation of the installation and operation of treatment planning systems.

Background

Documentation of the implementation and use of TPS is important for quality management in the treatment chain. The documentation includes, amongst others, the product requirements, the performed tests (the ones recommended by the vendor and the institute specific tests), user manuals, field safety notifications and configuration (NVZ et al., 2011). Some items are relatively static and require an ordered archive; others require more attention and management during the whole process. Radiotherapy departments have a large number of different treatment protocols and workflows. Given the central role of treatment planning, all these protocols may necessitate a large number of different treatment planning workflows (e.g. plan of the day, adaptations) and techniques. The workload of creating and maintaining the documentation can become quite substantial.

Suggestions and references listed below aid in organizing and documenting the implementation and use of the treatment planning system. Be aware that documenting is a continuous process: all work instructions and protocols need regular scheduled reviews to update and the deletion of obsolete documents.

Recommendations

- Use a document management system to maintain and update the protocols and work instructions. Review and revise all documentation periodically.
- Document instructions as well as the background and reasons for these.

- The rationale of documentation is that a user can easily find what he needs; therefore, documentation should:
    - Have a clear purpose; i.e. list instructions for a specific protocol or task; and very limited overlap with other documentation, use references instead.
    - Be written by, or at least together with, the intended users; system administrators speak a different language than (treatment) planners.
    - Have clear descriptive titles.
    - Be kept as concise as possible.
    - Use a single consistent template.
    - Have a responsible author and version specification.
- Provide actions for deviating situations. (e.g. discuss in a multidisciplinary group)
- Start writing the documentation in the last stage before clinical introduction when all choices concerning implementation have been made.
- Assign a responsible person for (keeping up to date) documentation.

1.6 Project management and resource planning

Scope

Provide suggestions for resource scheduling and project management for the introduction and use of a TPS.

Background

The acquisition, commissioning, introduction and maintenance of a TPS includes a considerable time investment of multiple disciplines. This time investment is easily underestimated, harming the project management, i.e. the introduction of a TPS and may lead to under- or misuse of the system.

Besides the actual introduction of a software package, there are multiple other time investments to be made, including:

Commissioning: For commissioning follow the specific recommendations listed in this report for:

- Testing of the software
- Implementation in IT environment
- Beam modelling
- QA of all aspects

Workflow: A change of TPS generally affects the workflow of a department considerably. All procedures should be revisited and changed accordingly. Beware of software and script dependencies; involve the responsible IT for connected systems in an early stage.

Documentation/protocols: All related documents have to be updated according to the new TPS. Furthermore, project documentation needs to be created.

Education: All users need adequate education. Skills should be proven and registered.

Updates: Most TPS vendors regularly release updated versions of the software. The introduction of updates requires time investments.

Registration: Maintenance, configuration, updates, IT related items (e.g. storage, OS updates, backups, connections to IT environment) need to be registered.

In most departments, the project-work and clinical work share the same resources. If time is limited, the clinical work is usually prioritised above the projects. Take this into account when setting up a project plan.

Recommendations

- Make a (project) plan, which includes a realistic estimate of time investments of all disciplines. Beware that the project group also has clinical duties that may conflict.
    - Include the introduction phase.
    - Include the post-introduction maintenance.
- Have (at least) two people involved for each item to ensure that knowledge is spread.
- Include an IT professional in the group. The workload of IT related issues is easily underestimated, especially during the introduction phase.
- Make an upgrade plan, including the time investment.
- Split the project in realistic milestones. Escalate if milestones are under pressure (e.g. due to shortage of resources/staff).
- Consider splitting the project in a base (mandatory) deliverable and optional (nice to have) deliverables. If resources become limited, optional deliverables can be cut.
- Include an evaluation of the introduction of the TPS after some experience is gained with the new system. This evaluation should review the implementation and list the residual items to formally end the implementation phase.

2 Commissioning of beam model and CT

2.1 Introduction

Commissioning of the beam model in a TPS has been extensively described in NCS report 15 (Bruinvis et al., 2005) along with comprehensive test suggestions. Since then, the radiotherapy delivery technique has greatly evolved. For example, the use of wedges and compensators is mostly replaced by the use of multi-leaf collimator (MLC); dynamic treatment delivery techniques such as volumetric modulated arc therapy (VMAT) and high precision linac-based stereotactic radiotherapy (SRT) have become a common practice in many departments (Heukelom et al., 2015; Mans et al., 2015; Van der Wal et al., 2013).

In addition to the basic beam data, more focus is needed on MLC modelling and clinical plan verification. One should realise that a good agreement of basic beam data will not automatically translate to good IMRT/VMAT plan QA. Hence, the final beam model often results from an iterative process wherein the modelling is repeatedly adjusted after validation measurements. This beam model validation is executed in steps, starting with basic beam data and finalised with IMRT/VMAT plan verification. After each step, the relevant parameter(s) can be adjusted if necessary in order to improve the model. For example, poor QA results of highly modulated treatment plans may implicate the need for adjustments of the MLC model parameters. The chronology of this process is visualized in figure 2.1 and reflected by the subsections in this chapter: Treatment machine definition, measurement of beam data, creation of a beam model and beam model verification. A final section is dedicated to the CT commissioning.

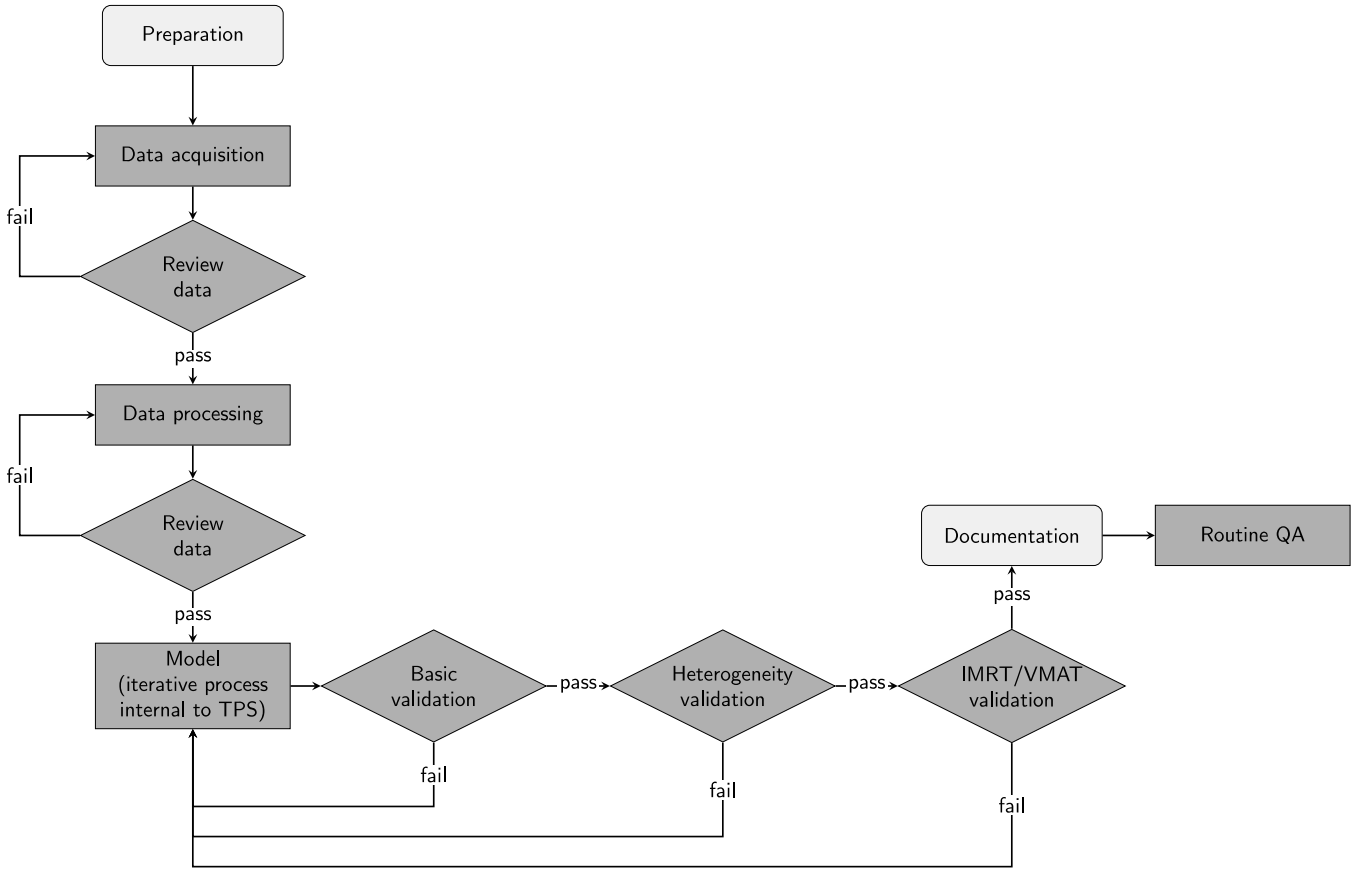

*Figure 2.*1 Workflow of TPS dose commissioning, validation and routine QA according to MPPG5 (Smilowitz et al., 2015)

2.2 Treatment machine definition

Scope

To ensure that the coordinate system and machine specifications are correctly defined in the TPS.

Background

A substantial part of TPS commissioning is the definition of beam parameters and mechanical limitations. Any mistake introduced in this definition can lead to unwanted interruption during treatment delivery and/or serious dosimetric consequences. A beam description starts with the definition of a coordinate system and motion directions as defined by IEC 61217 (IEC 61217, 2011).

To cope with the complex nature of IMRT and VMAT delivery, special attention should be given to the definition of mechanical parameters, their permitted variation, as well as their range e.g. MLC and gantry position, speed and range limitations, minimum/maximum dose rate variation. Not all TPS allow limits to be set explicitly.

Recommendations

- For treatment unit coordinate system definition, the IEC61217 (IEC 61217, 2011) standard is highly recommended.
- Use the tests in Table 2.1 to validate the correct beam definition.
- Gantry, couch, collimator, dose rate, MLC position and leaf speed limitations are usually provided by the linac vendor. NCS 24 (Mans et al., 2015) has suggested a series of validation tests. Within these limitations, parameters entered in the TPS could be adapted to local needs. The user could lower the maximum (speed) limit and/or increase the minimum dose rate in order to ensure a smooth treatment delivery without any possible interruptions.
- Some TPS offer a collision detection module. This functionality should be tested by performing dummy runs in most extreme positions (such as full gantry rotation with lateral couch shift). The user should also be aware that most collisions are caused by the positioning of the patient (e.g. position of the arms) and this is usually not covered by the detection module.

Table 2.1. Recommended test to validate the correct beam definition in the TPS.

	Test	Details
Beam and couch orientation	Isocenter position test	Create a beam with isocenter 10 cm below the surface of a phantom. Verify the position of the isocenter relative to the origin of the phantom. Check the SSD value stated by the TPS.
	Source-axis distance and field size	Measure the field size at the isocenter and verify with the X- and Y-value stated by the TPS. Measure the field size at the surface and verify the correct divergence. Repeat this test for several field sizes.
	Gantry rotation	Change the gantry angle from 0° to 30° and verify the correct direction of rotation. Verify the beam angle on the display with the value stated by the TPS.
	Collimator/couch rotation	Change collimator/couch angle from 0° to 30°. Verify the collimator/couch angle and the correct direction of rotation in BEV display.
	Limits of parameters	Vary the SSD, gantry angle, collimator angle and couch angle to exceed the minimum and maximum values provided by the linac vendor and check the system's response.
Field size and shape	Field size	Vary the field sizes by changing the values of X_1, X_2, Y_1 and Y_2. Verify the field sizes in BEV display.
	MLC	Define an irregular field shaped by the MLC. Check that the MLC settings agree with the specification (width, range, thickness, etc.). Check whether the jaws are placed properly.
	Limits of parameters	Vary the field size to minimum and maximum values, the over-travel of jaw for asymmetric fields to maximum value, the MLC leaves settings to minimum and maximum positions (inter-digitation) and check the system's response.
	Validity check	When a field shape has been conformed to a target volume, this is related to a specific beam orientation. Any change in gantry, collimator or couch angle, should result in other MLC positions and/or invalidation of the dose.

2.3 Measurement of beam data

Scope

To describe measurement sets for beam modelling and verification, including small fields and flattening filter free (FFF) fields.

Background

The generation of a beam model is usually performed using an extensive set of beam profiles, percentage depth doses (PDDs), output factors of square and rectangular fields (beam data) measured in a water tank, assuring acceptable scatter conditions. This beam data is extended with measurements specific for IMRT/VMAT modelling, such as dosimetric leaf gap, MLC/jaw transmission, etc. For the validation of these IMRT/VMAT plans, phantoms can be utilised in combination with film or high resolution 2D (or 3D) detectors. For beam modelling, vendors typically specify a required set of beam data. This data can vary between vendors and it can also vary over time, for instance due to the implementation of new dose calculation and optimization algorithms. A basic beam data set may not be sufficient to create an optimal beam model in the TPS. The data set should be established based on the clinical application of the TPS, e.g. commissioning of small fields for SRT treatments. Any uncertainties of the basic beam data for example caused by the time interval between measurements or setup inconsistency should be minimised.

A detailed description of measuring equipment (ionisation chamber, water tank, etc.) is out of scope of this report and can be found in the following literature (Das et al., 2008; IAEA TRS 430, 2004; IAEA TRS 483, 2017) which are summarised in Table 1-2 in AAPM MPPG 5.a (Smilowitz et al., 2015). Note that special attention should be given to the measurement of small fields and FFF beams, both described in TRS 483 (IAEA TRS 483, 2017).

For validation of the beam model an additional data set (MPPG 5.a) is acquired in both a water tank (profiles, PDD, output factors) and solid phantoms. Be aware that a single measurement device might not fit all clinical cases. A second measurement device (film or a high resolution detector) in combination with e.g. anthropomorphic phantoms can be used for dose measurement of complex plans. NCS22 (Van der Wal et al., 2013) has also discussed different measurement devices that can be used for IMRT/VMAT QA based on different measurements goals. Although traditional composite treatment fields have been widely used to commission the MLC model parameters, the method is not fully standardized and follows a trial-and-error approach. Instead, the use of a dynamic sweeping gap tests is recommended (Hernandez et al. Phys Med Biol 2017;62:6688-6707; Hernandez et al. Phys Med Biol. 2018;63 (24):245005; Saez et al. Phys Med Biol. 2020;(65):155006). The dynamic synchronous and asynchronous sweeping beams in combination with prior knowledge of the nominal leaf width and

simple Farmer chamber measurements can be used to commission the MLC transmission, leaf tip width, x-position offset and tongue-and-groove width.

Recommendations

- Although all basic beam data used for commissioning can be measured during the same session, it is recommended to repeat measurements of reference field(s) (e.g. 10 × 10 cm^2) to eliminate any possible setup or configuration errors. During each independent measurement session and long measurement series, such standard measurements should also be repeated as consistency check. As small dose deviations could be introduced by minor differences in experimental setup or variation in linac output, the consistency measurement should agree within 1.0% for output factors and 0.5%/1mm gamma criterion for PDD and profile measurements.
- If compliant with the vendor's specifications, the suggested reference conditions are SSD 90 cm and 10 cm depth, as it is more clinically relevant than measurements performed at SSD 100 cm.
- Verify and comply with the beam dataset required by the vendor. We recommend to include the output factor, PDD and beam profiles for field sizes ranging from 1 × 1 cm^2 up to the maximum possible field size allowed on the linac. Both inline and crossline dose profiles should be measured, at least at the following depths, D_{max}, 5 cm, 10 cm and 20 cm.
- If the TPS is intended to be used for treatments of very small lesions, small fields (≤ 2 × 2 cm^2) should also be measured. Be aware of increased measurement uncertainties when measuring small fields. Use appropriate measurement devices (IAEA TRS 483, 2017).
- Diagonal measurements of the largest field should also be included for beam modelling. If such measurements cannot be included in beam modelling, these could be used for verification.
- In addition to the basic beam data, the user should also perform measurements for jaw and MLC modelling using the tests as suggested in NCS22 (see summary in table 2.2) or using the dynamic sweeping gap tests as described by Hernandez et al. (Hernandez et al., 2018, 2017).
- As part of the validation process, the user should measure different field sizes outside reference conditions, e.g. different SSD, rectangular fields, off-axis measurements. Tests suggested by MPPG5.a (5.4-5.8) (Smilowitz et al., 2015) are applicable for IMRT/VMAT dose validation and tests 7.1 -7.2 in the same report can also be used. These measurements should be compared with dose calculations in the clinical planning module (i.e., not in the beam modelling application).

- The users should measure representative IMRT/VMAT cases using 2D/3D measurement equipment for verification of the beam model. These measurements should be performed according to NCS 22 and NCS 24 recommendations (Mans et al., 2015; Van der Wal et al., 2013).
- Be aware that dose grid resolution affects calculated profiles. Make sure that the dose grid resolution high (e.g. ≤ 1 × 1 × 1 mm^3) when modelling MLC parameters.

Table 2.2: NCS 22 recommended tests for MLC modelling

	MLC modelling	Suggested actions by NCS22
1	Leaf tip	Compare TPS calculated dose profiles of an IMRT field consisting of several small (elongated) field-segments (width 1 cm) with measured profiles.
2	Leaf position	Use abutting field set-up to verify leaf positioning modelling. Plan perfect matched fields and small gaps/overlaps in TPS and compare with film measurements.
3	Dosimetric leaf gap	Dosimetric leaf gap can be determined by the integral dose method using sweeping gaps of various widths (for sliding window technique only).
4	Tongue and groove effect	Add half fields orthogonal to the leaf direction and compare TPS results with film dosimetry or by measuring the full width at half maximum (FWHM) of narrow MLC determined fields with the jaws retracted.
5	Interleaf leakage and leaf transmission	Use radiochromic film or large ionization chamber to measure average interleaf leakage and leaf transmission. For separate modelling for interleaf leakage and leaf transmission, use radiochromic film to discriminate the differences.

2.4 Creation of a beam model

Scope

To obtain an optimal beam model and understand the limitations of the beam model.

Background

Creation of a beam model can be done by the user or by the TPS vendor depending on the TPS. The model consists of different parameters that are adapted to achieve the best possible fit between measurements and calculations. While some parameters can be directly correlated to certain physical properties (e.g. jaw transmission), some of those are less 'physical' as their name would suggest (e.g. dosimetric leaf gap). Lots of these parameters can be measured but the final model could be based on values which are slightly different from the measured values. These final parameters result from an iterative process. This process starts with fitting the beam model data as described above and ends with fine-tuning the model to fit the representative IMRT/VMAT cases. Part of the iterative process is to understand the limitations of the model and make the right compromises based on clinical practice. The optimal beam model is still just a model that will not fit all circumstances equally well (e.g. small versus large fields, doses in the build-up region vs doses at larger depths). The final model is a trade-off for various fields/techniques with the intention to give the most accurate results for clinically relevant cases.

Limitations of the model should be translated to clinical practice; a model meant for small lesions can for example have an upper limit for allowed field sizes.

Recommendations

- In case the TPS vendor creates the beam model based on measurements done by the user, it is important to verify the integrity of data transfer and the accuracy of the beam model. If the TPS vendor provides a beam model, e.g. based on standard beam data, that represents the average linac, then the TPS vendor should provide details about the data used. When the beam model should be created by the user, the TPS vendor should provide adequate training. The user should be aware that the order of the different steps taken during modelling could differ between TPS vendors (e.g. first flattening filter, then MLC parameters etc.).

- All post-processing of the basic measured beam data (smoothing, averaging and symmetrizing) should be applied with care. Use of such post-processing tools may lead to the loss of certain details (peak of PDD or penumbra gradient) of the beam profiles or PDDs.
- In case of beam-matching, the model should represent all matched treatment beams. The beam model and measurements should be within the same range. By example if, for a specific situation, the maximum difference between two machines is 1.5% (PDD, inline and crossline profiles for 4 × 4 to 20 × 20 cm^2) the beam model should not exceed this difference to any machine. The accepted range of beam data for matched linacs provides a useful guide to optimise the beam model. Once within the range, further optimisation has limited value.
- Compromises should be based on the intended clinical use of that particular model. E.g. if stereotactic delivery is mainly planned using one certain energy, focus of the modelling of that particular energy may be based on the accuracy of small fields.
- If a model that meets all requirements for all field sizes is unattainable, one could consider creating two different models for the same energy specially tailored to its specific clinical use. But be aware that this leads to practical downsides and necessitates additional checks.
- Although some parameters can be directly measured (e.g. MLC thickness and source to collimator distance), the user should not be refrained to adapt this value in order to obtain a better agreement. Adaptation of such parameters should be within the ranges provided by the vendors to avoid unintended deviations in non-standard situations.
- The user should document the main actions, the used data and the considerations and decisions made during the modelling process.
- All manually entered data and the final model should be independently checked by a medical physicist.

2.5 Beam model verification

Scope

To provide tests including tolerance levels for iterative verification of the beam model with increasing complexity .

Background

Beam modelling and beam verification are synergetic processes. In this iterative loop, the model is continuously verified with different measurements and, if necessary, adapted for better agreement. In some TPS, verification can be carried out in both the beam modelling and clinical module. In this case, the first verification can be performed in the physics module but the final verification should always be carried out in the clinical module as in some cases these modules might yield different results. The verification process should be carried out step by step. The first step verifies simple fields that deviate from the typical square fields (measured on-axis) used for the modelling itself. An additional step might be to verify simple fields in a heterogeneous phantom. The final step aims to mimic the clinical circumstances and consists of tests with increasing complexity. The QA results of clinical IMRT/VMAT plans could be used for validation and, if necessary, for fine-tuning of the MLC modelling. These changes in MLC parameters may have minimum impact in basic beam profiles and PDDs, but it could translate to noticeable dose deviations in IMRT/VMAT plans.

The final verification should provide a good understanding of the limitations/weaknesses of the model and disseminate this knowledge to daily clinical practice. For example, the poor calculation of out-of-field dose by the TPS has been well documented (Kry et al., 2017). This should be considered when dealing with the dose to sensitive electronics (pacemaker or ICD) or a foetus.

In case of the creation of beam model is not applicable (beam model supplied by the vendors), the verification test below should still be performed.

Recommendations

- For basic beam validation, profiles of various square/rectangular fields (on and off-axis) should be included. Table 2.3 presents a list of different fields that can be used for the verification process.
- For the analysis of the measured and calculated photon beam profiles, a 1D gamma analysis should be used with the following criteria taken from MPPG5a (Smilowitz et al, 2015):
    - 2%/2 mm global for standard fields
    - 5%/2 mm global for non-standard fields

The profiles should be normalized on a point where an absolute dose measurement was performed. For the field sizes an analysis of the distance between measured an modelled curves can be considered (e.g. at 50% central axis dose); these should correspond within 2 mm.

- As the iterative process can be repeated indefinitely, the user should avoid using too strict tolerance limits that may be unachievable for all field sizes and depths. Tolerance limits that are too loose can lead to large dosimetric inaccuracies.
- A wide range of clinical plans should be included in the verification process. The final model should achieve a minimum gamma pass rate of 95% with a 3%/2 mm dose difference global gamma criterion and a 10% threshold (Miften et al., 2018) for conventional treatments, somewhat tighter than suggested in NCS22 and NCS24. The result might lead to further adjustment of the MLC parameters. Although the changes in MLC modelling parameters are more pronounced in highly modulated IMRT/VMAT plans, the basic beam data should always be re-verified whenever a parameter is adapted. Any adaption made based on IMRT/VMAT QA should not significantly alter the results of the model's fit to the basic beam data.
- In case of SRT/SBRT a gamma pass rate of 95 for 5%/1 mm and a 10% threshold dose difference is recommended.
- A few standard plans should be chosen for an internal audit. These plans can be used as consistency check after software updates. For periodic checks, these plans should be recalculated and the dose distribution should agree with the old version within 1%/1mm (global). In case of larger differences, revalidate the beam model.
- The user should be aware of whether dose-to-water or to dose-to-medium is reported by the TPS. AAPM TG329 presents a clear overview of the type of dose reported by different algorithms used in a variety of commercially available TPS accompanied by the correction factor required to report dose-to-medium directly from the TPS algorithm (Kry et al., 2021, 2020).
- In heterogeneous media, the accuracy of different commercially available calculation algorithms compared to Monte Carlo simulation has been well studied (Carrasco et al., 2007; Han et al., 2011; Reis et al., 2019). For dose verification, point dose measurements can be measured in the direction of the beam on top of and below a known inhomogeneity. For example, point dose on central axis distal to lung-equivalent material can be measured and compared to those calculated in the TPS and the agreement should be within 3% (MPPG5). One can also consider external audits for these measurements.

- An end-to end (considering the treatment chain from CT to delivery) external audit is highly recommended as a final verification step.
- An external review of the model by either the TPS vendor or a colleague from another institute is highly recommended.

Table 2.3: List of suggested test fields to verify the beam model.

Field type	Field size	SSD (cm)	Additional configuration
Open	1 cm × 1 cm (if SRT/SBRT is performed) 3 cm × 3 cm 5 cm × 5 cm 10 cm × 10 cm 25 cm × 25 cm	90	-
Open	5 cm × 25 cm 25 cm × 5 cm	90	-
Open	10 cm × 10 cm	90	4 cm off axis inplane/crossplane
MLC	Maximal size MLC field	90	-

2.6 CT commissioning for dose calculation

Scope

To ensure that the CT number of a scan used for TPS dose calculation is mapped to a correct physical property.

Background

Image information in a CT scan of a patient is converted to a 3D model by the TPS. For dose calculation specific physical properties are assigned to each voxel by means of a CT density table which maps CT numbers to electron density (ED) or mass density relative to water. In some cases, the correct composition of the materials should be assigned for a more accurate dose calculation. Most of the time, patient QA is carried out in homogeneous phantom. Dose verification in heterogeneous media is challenging and not performed routinely. Therefore, any errors introduced in the CT to ED conversion

and the materials table, especially for extreme low or high density range, could go undetected and lead to systematic dose deviations.

Recommendations

- The CT numbers should be verified for all used tube voltages as well as metal artefact reduction (MAR) and extended Field of View (FOV) and all other possibly non Hounsfield unit preserving settings. This can be done using a phantom containing different inserts of known composition and electron densities, placed off-axis if needed. Imported in in the TPS, the density assignment of the TPS should correspond with the density of the insert.
- Basic checks for CT such as the CT geometry, orientation (e.g. HFS, FFP etc.) and resolution should also be verified in the TPS with a suitable phantom (like e.g. a Catphan phantom).
- The CT density table has to be independently validated for all density values. Be aware that some systems demand electron densities and others physical mass densities.

3 Patient modelling and dose reporting

3.1 Introduction

A radiotherapy treatment plan is based on a detailed anatomical patient model. Once the patient's anatomy is captured, in 3D or 4D by CT, MRI or PET acquisition, images are transferred to the TPS. The connectivity between the different imaging modalities and the TPS is established following DICOM standards (including radiotherapy supplements (DICOM, 1997)). Next, an anatomical description of the patient is created in the TPS, by means of contours that define the relevant anatomical structures. This anatomical description has to be validated. Once the patient model is finalised and the treatment plan is created, the dose representation and reporting should be accurate as this guides clinical decision making.

Next, verification methods are given to assess the accuracy of the radiotherapy images and the dose distribution. The presented verification methods mostly rely on a set of synthetic CT images. Such an image set is provided with the report. The use of a synthetic CT allows for a quantitative approach in analysing the results instead of a qualitative analysis. With predefined structure shapes, positions, grey-values and dose values, one can easily check the correct import and representation of data. Furthermore, by knowing the dimension and coordinates of the different synthetic structures, one can also check the correctness of the contours' operations, such as expansion, summation and Boolean operations.

The synthetic image set of the simple phantom has the following properties:

- Different intensity values (grey levels) in the phantom
- Simple contour sets, such as a cube, sphere and/or cylinder
- More complex shapes, such as the so-called "diabolo" volume (Bruinvis et al., 2005)
- Different dose distributions and dose grids bound to the structure set and the phantom
- Different phantoms for other modalities (MRI and PET)

A dataset is provided with this report along with a user manual and suggested tests, which can be found in the additional material 2.2.

This chapter will not cover deformable image registration nor automatic contouring of structures, as it is out of the scope of this report.

3.2 Patient modelling

The main purpose of this section is to validate the geometric representation of the primary image set, whether it is a CT, an MRI, or another 3D/4D image set. These should be accompanied by a routine end-to-end test.

3.2.1 Data import

Scope

To check if:

- Import of all DICOM RT data is correct, including registration objects;
- Imported data is displayed correctly.

Background

The first step in creating a patient model inside the TPS is to import the data either from an imaging device or another system, like delineation software or a PACS. Data in radiotherapy can be divided into 2 subgroups: imaging data versus RT specific data, such as RTPlan and RTDose. RT specific data is covered by the DICOM RT standard (1997) (DICOM, 1997) which is an extension for radiation therapy applications. A TPS should be able to correctly import all the objects necessary to define the patient and/or its treatment course.

Recommendations

- Patient demographic data transfer should be checked after import: check the ID, first name and last name, date of birth and gender. Specific attention may be required for non-basic ASCII characters such as ‘ä’.
- Try to import data with a non-matching patient ID into an existing patient and check if the TPS prevents it or shows a warning message.
- Verify the integrity of 3D CT scan parameters:
    - Check the Hounsfield Units and geometry, with known distance between landmarks and grey levels characteristics in ROIs.
    - Test the import of data with missing slices and their further impact on structures.
    - Import the DICOM images (additional material 2.0), structures and dose (RTStruct and RTDose) and check the geometry and dose values in the TPS.

- Verify the integrity of other 3D modalities (such as MRI and PET) acquisition parameters:
    - Check if the modality is correctly recognised, the units for each modality (e.g. series description, kVp, mAs) should match the information in the DICOM header, as well as the tilt in oblique images.
    - Not every TPS is able to import non-orthogonal slices. If import is possible the TPS can represent images incorrectly. When oblique slices for contouring, one should be sure that the slice angulation of oblique images is well recognised so that they are geometrically correct after import.
    - Registration objects, check if import is possible and that the transformation matrix is correctly linked. Visually inspect the result and validate the registration parameters (translation, rotation).
    - RTStruct, Import a data set. Check if all structures have been imported. Verify the volume, at the position (visually) and the HU statistics in known ROI, or by using tests implemented in the contouring section (3.2.3). Check also other relevant DICOM tags, such as the type of structure. See additional material 2.0 – 2.2.
- RTDose import and visualisation.
    - Check if isodose lines and DVHs are correctly represented (e.g. correct scaling, position and orientation) on reference data set. See additional material 2.
    - Check if RTDose can be imported without a RTStruct or RTPlan.

3.2.2 Rigid registration

Scope

To check

- The rigid registration algorithms
- Tools available for adjustment and verification of rigid registration.

Background

For the delineation of target volumes and/or organs-at-risk, multiple datasets are often used to complement the planning CT (e.g. contrast CT, PET, MR) as these are often capable of better visualisation of the tumour. By registering these datasets to the planning CT, the data can then be used to localise the tumour or organs-at-risk on the dataset used for creating the treatment plan. This registration is thus essential for proper target delineation. The proper functioning of the registration methods and tools for evaluating the results should be checked. In this report, only rigid registrations

are considered, as deformable image registration (DIR) will be covered in a future NCS report (although some of the testing described below also applies to DIR). For more information on deformable registration, the reading of AAPM TG132 report (Brock et al., 2017) is highly recommended.

Recommendations

- Verify if the transformation matrix (translation and rotation) is correct for a known registration of two datasets (mono- or multi-modality).
- The functionality of registration verification tools should be tested and documented, such as checkerboard, spy glasses, landmark verification, similarity measures, etc.
- Test all registration methods and compare the results. Are differences between methods as expected? Compare results to the provided dicom-reg object (Phantom1Tilt and Phantom1Shift in Additional material 2).

3.2.3 Contouring

Scope

To check if

- The structures are correctly displayed and the volume is accurately determined.
- The interpolation is consistent.
- Contouring tools function correctly
- Derived ROIs (ROIs generated from source ROIs) are consistent with the source ROIs.

Background

In radiotherapy, treatment planning is ROI-driven. The definition and properties of each structure should be clear. A naming standardisation is highly recommended, as stated in the AAPM report 263 (AAMP Task Group 263, 2018), with the addition of institutional conventions for control structures (planning and/or positioning).

Derived structures formulas should be kept by the TPS and if a change occurs in one of the “parent” structures, a notification should be available on the “child” (derived) one. If such functionality might not be available. Its absence should be assessed in the risk analysis.

Representation of ROIs can be stored in different ways by the TPS, for example like contours on slices, as in DICOM export process, like a surface, a mesh, or like a voxelised ROI. Depending on the contour usage, the ROI can be converted from one state to another. Such action might change the geometry of the ROI, specifically due to conversion inaccuracies at the ROI boundaries.

Recommendations

Please see additional material 2 for data that can be used for some of these tests.

- The vast majority of TPS need an external contour to be able to compute dose while other systems allow dose computation without defining an external contour. The user can test if the system will allow a dose computation on a CT without defining the external contour.
  If this is possible, take care of attenuation by the CT-couch (it differs from the treatment couch) and the effect of imaging artefacts. Especially when using an extended field of view.
- The correctness of the automatic generation of the external contour has to be tested.
- Make sure that a change in the geometry of a ROI is reflected in all representations (contours, mesh etc.)
- Phantom: Segment a known highly contrasted structure against its background (as a solid tumour inside lung tissue) and check for the volume, as described in the data import section.
- For margins, expand and shrink a diabolo structure with a known radius and compare the obtained volume with reference value. Also look at voxel effects and asymmetries in the expansion or contraction.
- Use different well-known structures, such as spheres or cubes, to check the expansion and contraction. Pay attention to the specific 0 mm margin expansion, as it could be different from copying the structure.
- For Boolean combinations, add and subtract known structures and visually verify if the result is correct. Also compare it with reference structures. There should be no (or a very small) residual volume between reference and 2 reciprocal Boolean operations result.
- Create a derived structure. Look for the formula and keep track of it. Change one of the “parent” structures and check if a notification is shown. The system should warn the user about structures changes that have implications on another structure. If derivations are not recorded in the TPS, the responsibility of updating structures lies with the users.
- Interpolation tools: the users should be aware of the method (linear or tri-linear) used by the TPS to interpolate and know its limitation and impact on volume. The visualisation can be checked with the diabolo structure. To check the interpolation, you can copy a simple structure (like a diabolo or a sphere), erase contours on several slices, interpolate and compare the interpolation with the original structure.
- Check the interpolation of branched structures.
- Check the interpolation of flat, rotated structures.

- Check the density override of a structure. For density override, pay special attention when there are overlapping structures. Be sure to understand how the TPS manages this: is there a prioritised structures option, or does the system prevent overlapping of structures with density overrides.
- Check the creation of boluses. Create a beam and generate a bolus that entirely covers the beam with a fixed density and thickness. Check its density and thickness over the aperture of the beam, either with assigned Hounsfield unit or mass density. Perform this check also in sagittal and coronal views (e.g. for bolus applied to a head).
- Check the available ROI types and whether there are types with a special status (e.g. a couch or support ROI) that might affect the dose distribution.
- Validate contouring in sagittal, coronal an oblique views.
- Test copying structures from CT to other modalities and vice versa, compare result with the Hausdorff distance, Dice -index or distance to agreement, validate if re-sampling introduces deviations.
- Check expansions that end in between slice positions at 0.25, 0.5 and 0.75 × slice thickness.

3.3 Dose representation

3.3.1 Dose display

Scope

To check if the dose representation is consistent and displayed correctly.

Background

Plan evaluation is a key step in the radiotherapy process, for which doses should be displayed correctly. The dose grid can be aligned with the image grid or with another reference (like an isocenter), depending on the TPS and/or algorithm used. The positioning and voxel size of the dose grid could change the dose statistics obtained after dose calculation, generally only by a small amount, but this could become significant for small structures, such as in brain SRT cases. One should always adjust the dose grid to clinical needs.

A difference can also occur between dose representation on CT slices and dose computed in the DVH dose statistics because the dose represented on the CT slices can be a visual interpolation of the computed dose and the dose statistics are based directly on the raw dose computation. The difference can be seen by switching to the non-interpolated dose visualisation.

Recommendations

- Isodoses and DVHs should be correct for imported reference data (see 3.2.1).
- Step-like *synthetic* isodoses and DVHs should be visually checked, both interpolated as in non-interpolated representation, if available.
- The grid size effect of the dose grid should be determined on DVHs and clinical goals (for all clinically used resolutions) (Benedict et al., 2010; ICRU 83, 2010; ICRU 91, 2014).
- If available in the TPS, check the visualisation of the DVH dose bin effect.

3.3.2 Dose reporting

Scope

- To advise about dose/volume reporting on targets and OARs, including clinical goals.
- To check whether the dose reporting is consistent with the dose displayed, to the interpolation uncertainty.

Background

To be able to link clinical outcome and toxicities with planning data, dose reporting should be well defined. For this purpose, the implementation of the ICRU reports 83 and 91 is highly recommended (ICRU 83, 2010; ICRU 91, 2014). The TPS should be able to report the requested dose parameters.
Special attention should be given to Monte-Carlo based dose calculations, for which point dose is not relevant, due to the inherent noise of the method. The influence of the statistical uncertainty is the highest for small volumes of interest.

Recommendations

- Verify with known data (Additional material 2), such as synthetic dose distribution with known properties, that mean dose, median dose, near-maximum and near-minimum dose can be correctly calculated and displayed.
- Check the availability and correctness of a tool providing D (*x*% of volume), D (*x* cc) and V (*x* Gy), in relative and absolute scales.

4 Treatment plan optimisation and dose calculation

4.1 Introduction

Radiotherapy treatment planning transitioned from primarily 3D conformal treatment planning to inverse treatment plan optimisation. Using inverse treatment planning, treatment goals are translated into a mathematical description, also known as cost function. This cost function consists of a sum of individual objective functions with resulting values or penalties. The sum of weighted objective values is then optimised. The challenging task is to find a set of objectives that provides the optimal trade-off between tumour coverage and dose to the normal tissues. This task is complicated as the optimisation objectives may not directly be related to the clinical goals.

Traditional inverse treatment planning depends on the experience of the treatment planner (Nelms et al., 2012; Verbakel et al., 2019) and therefore greatly benefits from an unambiguous description of each step in the treatment planning process. This description, also known as a class solution (NCS 22, NCS 24), aims to achieve a clinically acceptable dose distribution in a consistent and efficient approach, for example by the use of templates. The optimal plan for a patient may not be guaranteed and traditional manual tuning of the optimisation objectives may be needed. Once a class solution is defined, repetitive tasks (e.g. beam setup) can be automated using templates or scripting capabilities. Automated or semi-automated planning solutions embedding prior knowledge into algorithms or dose prediction models are available in most treatment planning systems. Note that despite of the use of automated treatment planning, users must retain their skills, knowledge and experience in manual treatment planning to assess and possibly improve treatment plans. Also, the configuration of automated treatment planning models should be maintained, evaluated and adapted over time.

This chapter provides recommendations about class solutions, machine, dose and plan optimisation parameters, automated treatment planning solutions and the QA of automated treatment planning.

4.2 Class solutions

Scope

To ensure consistency and efficiency in treatment planning and simplify the QA process.

Background

A class solution in radiotherapy planning consists of a set of predefined properties, such as delivery technique, objectives, software and beam settings that are sufficiently robust to consistently produce a clinically acceptable dose distribution. Class solutions are tumour site (and prescription) specific and are aimed to improve planning efficiency and quality. The use of class solutions requires consensus on treatment goals amongst the multidisciplinary team, which should consequently lead to improved plan consistency. Moreover, a class solution should result in treatment plans with comparable beam characteristics (e.g. number of beams/gantry angles, average MLC segment size and shape, number of MUs and dose rate). Assuming that other plans derived with the same class solution show a comparable accuracy, the dosimetric accuracy can then be assessed for a limited number of plans. The design and clinical implementation of a class solution can be time consuming, so the effort should therefore be weighed against the benefits.

Typical components of a class solution include:

- Dosimetric goals for target volumes and OARs, including the plan acceptance criteria and prioritization of clinical goals;
- A definition of delineated structures including naming;
- The margins for target volumes and Planning at Risk Volume (PRV) expansion;
- A description of the optimisation strategy, including a standard list of objective functions and the used optimisation settings, such as conventional inverse planning optimisation or automated treatment planning methods;
- Treatment delivery technique (3DCRT, IMRT, VMAT, coplanar, non-coplanar etc.);
- Machine parameters, such as the number of beams or arcs, gantry and collimator angles, minimum MU per field and maximum number of MU per Gy, minimum dose rate and maximum dose rate variation;
- Dose calculation settings (e.g. dose grid size and resolution or Monte Carlo statistical uncertainty).

Note that the optimisation objectives can depend on the geometry of the patient and in order to achieve optimal OAR dose sparing it can be necessary to adapt the objectives on a per patient basis,

preferably according to some rules defined in the class solution. Additionally, the class solution may be adapted over time because of finding an improved optimisation strategy (e.g. another objective prioritisation, new organs at risk) or increased planner experience, resulting in other treatment plans.

Recommendations

- Define class solutions for each tumour site, or at least for tumour sites with a substantial amount of patients (NCS 22, NCS 24).
- Ensure consistent volume definition, a reference to corresponding guidelines should preferably be given for delineated structures.
- Design and discuss the possible class solutions within a multidisciplinary team including radiation oncologists, planners and medical physicists.
- An end-to-end dummy run procedure is required to test the class solution, including plan transfer, deliverability and the dosimetry accuracy.
- Periodic checks, especially after TPS upgrades or changes in treatment protocol, should be performed to ensure that the intended class solution workflow is still intact.
- Periodically review or improve class solutions.

4.3 Dose calculation, machine and plan optimisation parameters

Scope

To describe and give recommendations on dose calculation, machine and plan optimisation parameters that affect the optimisation process, the final dose distribution and plan deliverability.

Background

At the time of writing of this report, most treatment planning systems are equipped with one (or more) of the 3 following dose calculation algorithms:

1. Collapsed cone convolution (Ahnesjö, 1989)
2. Linear Boltzmann transport equations (Bedford, 2019)
3. Monte Carlo (MC) (Ma et al., 2020)

These algorithms are now well established and numerous publications on dosimetric accuracy of these can be found in literature (Aarup et al., 2009; Ahnesjö and Aspradakis, 1999; Fogliata and Cozzi, 2017; Fotina et al., 2011; Kroon et al., 2013). In general, a trade-off is often made between calculation speed and dosimetric accuracy. A speedup could lead to inaccuracies in inhomogeneous media and high-density materials with non-water-like composition. Monte Carlo algorithms give the most accurate

result in inhomogeneous situations, at the cost of increased computation times. Dose calculation parameters that directly influence the dosimetric accuracy, as well as the computation time needed for the optimisation, are the dose grid size and resolution and in the case of Monte Carlo algorithms also the statistical uncertainty of the dose. GPU-based computing has greatly reduced computation times, enabling more accurate dose calculations without sacrificing computation speed.

During the plan optimisation process each iteration consists of performing a change in machine parameter settings (e.g. MUs and leaf position), a dose calculation, an objective function evaluation and the calculation of the search direction for the next iteration. For efficiency, a fast and simplified dose engine is often used during the first part of the optimisation process. This results in less accurate dose computations during the first optimisation steps, particularly in heterogeneous or very low density regions (e.g. in lung tissue with Hounsfield Units between -1000 and -800). Consequently, this results in a difference between the optimised and final dose distribution. This might lead to sub-optimal plans. An additional optimisation start, based on a first optimisation round (a.k.a warm start) usually limits this difference. Many TPS perform an accurate dose calculation after a certain amount of iterations.

In addition to the dose calculation algorithm, machine related parameters (e.g. minimum and maximum gantry rotation speed, dose rate or leaf travel speed) and dose optimisation parameters (e.g. minimum segment area or control point spacing) may impact the optimisation process, optimisation times, the final dose distribution quality and the deliverability (Mans et al., 2015). Note that these settings may be technique and target specific (e.g. SRT versus homogeneous prescriptions).

Recommendations

- Investigate the accuracy and limitations of the dose calculation algorithm by studying the available literature and comments provided by the vendor. Check if a simplified algorithm is used during optimisation and what impact this has on the optimisation results. E.g. For an in-homogeneous setting, check for differences in dose and DVH between the optimised and final (accurate) dose calculation.
- Machine-related and dose optimisation parameters should be investigated to assess their impact on the optimisation time, plan quality, dosimetric accuracy and deliverability. This evaluation should be performed during commissioning of the TPS, but also during development of site specific treatment protocols or class solutions (Mans et al., 2015; Van der Wal et al., 2013).

- For a final dose calculation, a dose grid spacing of 3 mm or smaller is recommended for the conventional treatments and 1-2 mm for SRT/SBRT treatments and small organs at risk.
- The desired statistical uncertainty for Monte Carlo treatment dose distributions should be ≤ 1%.
- Check that the machine parameter limitations (e.g. dose rate, aperture variability, leaf speed, etc.) correspond with machine specifications.
- Verify whether it is necessary to set some machine parameters (e.g. leaf speed, gantry rotation speed, minimum number of MU/segment, leaf gap) stricter than 1) specified by the vendor or 2) measurements to satisfy machine limitations and improve QA results.
- Verify that the TPS performs a deliverability check of the treatment plan at the end of the optimisation or after rescaling of the dose/MU.
- In general, a highly modulated treatment plan (e.g. large MLC movements, high MLC speeds, steep dose rate transitions, high amounts of MU/Gy) may increase the deviation between calculated and actually delivered dose and increase treatment times. It is recommended to set a maximum number of MUs per beam/arc/Gy and/or minimum segment size to limit plan complexity. A trade-off between plan complexity and quality should be investigated. This trade-off has to be considered for each treatment site separately.
- The use of plan complexity metrics can be considered to assess the deliverability of a treatment plan. It should be noted however that these metrics (like fluence map complexity, plan averaged beam irregularity/modulation) do not always relate to worse plan QA results (Antoine et al., 2019; Chiavassa et al., 2019; Kamperis et al., 2020). As these metrics depend on local factors, such as the optimisation method used in the TPS, the accuracy of the beam model or the QA equipment used. Correlations between plan complexity metrics and dosimetric accuracy cannot be directly translated from/to other institutions.

4.4 Automated treatment planning

Scope

To describe what requirements are needed to tune and perform QA of an automated treatment planning solution.

Background

The goal of radiotherapy planning is to find a favourable solution to a multidimensional problem that is preferably Pareto-optimal, i.e. no objective can be improved without deteriorating other objectives. This task is generally time consuming and the result is dependent on the experience of the treatment

planner. Automated treatment planning (ATP) has the potential to improve the efficiency and consistency of treatment planning, to improve the overall plan quality and to reduce errors (Hussein et al., 2018). Four different ATP paradigms can be distinguished:

1. **Protocol-based automated iterative optimisation**: The most time consuming and planner dependent part of treatment planning is the iterative and trial-and-error adjustments of the optimisation objectives. Several researchers and vendors automated the iterative adjustments of the optimisation objectives (Boylan and Rowbottom, 2014; Purdie et al., 2014; Tol et al., 2015b, 2015c, 2015a) to emulate the manual steps performed by the planner using a clinical decision hierarchy or 'dummy' objectives. The general idea is that objectives with higher priority will be fulfilled at the cost of objectives with lower priority, sometimes with some slack or tolerance values. Note that similar approaches can also be implemented using the scripting capabilities of treatment planning systems.
2. **Knowledge-based planning (KBP):** KBP is an implementation of machine learning. KBP directly utilises prior knowledge and experience to predict a DVH or full dose distribution for new patients of a similar population (Fotina et al., 2011; Ge and Wu, 2019; Moore, 2019; Tol et al., 2015a, 2015b; Vandewinckele et al., 2020). A model is trained using data (e.g. images, structures and dose distributions) from previously treated patients with a similar tumour site and dose prescription. The model is used to predict the dose-volume data (i.e. DVH points or the full DVH curve) or the full dose distribution for new patients given input parameters such as the patient's images and delineated structures. An optimisation algorithm then uses the predicted DVHs or dose distribution to achieve a machine deliverable dose distribution. A general limitation of the KBP methods is that the predictors (e.g. the images) of new patients should be within the range, or not far outside the range, of predictors from the plans included in the library (i.e. the training set of the model).
3. **Multi-criteria optimisation (MCO):** Various multi-criteria optimisation algorithms have been introduced that optimise multiple conflicting objectives simultaneously (Breedveld et al., 2019). In general, a distinction can be made between interactive and automated MCO (i.e. lexicographic optimisation) algorithms. In this report, the term MCO is limited to semi-automated planning with interactive Pareto surface navigation. The interactive method requires the generation of a library of treatment plans that have dose parameters in the relevant ranges for plan acceptance. This preparation step can be time consuming, especially when a relatively large number of criteria is used. The user can interactively navigate between the library plans to explore the various trade-offs, generally using sliders. The navigation

process requires plan averaging and interpolation and is usually performed in fluence map space. Depending on the number of criteria and number of plans generated, the interpolated plans may deviate from the actual Pareto front. Also the final step in plan optimisation, the conversion of the interpolated dose distribution to a deliverable dose, may deteriorate the dose distribution. The interactive MCO can be effectively used when patient specific trade-offs have to be explored.

4. **Lexicographic-based optimisation:** The automated lexicographic plan optimisation method is a combination of lexicographic (i.e., prioritised) optimisation and goal programming (Breedveld et al., 2019). Lexicographic plan optimisation results in a single (near) patient-specific Pareto-optimal treatment plan, where the optimal balance between all objectives is guided by the prioritisation defined in the treatment-specific protocol. The automated planning protocol is based on a prioritised wish-list with optimisation objectives, constraints and treatment goals and iteratively tries to fulfil the goals in their order of priority, e.g. by successively adding optimisation objectives to the optimisation problem. Once the conditions are fulfilled, all objectives have been minimised.

The four automated treatment planning paradigms have in common that the quality of the (semi-) automatically generated plans greatly depend on the configuration of the input parameters of the algorithm. If, for example, new knowledge reveals the importance of other priorities in OAR sparing, the configuration may not be valid anymore and needs to be updated. Furthermore, these automated treatment planning methods generally do not account for the optimisation of beam directions (in case of IMRT or partial arc VMAT) and restrict optimisation to machine parameter settings such as leaf positions, segment weights and number of monitor units.

Automated treatment planning modules within treatment planning systems should be investigated, configured and tested in detail before implementing them in routine clinical practice. Suboptimal plan generation may introduce an overall systematic error in the treatments for all patients of a particular tumour type which may be hard to detect when these automated solutions are used in daily clinical practice. A reference dataset containing a large set of (preferably anonymised) patient data (CT, structure set, representative clinical dose distribution) is required for configuration and testing of an automated workflow. This reference data is usually split into smaller datasets used in different stages of the creation of the automated workflow. Based on a training dataset, the initial configuration of the automated routine is performed; this stage may include both variable selection and parameter estimation (*training*). A comparison of the results with a benchmark set (*validation*), may lead to

adjustments in the parameters of the model. Finally, a test set (usually 1/3 of the reference data) is used to evaluate the performance of the automated workflow.

By using a database of reference plans, institutional and unconscious biases already present in the data set may be picked up by the algorithms. In addition, the automated routine might not be suitable for patients with deviating anatomy (e.g. much larger of smaller PTV size than used in the model (Tol et al., 2015c), post-surgery radiotherapy) or special needs (e.g. metal prosthesis, re-irradiation).

Recommendations

- Be aware of typical pitfalls regarding the type of automation. Knowledge about the model or algorithm, as well as its dependencies on input parameters and the effect on dosimetry is required. In addition to a description of the underlying algorithm, provided by the manufacturer as part of the release, tests of the system for simple cases (e.g. with a limited number of OAR) may reveal typical behaviour of the system. Be aware that changes in delineation protocols might also affect ATP results.
- It is strongly recommended to validate the configuration and clinical implementation in a multidisciplinary team consisting of planners, medical physicists and radiation oncologists. This facilitates discussions on preferences and clinical acceptability, revealing unquantified features in the desired dose distribution (e.g. dose conformity at certain distances, preferential sparing of one OAR at the cost of another). Clinical significance and preferences can be quantified using questionnaires and/or visual analogue scales. Other considerations such as treatment time, patient's background and medical history, availability of treatment machines and modalities should be discussed.
- Configuration, testing and validation of ATP should be done with independent (non-overlapping) datasets with clinically realistic data of high quality, preferably from the clinic's practice. Validation of ATP is performed with a dataset not used during the configuration or training phase. External validation by collaborating with other institutions can also be considered.
- A reference dataset should be used, containing high quality plans for a variety of anatomies typical for the patient population. It should include all structure delineations necessary to optimise and fulfil the clinical goals, i.e. the OARs, target volumes and auxiliary structures (e.g. rings to achieve dose conformity). The dataset should be critically reviewed and relevant patient characteristics (e.g. tumour locations and volumes) should be documented.

Use reference datasets to systematically evaluate updates of TPS or ATP models. The user should be aware that the validity of the reference data should be evaluated and maintained over time.

- Verify the model for cases not taken into account in the training set (e.g. with deviating anatomy or special requirements in the treatment plan) and describe the known exceptions in the protocol. If possible, warnings should be given when a case should be considered an outlier.
- Dosimetric accuracy of the generated plans should be validated with a dummy-run procedure and general patient-specific QA on the treatment machine (Mans et al., 2015; Van der Wal et al., 2013). In addition, the user can determine ranges of specific plan complexity parameters describing the typical plan (given a treatment site, segmentation parameters and ATP solution). Although these numbers may strongly depend on the TPS and type of treatments considered, threshold values might be determined to detect outlier plans that can be investigated in more detail and/or measured.
- Review the configuration of the ATP algorithm periodically, at least for a new version of the ATP algorithm or a change in treatment/medical protocol that influences the dose distribution. Additionally, planner experience or trends in plan strategies may change over years and might influence the ATP outcome and acceptability.
- Post-processing of an automatically generated treatment plan should be described in the clinical protocol (e.g. rescaling, changing beam configuration or segmentation settings) and should be clinically relevant.
- Evaluation of automated plan routines should consider both DVH metrics for PTVs and OARs, as well as visual inspection of the 3D dose distributions.
- Performance and quality of ATP may be assessed by manual planning of specific cases by experienced planners on a regular basis, aiming to improve on target coverage, OAR sparing or general plan quality after ATP and to maintain experience in manual planning.
- Review the automated plans and investigate (if considered relevant) whether automated plans can be improved manually or by an update of the model (Fogliata et al., 2019)). Also the use of other dose parameter prediction models (e.g. overlap volume histograms) may be used to detect suboptimal plan quality (Moore et al., 2015; Wang et al., 2017).
- After introduction of ATP in routine use, it is recommended to organise regular meetings between the users of the model and the implementation team to address issues in the implemented workflow.

- Make clear to which exceptions the ATP does not apply (e.g. prosthesis patients). The experience and skills of the treatment planning team must be guaranteed and trained, not only in the use of the ATP tool, but also in manual planning (both regular and exceptional cases), for the scenario that the ATP algorithm becomes (temporarily) unavailable.
- For interactive MCO, it is recommended to investigate the quality of the anchor plans, the general behaviour of Pareto front navigation (e.g. influence of number of objectives and size of plan library, plan quality loss during conversion to a deliverable plan) and to describe the required workflow in plan protocols.

5 IT and automation

5.1 Introduction

As a TPS is a complex system, IT related issues are important to consider during installation and commissioning. TPS specific demands determine the required type of hardware (server type, GPU) and platform. Furthermore, a TPS is integrated in the local network and connects with databases, imaging devices, treatment machines etc. The data stored in a TPS contains patient information that require measures with respect to privacy, security and archiving.

Most TPS facilitate automation of common tasks using templates, macros or scripting. These can be helpful to automate tasks, prevent user errors, or even aid in deciding whether a treatment plan is clinically acceptable. To prevent errors due to improper implementation or use of this automation, a development and testing procedure is recommended.

In this chapter, all the above items will be addressed. For each item, background information as well as suggestions on what should be considered during the implementation are given.

5.2 Hardware

Scope

Configuration and maintenance of hardware for treatment planning systems.

Background

Since the introduction of 3D treatment planning systems, IT and networking systems have massively evolved and are now used routinely in every clinic and hospital. As this hardware is now mainstream, a lot of previous recommendations have become obsolete.

The necessary hardware for treatment planning systems either can be part of the system acquired or has to be bought from third party suppliers according to specific hardware specifications from the TPS vendor.

During commissioning of the TPS, the hardware is implicitly tested. Explicit testing of the hardware as suggested in e.g. NCS-15 (Bruinvis et al., 2005) is not considered relevant anymore. After new installations or hardware updates consistency tests should be performed, to check the hardware configuration implicitly.

Recommendations

- Involve the local IT department early and discuss integration and compatibility of the TPS requirements with the existing network and IT infrastructure.
- Formulate minimum functional requirements and system performance. Make sure that the performance is not only dimensioned for the current workload, but also for future, higher demands (or patient throughput) during its expected life cycle. If specific performance demands (either by the vendor or the user of the TPS) are provided, make sure to verify these upon acceptance of the system.
- Perform a thorough check of the listed hardware specifications in collaboration with the vendor to guarantee whether the hardware is suitable for the TPS software. Examples of some specifications requiring further attention are: GPU floating point precision, the necessity of error-correcting code (ECC) memory and desired network bandwidths.
- Redundancy of the system: Consider the amount of time acceptable for (part of) the system to be offline. Adapt the hardware- and network infrastructure to make sure availability is on par with what is asked for. Check that an appropriate maintenance contract is available to replace faulty hardware within an acceptable timeframe.
- Ensure that the local IT department can provide first line support for troubleshooting; e.g. to check if it is an issue with the TPS hardware, the local infrastructure of the hospital, virtualisation software, license providing software etc.

5.3 Software platform

5.3.1 Software platform demands

Scope

Considerations for designing the software platform on which the TPS software is run (e.g. the operating system, remote access software, drivers).

Background

In order to run a treatment planning system, a software platform is needed on which it can be installed. This software platform provides the backbone functionality used by the software, like e.g. the basic Graphical User Interface (GUI) functionality or libraries needed by this system. The type of platform needed can depend on:

- Specific demands by the TPS on the type of platform (mainly the operating system and GPU driver versions, but also software for remote access to the systems) on which it has to run as it is implemented or validated on a specific platform.
- Integration and connectivity with other systems in the department.
- Specific demands by the local IT department (the IT architecture of the department or hospital) for example restricting the type of systems to be used, or the demand for virtual servers.

The platform used has to at least adhere to the specifications provided by the vendor, as a violation might result in the software not being certified any more, or might limit the support. These specifications might conflict with the local IT policies and potentially lead to problems with the integration of the system in the local IT infrastructure.

Recommendations

- Involve the IT specialists in an early stage in the design of the software platform so they can contribute in this process in order to integrate the system in the IT infrastructure of the hospital.
- Check the specifications for the software platform as provided by the TPS vendor and identify conflicts with local IT policies.
- If deviating from the requirements of the vendor, discuss the consequences and measures (e.g. support level) and consider additional validation tests before clinical use.
- If deviating from local IT policies, make arrangements with the IT department for the implementation and support. E.g. consider whether important security or stability updates have to be installed on the software platform and if these systems can be allowed to interact with the rest of the network of the hospital, or the outside world.
- If remote access to the systems running the TPS software is provided or possible (e.g. using remote desktop protocol (RDP), Citrix or VMware), a secure user authorization mechanism is required. Also consider other specific demands for these connections such as network bandwidth, network security, encoding compression, (lossless) image compression, GPU configuration, performance and licensing (whether the licensing allows remote connections).

5.3.2 Operation system updates or upgrades

Scope

To suggest actions needed to deal with updates of the operating system (OS) on which the TPS is running.

Background

Operating systems require regular updates to fix bugs, stability or security issues that would make the system vulnerable to the outside world. This is specifically relevant when the system is connected to the outside world via internet, as this could lead to leaks of patient data, data loss or system intrusion.

Recommendations

- Check if critical and security updates of the OS are mandatory by the vendor and if testing of the software is required after these updates, or that this is taken care of by the vendor itself.
- Consider to make critical and security updates a demand in the list of requirements during the process of selecting a new TPS.
- Consider not to install any other than critical updates as there is a chance that non critical updates, adding new functionality, might interfere with the TPS. More thorough testing needs to be considered when this is done.
- If critical and security updates are not allowed, the system is exposed to security issues, measures have to be taken to prevent any leakage or loss of patient data by isolating it from the outside world.

5.3.3 Virus scanning and virus updates

Scope

How to deal with virus scanning software on a TPS workspace.

Background

Most workspaces are required to have virus-scanning software to prevent data corruption or security leaks. A virus scanner continuously scans the software running on the workspaces to identify potential threats. As a result, this might interfere with the TPS software running on the system, as it will scan network traffic (e.g. communication with the database), creation of temporary files, memory transactions etc. This may result in degradation of the performance of the TPS software, or the TPS

can even be seen as a threat preventing the software to run. Virus definitions are regularly updated, be aware that the behaviour of these virus scanners can change over time.

Recommendations

- Check the policy regarding virus scanning software of the TPS vendor; is the use of this software allowed? Should certain files or file locations be excluded?
- When virus scanning is not allowed, take measures to prevent the system to be affected by harmful viruses. Isolate the system in the network environment, block internet access and block the possibility to use external storage devices on the TPS workstation.
- Make sure to get notified of any virus scan software or virus definition updates as these might cause the TPS system to malfunction.

5.3.4 Database and storage setup

Scope

To make sure that data is stored in a secure environment that is only accessible by authorised staff and that measures are taken to prevent data loss.

Background

The data stored in databases or file locations by the TPS contain information that falls under privacy legislation. It is of vital importance that this data is only accessible to authorised users. Furthermore, measures have to be taken to prevent the loss of data. The database and file storage servers should have a high availability as the treatment planning process will come to a halt when these are not available.

Recommendations

- Make use of local policies for data security when setting up the databases. Ensure that the system adheres to the security standards for patient data. This could be similar to the setup of the electronic medical record.
- Consider the maximum amount of data loss that is acceptable (e.g. is it acceptable to have a database backup of the previous day?) and make sure the backup policies are designed accordingly.
- Determine the maximum amount of downtime that is acceptable for the TPS. In general, a certain amount of downtime (about 1 day) is acceptable, as this will not lead to considerable

delay of the patient throughput. Choosing a reasonable downtime for the workflow will result in a good balance between cost of the system and impact on the clinic.

- Adapt the redundancy of the database server and storage system to the allowed downtime.
- Make sure that an appropriate maintenance contract is available for the storage and database server to replace faulty hardware within the required time-frame.

5.4 Considerations for software use

Scope

How to:

- deal with identity and access management.
- perform bug and issue tracking,
- handle field safety notices.

Background

During the selection and implementation of a TPS, identity and access management needs to be implemented. Proper administration of user accounts and permissions is mandatory to protect sensitive personal patient data (NEN 7510, 2017); (ISO/IEC 27001, 2018). Restricting ordinary users to change the configuration, such as templates, beam models, CT density tables etc., leads to a secure configuration and a better administration of the system, limiting the need to regularly check the consistency of the configuration.

Safe and secure daily usage of software also requires tracking and registration of known issues and crashes, as well as a procedure to follow up on field safety notices.

Recommendations

- Manage roles, rights and permissions for different account types; e.g. by only allowing selected users to change templates, or that only (a limited number of) physicists are allowed to change the beam models.
- Use individual user accounts and assign users to their appropriate role.
- Protect configuration by limiting the rights of users.
- After a software crash, register the crash and check the treatment plans that were opened when the crash occurred.
- Formally assign responsibility for tracking issues, crashes and field safety notices to the administrator of the software (ISO 9001, 2015).
- Examine log files in case of system crashes or unexpected behaviour.

5.5 Archiving and backup procedures

Scope

To implement a policy for archiving and backup procedures.

Background

The General Data Protection Regulation (GDPR) (European Commission, 2016) recognises 'data concerning health' as a special category of data. The underlying data protection principles (such as privacy by design, accuracy, integrity and confidentiality) must be implemented when using a TPS. This means that the department must have documented backup, retention and archiving policies for the medical data incorporated in the TPS. The staff involved in the backup and de-archiving procedures should be trained. Since national and EU laws regarding medical retention times of medical records is long compared to the life expectancy of a version of a TPS, it is recommended to perform a risk/benefit analysis of retaining the patient data within the TPS or outside the TPS in a PACS or Vendor Neutral Archive (VNA). To be able to read archives in the future, the use of open standards, i.e. DICOM (RT), is highly recommended.

Recommendations

- Define a patient data archiving policy, determine which TPS data must be retained.
- Train staff to use the archived and/or backup data
- Perform de-archiving procedure at least annually
- Perform data recovery procedure at least annually
- Monitor the backup procedure actively to ensure backup data integrity
- Ensure archives can still be read in the future: use open standards (DICOM RT).
- Make sure that archiving is done automatically, or is part of the standard workflow when finishing the medical treatment. Verify that the archival was successful.

5.6 Connectivity including DICOM

Scope

To test the connectivity and conformance of the TPS and to perform functional testing of the connectivity.

Background

The Digital Imaging and Communications in Medicine (DICOM) standard is widely implemented in radiotherapy. All TPS have DICOM import and export capabilities, regarding imaging objects (CT, MR, PET), image registration objects (REG) and radiotherapy specific DICOM RT objects (RTStruct, RTPlan, RTDose, RTImage, RT Treatment record). The DICOM objects are usually exchanged via the local area network (LAN) of the department or hospital. It is imperative that the network connecting the various DICOM export and import nodes is stable and secure. This is even more stringent for wireless networks and DICOM connections based on file exchanges. TPS vendors are required to write a conformance statement on their implementation of the DICOM standard. The impact of changes in the conformance statement should be assessed. Also on a functional level, each DICOM connection between the TPS and the other systems (such as treatment delivery, position verification and imaging systems) has to be assessed in the local situation.

Recommendations

- Document a list of clinical export- and import DICOM nodes with corresponding conformance statements
- Document the (network) architecture of the system including data transfer types (DICOM, HL7 etc.).
- Perform functional and end-to-end tests
- Push vendors actively to provide information on changes made in their DICOM conformance statement

5.7 Automation and scripting

Scope

To discuss the standards on developing scripts and other automation tools.

Background

Most treatment planning systems allow for some sort of automation via scripting, templates or macro's. These capabilities are widely in use for actions such as:

- the reduction of repetitive actions
- reduction of errors in human copying of data
- speeding up treatment planning
- performing automatic checks
- providing additional evaluation tools.

Development and governance of these automation tools need to be embedded in documented procedures.

In Europe, the Medical Device Regulation (MDR) (European Commission, 2017) defines the legislative framework for medical devices including software, which has stringent requirements for the in-house development of software. Since some forms of automation qualify as a medical device, the regulations as given in de MDR apply. In MDR Annex 1, a list of general safety and performance requirements provides details on the topics of quality management systems, risk management, development processes and product safety. Further information on these topics can also be found in a number of other publications (FDA, 2002); (IMDRF, 2013); (ISO 13485, 2016); (IEC 62304, 2006) (IEC 82304-1, 2016).

Although we refrain from giving a precise interpretation of what is to be considered a medical device, we give some examples of what should always be considered a medical device and what should not. Simple automation tools that automate a sequence of repetitive tasks to steer the TPS for the preparation of the plan should not be considered medical devices. However, scripts or software packages that calculate or summarise parameters on which treatment decisions are based, such as dose volume histograms, biological equivalent doses, etc., should be developed as being medical devices themselves, since they directly affect the treatment of a patient.

Recommendations

The recommendations listed below are some basic suggestions in line with literature for quality management of software.

- Start with a risk evaluation of the new, automated workflow.
- Explicitly consider risks associated to the situation with and without automation.
- Use version management and traceability of modifications to source code and configuration files.
- Document the scope, use and implementation of the automation.
- Have a test environment closely resembling the clinical environment to test new automation.
- Document the risk-analysis motivated test procedure together with test results for all versions that will be clinically released.
- Have a (restrictive) policy about which user/role has the permissions validate and commission a tested script in the clinical environment and do this only following the documented procedure.
- Have a protocol for error detection and bug tracking and fixing for all software, including in house developed software.

6 Updating and upgrading of TPS

6.1 Introduction

After the initial installation of the TPS, new software versions are regularly released containing bug fixes as well as new or improved functionality. New versions must be accompanied by relevant and concise release notes. These new versions may be mandatory to fix critical issues communicated in Field Safety Notices. Regular updates might also be required to maintain support, as older versions are often only supported for a limited amount of time and can be a source of discussion when fixing issues with the software.

Before a new version of the software can be used safely in the clinic, it needs to be tested to detect any changes in behaviour. The amount of testing needed depends on the specific modifications and additions in the software, but does not have to be as rigorous as during the installation of a completely new planning system. Generally, a distinction between updates and upgrades is made:

- Update: A new release in which only small bug fixes or minor improvements to existing functionality are added. These changes only have limited impact on the daily clinical workflow, do not significantly influence the quality of the treatment plans and do not significantly change the underlying algorithms for dose calculation, representation or treatment plan optimization.
- Upgrade: A major new release adding new, previously not used and tested functionality that requires a new workflow, or changes to the underlying algorithms that might change the behaviour and outcomes of the system (e.g. of contours, dose or treatment plans).

In case of updates, the primary goal for testing is to verify the consistency of all relevant functionality for the clinic in the new version compared to the currently used clinical version. These tests aim to verify that the system can still be used with the existing workflows and that the resulting treatment plans are comparable to the ones in the current clinical version (both in plan quality as well as in deliverability). Purpose of the testing is not to learn the approximations and limitations of the system as this has already been done during the initial installation of the software. If the update consists of relevant bug-fixes, these should be tested explicitly.

For upgrades, a more thorough testing has to be performed of the modules containing new functionality or significant changes. These tests aim to verify the correct functioning of these modules, as well as to get familiar to the behaviour and limitations of these modules just as with the installation of a completely new planning system. For the rest of the TPS, a consistency check similar to the one performed for updates can be done.

In practice, it is sometimes hard to make a clear distinction between an update and an upgrade. It is up to the medical physicist to determine what should be considered an update or an upgrade based on information provided by the vendor (release notes or other sources of information) and careful evaluation of the software.

6.2 General procedure for new TPS versions

Scope

To advise on a general procedure and prerequisites for updating and upgrading the TPS software.

Background

An update or upgrade of the treatment planning software requires a number of actions to be taken, such as installation of the new software, reviewing the changes, testing, staff training, documentation and clinical introduction. This process can require a significant amount of time from different staff members of the department, most notably from medical physics, IT and RTTs. As these updates usually have to be performed regularly, the development of a good procedure for these can be beneficial and save time in the long run.

Recommendations

- It is strongly recommended to create a test environment in which new versions of the TPS can be installed. The test environment should preferably be on separate hardware from the clinical version and linked to (test) environments of systems it connects to, like the R&V system. In practice, it is difficult to create a complete standalone test environment for the entire clinical workflow, therefore users of this environment should know its limitations. Final testing with an end-to-end test should always be performed in the clinical environment.
- Involve the local IT department early in the process. Check if IT related requirements have changed. Schedule time for the installation of the new version, database connections and making it available (e.g. Citrix) to users. Ask IT to provide additional support following the installation.
- For each update that is released, check if installation is deemed mandatory by the vendor, either because it contains essential bugfixes, or it is required to receive software support. If this is not the case, a critical review of the added value of a new version should be performed to justify the time investment in testing and updating the TPS to a new version.

- Review the release notes and DICOM conformance statements provided by the vendor to see what changes were made to the software and whether these changes can be considered as an update or an upgrade. Be aware that not all changes might be documented in these release notes. Create a test plan based on the changes documented in the release notes, but also check on consistency of all other features relevant for the clinical workflow such as DICOM import/export, ROI expansions, dose calculation, etc.
- Perform a risk analysis for major new functionality to understand its risks and weaknesses.
- Consider what workflow is needed for patients that are already in the treatment preparation phase during the clinical release of the software. For this group of patients often additional actions and checks have to be performed to continue the workflow, especially if plan adaptation is foreseen.
- Consider what kind of training is needed for the users to safely use the updated or new functionality. Specifically, pay attention to changes in behaviour compared to the previous version.
- Update the user documentation describing the clinical workflow to reflect the changes in the software.
- Formally notify the users of the release of the new version; consider a convenient time for performing the update.
- Create a release document describing the update process and testing of the new version. Document the exact (sub)version of the new installation, as well as the date at which it was introduced. Also report when a system or version is decommissioned
- Prepare a roll-back scenario in case the update/upgrade fails. The update/upgrade process may also involve a conversion of the (clinical) patient data so that it can be used by the new version. This scenario includes creating backups of the patient data just prior to the upgrade and going back to the previous software release when final testing is unsuccessful.
- Facilitate an increased support level by experts after clinical introduction of the new version to help users make a smooth transition and identify potential problems not foreseen during the testing and upgrade process.

6.3 Software updates: consistency testing

Scope

To suggest tests that need to be performed before clinical introduction of a TPS update.

Background

For updates of the TPS the amount of testing does not have to be as extensive as when installing a completely new planning system. As the behaviour and limitations of the software have already been examined in the commissioning phase, testing can focus on consistency of the results between the current clinical version and the new release. In order to identify what changes have been made, tests should be performed to confirm the consistency of isolated features of the software (e.g. contour representation, DICOM import, DVH calculation, etc.). Furthermore, the correct functioning of the entire clinical workflow should be validated.

Recommendations

- Perform consistency checks of all features relevant for the workflow. An overview of suggested tests is given in Table 6.1. These tests should be further expanded based on the changes made to the TPS. Preferably use a mix of relevant clinical cases with a variety of characteristics (e.g. large & small ROIs, different treatment techniques, small field sizes etc.). Evaluation is done by comparing the results in the current clinical version of the TPS and in the version to be installed.
- Perform end-to-end tests including dosimetric verification to ensure that the entire treatment chain (including the connectivity with other systems) still functions as it should. Make sure that the clinical workflow is followed and use dummy patients representing typical clinical cases. Create dummy runs for all the different techniques available in your clinic. If no or only minor changes were made to the dose calculation, DICOM export and optimization/segmentation algorithms, the dosimetric verifications can be limited to a few cases.

Table 6.1 - Recommendations for consistency checking of TPS updates

Feature	Suggested test
1. Patient demographics	Import a new patient, make sure that all relevant demographics are imported and displayed correctly.
2. DICOM import	Check if all relevant DICOM objects can be imported (CT, MR, PET, RTPlan, RTStruct, RTDose, etc) and are displayed consistently. Be sure to also check this for historical data.
3. Contours	Import structures from the previous version and check for consistency in contour representation and volume calculation.
4. ROI expansion	Verify that the expansion of ROIs (e.g. generation of PTVs) is still producing the same volumes.
5. External geometry	Check the consistency of external geometry generation that is used for determining the patient contours for dose calculation.
6. Image registration	Check if the image registration algorithm is producing the same result as the old version for a given set of patient data. Check for different image modalities as sometimes different algorithms are used.
7. Densities	Check if the HU values are still converted to the right densities in datasets used for dose calculation.
8. Density override	Verify consistency of handling density overrides by e.g. checking the attenuation of a couch model or bolus material.
9. Dose representation	Import a dose distribution (RTDose) and check if consistent dose values are calculated (point doses as well as dose statistics on ROIs). Also perform a visual check of the dose distribution.
10. DVH calculation	For an imported dose distribution, verify the consistency of the DVH and calculated DVH values.
11. Dose calculation	For a mix of clinical cases, import the patients in the new version, recalculate the dose and compare the dose distribution with the one of the previous version. This can e.g. be done by DICOM import of the RTDose from the previous version.
12. Optimisation	For a mix of clinical cases, perform optimisations in both old and new versions of the software and check if comparable plans are created, both dosimetrically, as in the type of segments created. Make sure that the optimisation is performed in the same way.
13. Connectivity	Test the network connections with all systems the TPS connects to, both for import as well as export.

14. Archiving	Check that old patient data can still be read in the new version
15. Scripting	If the TPS has scripting capabilities and these are used clinically, check if the scripts used for the clinical workflow are still functioning correctly and give the same results as in the previous version.
16. End-to-end tests	Using dummy patients, go through the entire clinical workflow to detect any changes in the workflow automation, import/export, user interface, etc. Perform a QA measurement to verify that the delivered dose matches the calculated dose in the TPS. Make sure that a proper mix of different techniques is used for these tests (IMRT, VMAT, stereotactic treatments, different photon energies, etc.).

7 Bibliography

AAMP Task Group 263, 2018. Standardizing Nomenclatures in Radiation Oncology.

Aarup, L.R., Nahum, A.E., Zacharatou, C., Juhler-Nøttrup, T., Knöös, T., Nyström, H., Specht, L., Wieslander, E., Korreman, S.S., 2009. The effect of different lung densities on the accuracy of various radiotherapy dose calculation methods: Implications for tumour coverage. Radiother. Oncol. 91, 405–414. https://doi.org/10.1016/j.radonc.2009.01.008

ACR - ASTRO, 2018. ACR–ASTRO PRACTICE PARAMETER FOR RADIATION ONCOLOGY [WWW Document]. URL https://www.acr.org/-/media/acr/files/practice-parameters/radonc.pdf

Ahnesjö, A., 1989. Collapsed cone convolution of radiant energy for photon dose calculation in heterogeneous media. Med. Phys. 16, 577–592. https://doi.org/10.1118/1.596360

Ahnesjö, A., Aspradakis, M.M., 1999. Dose calculations for external photon beams in radiotherapy. Phys. Med. Biol. 44, R99–R155. https://doi.org/10.1088/0031-9155/44/11/201

Antoine, M., Ralite, F., Soustiel, C., Marsac, T., Sargos, P., Cugny, A., Caron, J., 2019. Use of metrics to quantify IMRT and VMAT treatment plan complexity: A systematic review and perspectives. Phys. Medica 64, 98–108. https://doi.org/10.1016/j.ejmp.2019.05.024

Bedford, J.L., 2019. Calculation of absorbed dose in radiotherapy by solution of the linear Boltzmann transport equations. Phys. Med. Biol. 64, 02TR01. https://doi.org/10.1088/1361-6560/aaf0e2

Benedict, S.H., Yenice, K.M., Followill, D., Galvin, J.M., Hinson, W., Kavanagh, B., Keall, P., Lovelock, M., Meeks, S., Papiez, L., Purdie, T., Sadagopan, R., Schell, M.C., Salter, B., Schlesinger, D.J., Shiu, A.S., Solberg, T., Song, D.Y., Stieber, V., Timmerman, R., Tomé, W.A., Verellen, D., Wang, L., Yin, F.-F., 2010. Stereotactic body radiation therapy: The report of AAPM Task Group 101. Med. Phys. 37, 4078–4101. https://doi.org/10.1118/1.3438081

Boylan, C., Rowbottom, C., 2014. A bias-free, automated planning tool for technique comparison in radiotherapy - application to nasopharyngeal carcinoma treatments. J. Appl. Clin. Med. Phys. 15, 213–225. https://doi.org/10.1120/jacmp.v15i1.4530

Breedveld, S., Craft, D., van Haveren, R., Heijmen, B., 2019. Multi-criteria optimization and decision-making in radiotherapy. Eur. J. Oper. Res. 277, 1–19. https://doi.org/10.1016/j.ejor.2018.08.019

Brock, K.K., Mutic, S., McNutt, T.R., Li, H., Kessler, M.L., 2017. Use of image registration and fusion algorithms and techniques in radiotherapy: Report of the AAPM Radiation Therapy Committee Task Group No. 132. Med. Phys. 44, e43–e76. https://doi.org/10.1002/mp.12256

Bruinvis, I.A.D., Keus, R.B., Lenglet, W.J.M., Meijer, G.J., Mijnheer, B.J., Van 't Veld, A.A., Venselaar, J.L.M., Welleweerd, J., Woudstra, E., 2005. NCS Report 15: Quality assurance of 3-D treatment planning systems for external photon and electron beams, Nederlandse Commissie voor Stralingsdosimetrie. Delft. https://doi.org/10.25030/ncs-015

Chiavassa, S., Bessieres, I., Edouard, M., Mathot, M., Moignier, A., 2019. Complexity metrics for IMRT and VMAT plans: a review of current literature and applications. Br. J. Radiol. 92, 20190270. https://doi.org/10.1259/bjr.20190270

Das, I.J., Cheng, C.-W., Watts, R.J., Ahnesjö, A., Gibbons, J., Li, X.A., Lowenstein, J., Mitra, R.K., Simon, W.E., Zhu, T.C., 2008. Accelerator beam data commissioning equipment and procedures: Report of the TG-106 of the Therapy Physics Committee of the AAPM. Med. Phys. 35, 4186–4215. https://doi.org/10.1118/1.2969070

DICOM, 1997. Supplement 11 Radiotherapy Objects [WWW Document]. URL https://www.dicomstandard.org/News/ftsup/docs/sups/sup11.pdf

European commission, 2015. General guidelines on risk management in external beam radiotherapy. European Commission.

European Commission, 2017. MDR: EU Medical Device Regulation [WWW Document]. URL https://eur-lex.europa.eu/eli/reg/2017/745/oj

European Commission, 2016. General Data Protection Regulation [WWW Document]. URL http://data.europa.eu/eli/reg/2016/679/2016-05-04

FDA, 2002. General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

Fogliata, A., Cozzi, L., 2017. Dose calculation algorithm accuracy for small fields in non-homogeneous media: The lung SBRT case. Phys. Medica 44, 157–162. https://doi.org/10.1016/j.ejmp.2016.11.104

Fogliata, A., Cozzi, L., Reggiori, G., Stravato, A., Lobefalo, F., Franzese, C., Franceschini, D., Tomatis, S., Scorsetti, M., 2019. RapidPlan knowledge based planning: iterative learning process and model ability to steer planning strategies. Radiat. Oncol. 14, 187. https://doi.org/10.1186/s13014-019-1403-0

Ford, E., Conroy, L., Dong, L., Los Santos, L.F., Greener, A., Gwe-Ya Kim, G., Johnson, J., Johnson, P., Mechalakos, J.G., Napolitano, B., Parker, S., Schofield, D., Smith, K., Yorke, E., Wells, M., 2020. Strategies for effective physics plan and chart review in radiation therapy: Report of AAPM Task Group 275. Med. Phys. 47. https://doi.org/10.1002/mp.14030

Fotina, I., Kragl, G., Kroupa, B., Trausmuth, R., Georg, D., 2011. Clinical Comparison of Dose Calculation Using the Enhanced Collapsed Cone Algorithm vs. a New Monte Carlo Algorithm. Strahlentherapie und Onkol. 187, 433–441. https://doi.org/10.1007/s00066-011-2215-9

Fraass, B., Doppke, K., Hunt, M., Kutcher, G., Starkschall, G., Stern, R., Van Dyke, J., 1998. American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: quality assurance for clinical radiotherapy treatment planning. Med. Phys. 25, 1773–829.

Ge, Y., Wu, Q.J., 2019. Knowledge-based planning for intensity-modulated radiation therapy: A review of data-driven approaches. Med. Phys. 46, 2760–2775. https://doi.org/10.1002/mp.13526

Hernandez, V., Vera-Sánchez, J.A., Vieillevigne, L., Khamphan, C., Saez, J., 2018. A new method for modelling the tongue-and-groove in treatment planning systems. Phys. Med. Biol. 63. https://doi.org/10.1088/1361-6560/aaf098

Hernandez, V., Vera-Sánchez, J.A., Vieillevigne, L., Saez, J., 2017. Commissioning of the tongue-and-groove modelling in treatment planning systems: From static fields to VMAT treatments. Phys. Med. Biol. 62, 6688–6707. https://doi.org/10.1088/1361-6560/aa7b1a

Heukelom, S., Hoffmans-Holtzer, N., Marijnissen, H., Nulens, A., Pittomvils, G., Raaijmakers, E., Verellen, D., Vieira, S., Hermans, J., 2015. NCS Report 25: Process management and quality assurance for intracranial stereotactic treatment. Delft. https://doi.org/10.25030/ncs-25

Hussein, M., Heijmen, B.J.M., Verellen, D., Nisbet, A., 2018. Automation in intensity modulated radiotherapy treatment planning—a review of recent innovations. Br. J. Radiol. 91, 20180270. https://doi.org/10.1259/bjr.20180270

IAEA TRS 430, 2004. Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer, TRS 430. ed. IAEA, Vienna.

IAEA TRS 483, 2017. Dosimetry of Small Static Fields Used in External Beam Radiotherapy. Tech. Reports Ser.

ICRP 86, 2000. Prevention of Accidents to Patients Undergoing Radiation Therapy.

ICRU 83, 2010. Prescribing, Recording, and Reporting Photon-Beam Intensity-Modulated Radiation Therapy (IMRT), Journal of the ICRU. https://doi.org/10.1093/jicru/ndq025

ICRU 91, 2014. Prescribing, recording, and reporting of stereotactic treatments with small photon beams, Journal of the International Commission on Radiation Units and Measurements. https://doi.org/10.1093/jicru/ndx017

IEC 61217, 2011. Radiotherapy equipment - Coordinates, movements and scales.

IEC 62083, 2009. Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems.

IEC 62304, 2006. Medical device software – software life cycle processes.

IEC 82304-1, 2016. Health software — Part 1: General requirements for product safety.

IMDRF, 2013. International Medical Device Regulators Forum documents [WWW Document]. URL

https://www.imdrf.org/documents
ISO/IEC 27001, 2018. Information security management.
ISO 13485, 2016. Medical devices — Quality management systems — Requirements for regulatory purposes.
ISO 9001, 2015. Quality management systems -- Requirements. Geneva.
Kamperis, E., Kodona, C., Hatziioannou, K., Giannouzakos, V., 2020. Complexity in Radiation Therapy: It's Complicated. Int. J. Radiat. Oncol. 106, 182–184. https://doi.org/10.1016/j.ijrobp.2019.09.003
Kroon, P.S., Hol, S., Essers, M., 2013. Dosimetric accuracy and clinical quality of Acuros XB and AAA dose calculation algorithm for stereotactic and conventional lung volumetric modulated arc therapy plans. Radiat. Oncol. 8, 149. https://doi.org/10.1186/1748-717X-8-149
Kry, S.F., Bednarz, B., Howell, R.M., Dauer, L., Followill, D., Klein, E., Paganetti, H., Wang, B., Wuu, C.-S., George Xu, X., 2017. AAPM TG 158: Measurement and calculation of doses outside the treated volume from external-beam radiation therapy. Med. Phys. 44, e391–e429. https://doi.org/10.1002/mp.12462
Kry, S.F., Feygelman, V., Balter, P., Knöös, T., Charlie Ma, C. -M., Snyder, M., Tonner, B., Vassiliev, O.N., 2020. AAPM Task Group 329: Reference dose specification for dose calculations: Dose-to-water or dose-to-muscle? Med. Phys. 47. https://doi.org/10.1002/mp.13995
Kry, S.F., Glenn, M.C., Peterson, C.B., Branco, D., Mehrens, H., Steinmann, A., Followill, D.S., 2019. Independent recalculation outperforms traditional measurement-based IMRT QA methods in detecting unacceptable plans. Med. Phys. 46, 3700–3708. https://doi.org/10.1002/mp.13638
Kry, S.F., Lye, J., Clark, C.H., Andratschke, N., Dimitriadis, A., Followill, D., Howell, R., Hussein, M., Ishikawa, M., Kito, S., Kron, T., Lee, J., Michalski, J., Filippo Monti, A., Reynaert, N., Taylor, P., Venables, K., Xiao, Y., Lehmann, J., 2021. Report dose-to-medium in clinical trials where available; a consensus from the Global Harmonisation Group to maximize consistency. Radiother. Oncol. 159, 106–111. https://doi.org/10.1016/j.radonc.2021.03.006
Ma, C.M.C., Chetty, I.J., Deng, J., Faddegon, B., Jiang, S.B., Li, J., Seuntjens, J., Siebers, J. V., Traneus, E., 2020. Beam modeling and beam model commissioning for Monte Carlo dose calculation-based radiation therapy treatment planning: Report of AAPM Task Group 157. Med. Phys. 47. https://doi.org/10.1002/mp.13898
Mans, A., Schuring, D., Arends, M., Vugts, L., Wolthaus, J.W.H., Lotz, H., Admiraal, M., Louwe, R., Öllers, M., Van de Kamer, J.B., 2015. NCS Report 24: Code of practice for the quality assurance and control for volumetric modulated arc therapy. Delft. https://doi.org/10.25030/ncs-024
Miften, M., Olch, A., Mihailidis, D., Moran, J., Pawlicki, T., Molineu, A., Li, H., Wijesooriya, K., Shi, J., Xia, P., Papanikolaou, N., Low, D.A., 2018. Tolerance limits and methodologies for IMRT measurement-based verification QA: Recommendations of AAPM Task Group No. 218. Med. Phys. 45, e53–e83. https://doi.org/10.1002/mp.12810
Moore, K.L., 2019. Automated Radiotherapy Treatment Planning. Semin. Radiat. Oncol. 29, 209–218. https://doi.org/10.1016/j.semradonc.2019.02.003
Moore, K.L., Schmidt, R., Moiseenko, V., Olsen, L.A., Tan, J., Xiao, Y., Galvin, J., Pugh, S., Seider, M.J., Dicker, A.P., Bosch, W., Michalski, J., Mutic, S., 2015. Quantifying Unnecessary Normal Tissue Complication Risks due to Suboptimal Planning: A Secondary Study of RTOG 0126. Int. J. Radiat. Oncol. 92, 228–235. https://doi.org/10.1016/j.ijrobp.2015.01.046
Nelms, B.E., Robinson, G., Markham, J., Velasco, K., Boyd, S., Narayan, S., Wheeler, J., Sobczak, M.L., 2012. Variation in external beam treatment plan quality: An inter-institutional study of planners and planning systems. Pract. Radiat. Oncol. 2, 296–305. https://doi.org/10.1016/j.prro.2011.11.012
NEN 7510, 2017. Informatiebeveiliging in de zorg - register NEN 7510.
NVZ, NFU, RN, 2011. Convenant Veilige Toepassing van medische technologie in het ziekenhuis.
Purdie, T.G., Dinniwell, R.E., Fyles, A., Sharpe, M.B., 2014. Automation and intensity modulated

radiation therapy for individualized high-quality tangent breast treatment plans. Int. J. Radiat. Oncol. Biol. Phys. 90, 688–695. https://doi.org/10.1016/j.ijrobp.2014.06.056

Smilowitz, J.B., Das, I.J., Feygelman, V., Fraass, B.A., Kry, S.F., Marshall, I.R., Mihailidis, D.N., Ouhib, Z., Ritter, T., Snyder, M.G., Fairobent, L., 2015. AAPM Medical Physics Practice Guideline 5.a.: Commissioning and QA of Treatment Planning Dose Calculations - Megavoltage Photon and Electron Beams. J. Appl. Clin. Med. Phys. 16, 14–34. https://doi.org/10.1120/jacmp.v16i5.5768

Tol, J.P., Dahele, M., Delaney, A.R., Slotman, B.J., Verbakel, W.F.A.R., 2015a. Can knowledge-based DVH predictions be used for automated, individualized quality assurance of radiotherapy treatment plans? Radiat. Oncol. 10, 234. https://doi.org/10.1186/s13014-015-0542-1

Tol, J.P., Dahele, M., Peltola, J., Nord, J., Slotman, B.J., Verbakel, W.F.F.A.R., 2015b. Automatic interactive optimization for volumetric modulated arc therapy planning. Radiat. Oncol. 10, 75. https://doi.org/10.1186/s13014-015-0388-6

Tol, J.P., Delaney, A.R., Dahele, M., Slotman, B.J., Verbakel, W.F.A.R., 2015c. Evaluation of a Knowledge-Based Planning Solution for Head and Neck Cancer. Int. J. Radiat. Oncol. 91, 612–620. https://doi.org/10.1016/j.ijrobp.2014.11.014

Van der Wal, E., Wiersma, J., Ausma, A.H., Cuijpers, J.P., Tomsej, M., Bos, L.J., Pittomvils, G., Murrer, L., Van de Kamer, J.B., 2013. NCS Report 22: Code of practice for the quality assurance and control for intensity modulated radiotherapy, 2013. Delft. https://doi.org/10.25030/ncs-022

Vandewinckele, L., Claessens, M., Dinkla, A., Brouwer, C., Crijns, W., Verellen, D., van Elmpt, W., 2020. Overview of artificial intelligence-based applications in radiotherapy: Recommendations for implementation and quality assurance. Radiother. Oncol. 153, 55–66. https://doi.org/10.1016/j.radonc.2020.09.008

Verbakel, W.F.A.R., Doornaert, P.A.H., Raaijmakers, C.P.J., Bos, L.J., Essers, M., van de Kamer, J.B., Dahele, M., Terhaard, C.H.J., Kaanders, J.H.A.M., 2019. Targeted Intervention to Improve the Quality of Head and Neck Radiation Therapy Treatment Planning in the Netherlands: Short and Long-Term Impact. Int. J. Radiat. Oncol. 105, 514–524. https://doi.org/10.1016/j.ijrobp.2019.07.005

Wang, Y., Heijmen, B.J.M., Petit, S.F., 2017. Prospective clinical validation of independent DVH prediction for plan QA in automatic treatment planning for prostate cancer patients. Radiother. Oncol. 125, 500–506. https://doi.org/10.1016/j.radonc.2017.09.021

Zhu, T.C., Stathakis, S., Clark, J.R., Feng, W., Georg, D., Holmes, S.M., Kry, S.F., Ma, C.C., Miften, M., Mihailidis, D., Moran, J.M., Papanikolaou, N., Poppe, B., Xiao, Y., 2021. Report of AAPM Task Group 219 on independent calculation-based dose/MU verification for IMRT. Med. Phys. 48. https://doi.org/10.1002/mp.15069

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