

Radiation Therapy Facilities - Prescription and Treatment Sheets

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Summary This policy prescribes the mandatory data items to be collected and verified by NSW Health Radiation Oncology Treatment Centres during the prescription, planning and treatment stage for megavoltage, superficial and orthovoltage radiation therapy. The policy also includes the principles for developing radiation therapy prescription and treatment sheets, as well as a checklist for critical activities conducted during the planning and delivery of radiation therapy, that must be checked to avoid errors.

Replaces Doc. No. Radiotherapy - Prescription and Treatment Sheets for NSW Health Radiation Therapy Facilities [PD2006_039]

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This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

Statewide Services Development Branch

**Development of Prescription
and Treatment Sheets for
NSW Health Radiation
Therapy Facilities**

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**Development of Prescription and Treatment Sheets
for NSW Health Radiation Therapy Facilities**

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Preface

The success of a radiation oncology treatment is dependent on the accurate delivery of a specified dose to the selected target.

This Policy prescribes the mandatory data to be collected and verified by NSW Health Radiation Oncology Treatment Centres during the prescription, planning and treatment stages for megavoltage, superficial and orthovoltage radiation therapy. The Policy also includes principles for developing radiation therapy prescription and treatment sheets, as well as a checklist for critical activities conducted during the planning and delivery of radiation therapy treatment that must be checked to avoid errors.

The intent of checking and collecting these mandatory data items is to ensure that errors do not occur which might cause treatment complications or impact on the intent of treatment, whether curative or palliative.

The Policy also requires Area Health Services to conduct regular audits of Radiation Oncology Treatment Centres' processes to verify compliance with this Policy.

The Policy should be brought to the attention of all staff working at Radiation Oncology Treatment Centres responsible for collection and checking of data items in relation to the prescription, planning and treatment of patients using radiotherapy, including:

- Directors of Radiation Oncology Treatment Centres.
- Radiation Oncologists.
- Chief Radiation Therapists.
- Radiation Therapists.
- Radiation Therapist Graduates in their Professional Development Year.
- Radiation Therapist Tutors.
- Medical Physicists.
- Nursing staff.
- Data Managers.
- Quality Assurance Radiation Therapists and other relevant improvement performance staff in the Area Health Service who may be involved in conducting an audit of processes at Radiation Oncology Treatment Centres.

The policy replaces PD2006_039.

The expertise of the review group, consisting of Medical Physicists, Chief Radiation Therapists and Directors of Radiation Oncology representing public and private radiation treatment centres, is appreciated and acknowledged.

PART ONE

1.0 Introduction

In 1997 as part of a review of standard policies and practices in radiotherapy administration, NSW Health issued a list of data components to be incorporated in prescription and treatment sheets for megavoltage, superficial and orthovoltage treatment, as well as a Radiation Therapy Planning Checklist. These lists were issued by letter to Directors of Radiation Oncology Treatment Centres as a recommended 'better practice' protocol for inclusion in the design of prescription, treatment and planning sheets.

It was anticipated that the standardisation of factors identified as critical points in the planning and treatment process would add to quality improvement processes and enhance quality of care in NSW radiation oncology departments.

The Department of Health undertook the coordination of a review of these lists of data elements and processes. During 2005, a group of experts representing public and private radiation treatment centres, worked with Department staff to review and update the lists to reflect current technology and treatment processes.

The Policy *Developing Prescription and Treatment Sheets for NSW Health Radiation Therapy Facilities* (PD2006_039) prescribed mandatory data to be collected and verified during the prescription, planning and treatment stages for megavoltage, superficial and orthovoltage radiation therapy. The Policy also included principles for developing radiation therapy prescription and treatment sheets, a checklist for critical activities conducted during the radiation therapy stages that must be checked to avoid errors, and a requirement that regular audits of Radiation Oncology Treatment Centres be conducted to measure compliance with the Policy and to implement remedial action where necessary.

The Policy was reviewed and is now replaced by this version which represents review by Medical Physicists, Chief Radiation Therapists and Directors of Radiation Oncology representing public and private radiation treatment centres, working with Department staff.

1.1 MAIN CHANGES MADE IN THIS POLICY

As a result of the review of the 2006 policy, the main changes made in this 2008 policy are:

- Inclusion of references to new relevant NSW Health policies including Correct Patient, Correct Procedure, Correct Site policy (PD2007_079), and the Client Registration Policy (PD2007_094);
- Review and update of references to other NSW Health policies which may have changed;
- Inclusion of additional mandatory data items in the 'Administrative Data Requirements' as per the Client Registration Policy;
- Update of the 'Obtaining Patient Consent' section (6.0);
- It is no longer mandatory that a final set of verification images be signed by a Radiation Oncologist, as outlined in Part Three, 8.6, item 3 in this policy. Each Radiation Oncology Department will have its own imaging policy regarding checking and sign-off by Radiation Oncologists of verification images. It is noted that new Oncology Treatment Verification codes came into effect for the Medicare Benefits Schedule from 1 July 2008.

Changes have also been made to a number of individual data items.

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2.0 Purpose

The purpose of this Policy is to provide a quality assurance framework which will ensure the accurate delivery of specified dose of radiation to the selected targets by mandating data items to be recorded and checked during the radiation therapy prescription, planning and treatment process.

This Policy applies to public Radiation Oncology Treatment Centres in NSW, however, as a better practice document, it is recommended that private Radiation Oncology Treatment Centres in NSW also adhere to the Policy.

Part One of the Policy outlines the general principles for developing treatment sheets; the stages in delivery of radiotherapy treatment; considerations for the design of paper treatment sheets; security requirements for data items recorded either in an electronic or paper-based system; and requirements for obtaining patient consent.

Part Two of the Policy is the Radiotherapy Planning Checklist, which provides a guide as to how an error in particular activities is likely to impact as an error in the dose delivered to the patient. The Radiotherapy Planning Checklist identifies these critical activities that must be checked to avoid errors, as part of a quality assurance program for planning and treatment to ensure safe radiation therapy practices. Part Two also outlines the requirement for an audit process to be implemented, so that compliance with this Policy can be measured and improved performance implemented.

Part Three and Part Four of the Policy lists the mandatory data items identified as indicators of critical points in the process of planning for, and treating of, patients using megavoltage, superficial and orthovoltage radiation therapy.

NSW Health Radiation Oncology Treatment Centres must collect each of these data items, verifying as necessary, and the data items must be incorporated into radiation therapy planning and treatment sheets which the centres have developed and use locally. It is noted that the section 'Administrative Data Requirements' includes Client Registration Data items required to be collected and recorded in the Area Health Service-wide client registration database (i) when a booking is made for the first service, and (ii) at the time of service provision, as outlined in the *Client Registration Policy* (PD2007_094). Some of these data items may already have been collected for patients in the Area-wide client registration database prior to data collection processes by Radiation Oncology Treatment Centres.

The success of a radiation oncology treatment is dependent on the accurate delivery of specified doses to the selected targets. The delivery of incorrect doses of radiation to patients may result in a range of complications.

The intent of checking and collecting these mandatory data items is to ensure that errors do not occur which might cause treatment complications or impact on the intent of treatment, whether curative or palliative.

These data items are arranged according to type of radiation therapy treatment (megavoltage, superficial and orthovoltage) and stage of treatment (prescription and planning stage or treatment stage).

This documentation does not preclude the need for an appropriate patient clinical record where other pertinent information is recorded, for example, patient history, details of patient examination recorded, and results of "time out" processes for final patient safety check.

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Part Five of the Policy lists additional data items that Area Health Services may find of assistance to also include in their local data collection activities.

3.0 General Principles for Developing Treatment Sheets

In addition to the specific data items that must be collected and verified by NSW Health Radiation Oncology Treatment Centres (Part Three and Part Four of the Policy), the following general principles also apply:

- All mandatory checkpoints (Senior Radiation Therapist Check, the Independent Physics Check, the New Case Check and the Weekly History Check) should include verification of the original prescription and dosimetry. The relevant forms should be modified to include a check box indicating the checker has referred back to the original prescription and checked the dosimetry and number of fractions, and should include the checker's printed name, signature and date.
- The processes for ensuring the correct patient, correct procedures and correct site, as outlined in the *Correct Patient, Correct Procedure and Correct Site* policy (PD 2007_079), must be followed for each stage of the delivery of radiotherapy and interactions with the patients. This would include, for example, simulation and delivery of each fraction of treatment.
- Each patient's Planning and Treatment documentation must remain together. The unique identifier for the patient must be included on each page, preferably at the top, in order to minimise the risk of error.
- There must be a treatment summary produced at the end of treatment.
- The prescription must contain redundancy checks. For example:
$$\text{Total prescribed dose} = \text{dose per fraction} \times \text{number of fractions.}$$
- The prescription must be clear. For example, a single description for each site, clearly indicate where different beam types or energies are to be used.
- The prescription must be unambiguous. For example, a glossary of abbreviations is advisable.
- Appropriate information must be recorded for each data item on the locally developed planning and treatment sheets, and fields must not remain blank. For example, where the Policy notes "Planning / simulation Remarks" and the Centre has no remarks to make, "No remarks" should be recorded.

3.1 CHANGES TO THE PRESCRIPTION

Any changes to the prescription, **BEFORE** treatment commences, must include **ALL** of the following:

- A single line cross out of the original prescription
- Initialling the change
- Dating the change
- For paper versions of original prescriptions, include an identifier such as a tick box , indicating that the prescription has been amended, and refer to the remarks section for the new prescription. The tick box should be in a prominent position that will not be missed when looking at the prescription. Where prescriptions are stored electronically,

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the systems' audit procedures must be capable of tracking changes to the electronic prescription.

Changes AFTER treatment has commenced should be made in the "Remarks" section of the treatment record and dated so that it is obvious to the Treatment Radiation Therapist. A designated area for documentation of these changes is recommended, for example (see below):

<i>Date</i>	<i>Field number(s)</i>	<i>Site and Field Description</i>	<i>Change</i>	<i>Radiation Oncologist (printed name and signature)</i>

As outlined in Policy Directive PD 2005_127 *Records – Principles for Creation, Management, Storage and Disposal of Health Care Records*, no alteration and correction of records is to render illegible information that is already contained in the record. An original incorrect entry should remain readable.

3.2 COMPUTERISED RECORD AND VERIFY SYSTEMS

All computerised Record and Verify Systems should incorporate adequate checks and balances to prevent errors, since computerised systems are still dependent on data that at some point has been entered by humans. Further information on quality assurance is outlined in the Radiotherapy Planning Checklist.

4.0 Electronic and Paper-Based Systems

All prescription and treatment sheets, whether recorded in an electronic system or a paper-based system, or a combination of the two, must comply with the principles and data item requirements of this policy.

4.1 ELECTRONIC SYSTEMS

Recording of prescription, planning and treatment data items may be completed in paper based or electronic systems, or a combination of the two. For example, in a paper-based system, the convention would be that the responsible officer (Radiation Therapist, Radiation Oncologist etc) prints their full name (to avoid confusion over illegible signatures), signs and dates the sheet which indicates the officer responsible, and that the task has been completed. In an electronic system, the convention might be a digital signature or password or tracking system, or a combination of these, dependent on the capabilities of the electronic system, to generate the relevant officer's name and details, or some other secure authentication method.

This Policy outlines various checkpoints when the printed name and signature of the relevant officer is required and the date when the check is conducted. Area Health Services must ensure that their Radiation Oncology Treatment Centres have systems in place which unambiguously identifies the name of the person responsible for that treatment task / check, the date the task was completed and verify that the appropriate person has "signed-off" on the task, prescription notation, remark etc.

Radiation Oncology Treatment Centres must identify the risks and be able to demonstrate that their identification and authentication systems meet the quality assurance requirements. Appropriate security arrangements to ensure authenticity of all relevant parties and secure

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access to information should be implemented in accordance with Policy Directive PD2008_052 *Electronic Information Security Policy – NSW Health*.

Policy Directive PD2005_127 *Records – Principles for Creation, Management, Storage and Disposal of Health Care Records* includes the principle ‘responsibility for documentation.’ This principle requires that all computerised and hand-written systems have the capacity to enable identification of individual health personnel. In a computerised system, this will require the use of an appropriate identification system, for example, electronic signatures.

4.2 DESIGN OF PAPER-BASED SYSTEMS

The mandatory data items are to be incorporated into radiation therapy planning and treatment sheets. Radiation Oncology Treatment Centres have mechanisms in place to collect and verify the data items using locally developed planning and treatment sheets. This Policy does not prescribe a particular format for planning and treatment sheets, as long as the mandatory data items are recorded and incorporated into the relevant stages of the process.

However, some operational practices used to record the data, such as the physical design of the sheet, will reinforce the processes for accurate delivery of radiation to the patients. The following are provided for consideration, however all operational practices must comply with the principles outlined in the Policy Directive PD2005_127 *Records – Principles for Creation, Management, Storage and Disposal of Health Care Records*.

- The physical design of the treatment sheets must be robust to handle the day-to-day usage and handling (eg. 150gsm paper).
- Light coloured treatment sheets assist with the readability of information in darkened treatment rooms, and the avoidance of possible set up errors.
- Treatment sheets specific to particular Centres, which have common parameters between patients such as set up instructions, isocentre instructions and other requirements, could be pre-printed with these parameters on the sheet. This may result in time saved when writing up treatment sheets. Pre-printed parameters on the sheets eliminates potential errors that can occur due to illegible handwriting, and saves time as information can be highlighted instead of written each time.
- Centres also use other strategies such as different colour pens, colour coding of ink, or highlighting of pertinent information to distinguish critical information contained on the treatment sheet. Such colour coding approaches may provide a visual warning of items such as accessories, field sizes and monitor units.

It is necessary, however, to be aware that colour coding used to denote one meaning in a particular Radiation Oncology Treatment Centre may have a quite different meaning in another Centre.

- As outlined in Policy Directive PD2005_127 *Records – Principles for Creation, Management, Storage and Disposal of Health Care Records*, Area Health Services must ensure the durability of health care records. Entries should be made in a manner that will ensure their permanence. Non-permanent ink that can fade over time, pencil or erasable writing materials, must be avoided.

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4.3 RETENTION AND DISPOSAL - PATIENT RECORDS – RADIOTHERAPY TREATMENT

The General Retention and Disposal Authority Public Health Services: Patient / Client Records GDA 17 covers the requirements for records documenting radiation dose delivery to patients. It requires that radiotherapy treatment records, which are usually maintained in Radiotherapy Departments, be retained at a minimum of:

- 10 years after the patient would have attained the aged of 70 or after the last attendance, whichever is longer, or
- where the service has received notification of the date of death, 10 years after date of death, then be destroyed.

GDA 17 can be found at:

http://www.records.nsw.gov.au/recordkeeping/general_retention_and_disposal_996.asp

5.0 Stages in Delivery of Radiotherapy Treatment

5.1 PRESCRIPTION AND PLANNING STAGE

The Radiation Oncologist examines the patient and, in discussion with the patient, determines the appropriate treatment required. The Radiation Oncologist prescribes the treatment in the form of a prescription and includes details of the region to be treated and the dose to be delivered to the patient. For the purpose of this Policy, the prescription and planning stage includes those activities in the simulation process, planning process and prescription documentation.

5.1.1 Simulation Process

The Simulation Process commences when the Radiation Therapist receives a request for a patient to be treated and is complete when the simulation, virtual simulation or mark up, has been completed and the documentation is transferred to the planning room.

The Simulation Process includes documentation detailing:

- Booking information;
- The ready for care date;
- Information gained in the simulator such as:
 - Patient position;
 - Accessories used for patient immobilisation;
 - Field parameters where set;
 - Scan information to enable cross-checking and QA of various items in cases such as gated scanning, contrast and non-contrast; or any other instance where multiple scans exist;
 - Tattoo location with respect to landmarks;
 - Signatures of responsible Radiation Therapists.

5.1.2 Planning Process

The Planning Process commences when the simulation details are received in the planning room and concludes when the treatment sheet has been produced, and plans and calculations have undergone the QA process and are transferred to the treatment unit.

The Planning Process documentation must include all plan information such as:

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- Initial Reference Image (DRR) for subsequent verification of field position;
- Field names;
- FSD's;
- Collimator settings;
- Gantry angles;
- Floor rotation;
- Wedge information;
- Compensator information;
- Monitor unit details;
- Specific treatment unit details;
- Isodose plans;
- Maximum and minimum dose information;
- Critical organ doses;
- Monitor unit calculations; and
- Independent checks of MU calculations.

The responsible Radiation Oncologist must sign the written or electronic plans. This documentation should be retained as part of the treatment sheet and forms part of the prescription details, along with the "front" prescription sheet.

5.1.3 Final Planning Documentation

The final planning documentation comprises all of this information collected during the simulation and planning processes described above and the treatment prescription. The treatment prescription must be completed, signed and dated by the Radiation Oncologist.

5.2 TREATMENT STAGE

The Treatment Stage commences when the treatment sheet, including all the above documentation arrives at the treatment unit for examination prior to patient treatment, and concludes when the patient has completed the course of treatment.

The treatment documentation must include items such as a daily record of monitor units and dose delivered, cumulative dose, and signatures of two responsible treating radiation therapists.

Imaging DRRs should also be reviewed by the two treating Radiation Therapists and ideally also by the Radiation Oncologist. This documentation is inclusive of Record and Verify systems and DRR.

6.0 Obtaining Patient Consent

"Written consent obtained" is a mandatory data item in this policy. Complete details on patient consent are in Policy Directive PD2005_406 *Patient Information and Consent to Medical Treatment*. This Policy Directive applies to all public health organisations (Area Health Services, Statutory Health Corporations and Affiliated Health Corporations in respect of their recognised establishments and recognised services) and to all people who work within these organisations including employees, contractors and other health service providers. The Policy Directive is available on the NSW Health intranet site at:

http://www.health.nsw.gov.au/policies/PD/2005/PD2005_406.html

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As a general rule, no operation, procedure or treatment may be undertaken without the consent of the patient, if the patient is a competent adult. Adequately informing patients, obtaining consent in regard to an operation, procedure or treatment is both a specific legal requirement and an accepted part of good medical practice.

The *Patient Information and Consent to Medical Treatment* advises that written consent using the model consent form (found in PD2005_406) is to be sought for major procedures including any invasive procedure or treatment where there are known significant risks or complications. Radiotherapy is an invasive procedure where there are known risks and complications.

Of particular note are the implications of radiation therapy delivered to female patients of child-bearing age who may be pregnant, or may become pregnant during treatment.

A medical practitioner has a legal duty to warn a patient of material risk inherent in the proposed treatment. What amounts to a material risk is explained in section 7 of PD2005_406. Failure to do this may be a breach of the practitioners' duty of care to the patient and could also give rise to a legal action for negligence.

The model consent form is the document which Radiation Oncology Treatment Centres must use when obtaining consent. If information regarding the risks particular to radiation therapy treatment is considered necessary in addition to the information contained in the consent form, it is recommended that an additional information sheet be developed to inform patients. Reference to the risk or complications (outlined in the information sheet) as having been explained to the patient should be noted by the treating doctor on the consent form signed by patients. Alternatively, Centres may choose to incorporate the information about particular risks into the consent form template.

Regarding timing of obtaining consent, it is recommended that written consent be obtained by the relevant medical practitioner (usually the Radiation Oncologist) at consultation and prior to the patient presenting for simulation / planning. This will assist when ensuring booked planning / treatment slots are not wasted due to lack of consent. A new consent form must be completed for each course of treatment or treatment to a new physical site on the patient.

Patient consent for use or disclosure of a person's information (for example, discussion of patient's information in a multidisciplinary team case review) is a separate matter and is covered by the Privacy Manual (PD 2005_593) and Health Records and Information Privacy Act 2002. Radiotherapy treatment is generally given as part of a multidisciplinary approach to cancer care and treatment.

Information about privacy can also be obtained in the Proforma NSW Health Privacy Leaflet for patients which can be obtained on the NSW Health intranet site or by emailing privacy@doh.health.nsw.gov.au

With regard to private hospitals, Schedule 1, Part 6 of the Private Hospitals Regulation 1996 refers to what must be contained in the clinical record of a patient including consent or request forms if applicable.

PART TWO

7.0 Radiotherapy Planning Checklist

7.1 PURPOSE OF THE RADIOTHERAPY PLANNING CHECKLIST

A quality improvement framework requires routine examination of all incidents that cause patient harm (Policy Directive PD2005_608 *Patient Safety and Clinical Policy Program*). Preventing these incidents depends on identifying the deficiencies that allow the event to occur and fixing these problems. The Radiotherapy Planning Checklist's purpose is to outline the checks that each Radiation Oncology Treatment Centre must make as part of its quality assurance program to minimise the risk of errors occurring in delivery of the radiotherapy treatment.

Each Planning Checklist item must be checked. These check items have been grouped as Fundamental, Dosimetry, Record and Verify, and Administrative Checks. These categories serve as a guide as to how an error in one of the activities is likely to impact as an error in the dose delivered to the patient, and will assist each Radiation Oncology Treatment Centre in the development of its performance improvement and safety program.

Area Health Services may conduct additional checks.

7.2 BACKGROUND – QUALITY CONTROL AND RADIATION SAFE PRACTICES

The success of a radiation oncology treatment is dependent on the accurate delivery of specified doses to selected targets. The margin between tumour control and induced complications is frequently a small one^{1,2}. Therefore, the cure rate for a particular treatment protocol relies heavily on the accuracy of the initial calibration of the treatment machine and its ongoing consistency in delivering the same dose under the same standard conditions¹⁻⁵.

The patient's radiation dose prescribed and delivered is usually extremely high and there is little room for error. Therefore, the quality assurance program for the planning and treatment details should be designed to ensure that errors do not occur and cause either treatment complications or failure to successfully cure the patient.

7.3 POTENTIAL FOR ERRORS AND ACCIDENTAL EXPOSURE

There is a myriad of potential errors to consider^{6,7}. Radiation incidents can differ in severity. Overdoses may take some time to be detected clinically, with severe repercussions to the patients treated, particularly if a systemic error has occurred (ie multiple incorrect treatments given either to one patient or many patients). An error that leads to an underdose may never be detected clinically and may only manifest itself as an unsuccessful patient treatment. The potential magnitude of a dose error can vary, depending on the specific planning error involved.

7.3.1 Fundamental checks

Errors arising from not conducting the "Fundamental" checks are likely to cause a major exposure error. For example, not checking that the plan matches the prescription may result in treatment on the wrong site or beam type for the whole course of treatment.

Incorrect patient, incorrect procedure, incorrect site procedures and the use of incorrect implants/prostheses and equipment are relatively rare serious incidents in healthcare, and

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may be devastating when they occur, not only for the patient and their families or carers, but also for the staff involved.

In 2004, the *Patient Identification*, Model Policy Directive PD2005_380 was introduced as part of the NSW Patient Safety and Clinical Quality Program. In 2007, the Correct Patient, Correct Procedure and Correct Site policy was reviewed and amended in response to the increasing number of incidents being notified in Incident Information Management System (IIMS) from non surgical areas. Analysis of these cases indicated the major contributing factors are the lack of a standardised checking process and a degree of staff automaticity (checking without thinking) in the pre-procedure check routines.

The policy (PD2007_079) outlines principles to ensure patient safety and risk minimisation strategies of system error.

7.3.2 Dosimetry checks

Some of the items listed do not have automatic electronic checks on the radiotherapy equipment and therefore must be adequately checked by an independent check method. Other dosimetry errors vary in complexity depending upon the computer planning system, treatment equipment and the radiation mode.

7.3.3 Record and Verify checks

In centres where 'record and verify' treatment facilities are available, data from the planning system to the treatment machine server is normally transferred automatically. Very little human intervention occurs in the RV system. However, errors may arise from equipment malfunction or from software errors, particularly when software upgrades are introduced, or from a fundamental error during the manual transcription of the prescription into the planning system. RV systems should incorporate adequate checks and balances to prevent errors.

Thus the depth and range of checks is highly dependent on the confidence level for the database system in use. It is important to continually keep a vigilant survey of the RV's integrity. Treatment Radiation Therapists should ensure at the time of the first treatment that there are alternative sources of information from which to check the patient's information.

The treatment plan, the patient's record, information from the planner, the patient's treatment set-up and isocentre heights are examples of other independent checks to use.

In centres where the treatment machine does not have a Record and Verify system, then this Record and Verify list of checks must have a detailed check procedure. Beam mode and energy, collimator/applimator size, treatment distance or monitor units/treatment time become dosimetry checks.

7.3.4 Administrative checks

Administrative checks should also be completed to ensure that the treatment sheet is (legally) authorised by the Radiation Oncologist and is completed as checked by other authorised staff.

At each appropriate stage, relevant parties need to cross-check data against medical records, for example histology and referrals, for validation of laterality and site.

7.4 PERFORMANCE IMPROVEMENT STRATEGIES

In order to reduce the likelihood of errors occurring, radiotherapy staff should have received adequate training on the equipment and the procedures for that treatment centre. The performance improvement program should have a 'defence-in-depth' strategy for work practices so that there is more than one opportunity to detect a mistake that might have occurred. Guidelines on the design and implementation of a radiation protection and safety program for radiotherapy is described in the International Atomic Energy Agency publication 1296⁸.

Radiotherapy centres should develop a performance improvement program that takes into account the local situation. A performance improvement program is based upon achieving what are considered to be adequate standards of best practice and safety in radiotherapy. The number and experience of the staff, workload, the radiotherapy equipment used and the complexity of treatment techniques must satisfy the industry's standards.

Since the radiotherapy facilities and work conditions may vary from centre to centre, the performance improvement program and the 'defence-in-depth' strategy may also vary. For example, where there are linear accelerators that are different in type or make, more attention would need to be paid to the depth of checking carried out than when all the treatment machines are the same with common data.

Special procedures such as brachytherapy, stereotactic radiotherapy, total body x-ray or electron therapy, requires a carefully planned checking procedure and is not covered further in this document.

7.5 RISK ASSESSMENT FOR CONVENTIONAL TREATMENT PLANNING

The initial preparation, calculation and documentation of conventional treatment plans is a critical first step where errors might occur, affecting the accuracy of dose delivered to the patient. For example, human error during a manual transcription of the prescription into the treatment system may result in an incorrect number of fractions being recorded and delivered. Each Centre's performance improvement and safety program should include:

- Consideration of a suitable method, frequency and time taken for each check procedure;
- Training of radiotherapy staff and students on the relative severity of each type of error;
- Notification in the Incident Information Management System (IIMS) as outlined in the Incident Management Policy (Policy Directive PD2007_061);
- Regular review of incidents to assess incidents types, trends and whether improvements are being made;
- A departmental review of planning errors will need a thorough review and investigation as to how the incident occurred, and the impact that the error may have had on the patient's intended treatment; and
- An audit process to be established and conducted regularly to verify compliance with this Radiation Therapy Prescription and Treatment Sheet Policy.

It is recommended that the audit process be undertaken at least quarterly.

7.5.1 Audit

Policy Directive PD2005_608 *Patient Safety and Clinical Policy Program* lists standards with which Area Health Services must comply. The Program is based on standards against which a health service's quality system will be assessed. Standards include the requirement to

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have in place a system to periodically audit a quantum of medical records and clinical practice and, where necessary, implement strategies for improving practice.

Area Health Services must develop a program in conjunction with officers with relevant skills and knowledge from the Area and Radiation Oncology Treatment Centres to:

- Regularly conduct an audit of processes in place at the Radiation Oncology Treatment Centres against the requirements of this policy for Development of Prescription and Treatment Sheets for NSW Health Radiation Therapy Facilities;
- Verify compliance with this Policy; and the *Correct Patient, Correct Procedure and Correct Site* policy (PD2007_079);
- Ensure notification and appropriate feedback of incidents, near misses and complaints are notified in the Incident Information Management System (IIMS) in accordance with Policy Directive PD2007_061 *Incident Management*; and
- Implement improved practices if required in order to comply with the above mentioned policies.

7.6 MANDATORY ITEMS CHECKLIST

7.6.1 Fundamental Checks	
<input checked="" type="checkbox"/>	Plan matches prescription
<input checked="" type="checkbox"/>	Unique patient identifier on each page of documentation
<input checked="" type="checkbox"/>	Treatment site and laterality
<input checked="" type="checkbox"/>	Total dose at isocentre or prescription point, devices transferred to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Fractionation
<input checked="" type="checkbox"/>	Daily dose at isocentre or prescription point devices transferred to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Treatment machine
<input checked="" type="checkbox"/>	Beam type and energy
<input checked="" type="checkbox"/>	Special instructions devices transferred to treatment sheets, record and verify - blood counts, "bladder full", etc
<input checked="" type="checkbox"/>	Simulator images labelled with patient details, orientation and laterality
<input checked="" type="checkbox"/>	Image verification, EPI instructions as per prescription or protocol
<input checked="" type="checkbox"/>	Changes to isocentre location documented

7.6.2 Dosimetry Checks	
<input checked="" type="checkbox"/>	Maximum and critical organ doses not exceeded, OR accepted where compromised
<input checked="" type="checkbox"/>	Isocentre location in relationship to landmarks or simulator images (moves from reference plane verified)
<input checked="" type="checkbox"/>	'Wedge – angle and orientation data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Individual shielding – orientation and construction
<input checked="" type="checkbox"/>	Compensator trays – orientation and construction
<input checked="" type="checkbox"/>	Magnification factor related to planning and dosimetry checks
<input checked="" type="checkbox"/>	Independent method of calculation and MU check including investigation where independent and planned MUs differ by more than 3%. Note: Calculation limitations of independent MU check programs may contribute to such MU differences. The investigation into such discrepancies may require measurements performed on a phantom by physics to validate planned MU calculations.
<input checked="" type="checkbox"/>	Total prescribed dose at correct reference point / volume
<input checked="" type="checkbox"/>	Normalisation
<input checked="" type="checkbox"/>	Appropriate inhomogeneity corrections applied
<input checked="" type="checkbox"/>	Correct bolus used where prescribed
<input checked="" type="checkbox"/>	Target volume and field size correlate

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<input checked="" type="checkbox"/>	Appropriate computer calculation parameters
<input checked="" type="checkbox"/>	Appropriate placement of calculation points
<input checked="" type="checkbox"/>	Appropriate off-axis isodose distributions examined
<input checked="" type="checkbox"/>	Templates
<input checked="" type="checkbox"/>	Appropriate computer dose grid used

7.6.3 Record and Verify	
<input checked="" type="checkbox"/>	Beam energy settings transferred correctly
<input checked="" type="checkbox"/>	Field and site description data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Collimator settings transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Bolus – thickness and position data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	FSD / SSD / FAD / SAD data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Compensators data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Floor couch, gantry, collimator angles data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	MLC or shielding tray data transferred correctly to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Set up instructions including positioning devices transferred to treatment sheets, record and verify
<input checked="" type="checkbox"/>	Monitor units transferred to treatment sheets, record and verify
<input checked="" type="checkbox"/>	DRRs / reference images transferred correctly to treatment sheets, record and verify

7.6.4 Administrative Checks	
<input checked="" type="checkbox"/>	Total number of fractions and final fraction clearly indicated
<input checked="" type="checkbox"/>	Prescription complete, signed and dated
<input checked="" type="checkbox"/>	Treatment plan signed and dated by Radiation Oncologist and Planner
<input checked="" type="checkbox"/>	Simulation record signed by responsible radiation therapist
<input checked="" type="checkbox"/>	Data entry into record and verify system complete and checked
<input checked="" type="checkbox"/>	Photos where indicated
<input checked="" type="checkbox"/>	Diagrams noting landmarks, shielding and tattoos and outline levels
<input checked="" type="checkbox"/>	Written patient consent completed prior to commencement of CT Sim
<input checked="" type="checkbox"/>	“Time out” (final patient safety check undertaken immediately before commencing the procedure) completed, and documented on patient medical records

7.7 REFERENCES

1. ICRP *Protection of the patient in radiation therapy*, Annals of the ICRP, ICRP Publication 44, (Pergamon Press, Oxford) 15, No. 2, 1985.
2. Report of the Inter-Society Council for Radiation Oncology sponsored by American Association of Physicists in Medicine, American College of Radiology, American College of Medical Physics, American Radium Society, American Society for Therapeutic Radiology and Oncology, North American Hyperthermia Group, Radiation Research Society, Radiological Society of North America and Society of Chairmen of Academic Radiation Oncology Programs, *Radiation Oncology in Integrated Cancer Management* ("The Blue Book"), 1991.
3. American Association of Physicists in Medicine Scientific Report, *Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40*, Med. Phys. 21, 581-618, 1994.
4. American Association of Physicists in Medicine Scientific Report, *AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Task Group 45*, Med. Phys. 21, 1093-1121, 1994.
5. International Commission on Radiation Units and Measurements Inc (ICRU), *Determination of absorbed dose in a patient irradiated by beams of X or gamma rays in radiotherapy procedures*; ICRU Publications, Washington, Report 24, 1976.
6. IAEA Safety Report Series No. 17, *Lessons learned from accidental exposures in radiotherapy*; IAEA Publications, Vienna, 2000.
7. International Commission on Radiological Protection. *Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy*; Annals of the ICRP Publication 86, Pergamon, 2001.
8. *Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects* (Publication 1296). Vienna, International Atomic Energy Agency (IAEA), 2008.

PART THREE

Unique Patient Identifier on each page of documentation

8.0 Megavoltage Documentation – Mandatory Data Items

8.1 ADMINISTRATIVE DATA REQUIREMENTS

The items below are inclusive of Client Registration Data items required to be collected and recorded in the Area Health Service-wide client registration database (i) when a booking is made for the first service, and (ii) at the time of service provision, as outlined in the *Client Registration Policy* (PD2007_094). Some of these data items may already have been collected for patients in the Area-wide client registration database prior to data collection processes by Radiation Oncology Treatment Centres.

1. Patient Name:
 - Family name;
 - Given name,
 - Middle name(s);
 - Alias name(s) (including maiden name and any other name used at any time)
2. Unique Patient Identification Number
3. Date of Birth
4. Sex
5. Address of usual residence and Mailing address (if different from Address of usual residence)
6. Mailing address (if different from Address of usual residence)
7. Telephone number(s) – home, work, and/or mobile
8. Preferred language
9. “Interpreter required” Yes / No
10. Country of birth
11. Aboriginal and Torres Strait Islander origin
12. Medicare eligibility and Medicare number, if eligibility for Medicare as a factor in service provision or billing)
13. Department of Veterans Affairs (DVA) file number and card type (if a DVA Card holder)
14. Health fund and health membership number (if the health service intends to make a claim against a private fund for services provided)
15. Person to contact (name, address, telephone numbers, relationship to client / patient) – for clients/patients under 16 years of age
16. Radiation Oncologist
17. Phone number for contacting patient – home, work and/or mobile
18. Patient ID photograph
19. Written consent obtained
20. Accommodation (eg outpatient, inpatient)
21. Transport (hospital or other transport for outpatients, indication of whether the patient walks, requires a chair or stretcher, accompanied by O₂, etc)

8.2 SIMULATION / PLANNING DATA REQUIREMENTS

Unique Patient Identifier on each page of documentation

1. Planning date
2. Responsible simulation Radiation Therapist (printed name, signature & date)
3. Simulation checked by (printed name, signature & date)
4. Shielding arrangement
5. Total target absorbed dose – at International Commission on Radiation Units and Measurements, Inc (ICRU) reference point
6. Total target absorbed dose – maximum
7. Total target absorbed dose – minimum in Planning Target Volume (PTV) (International Commission on Radiation Units and Measurements, Inc. (ICRU) 50)
8. Field size or collimator setting
9. Field description, eg. Anterior, oblique etc
10. Correction for heterogeneity
11. Patient measurements eg patient separation, outline etc.
12. Equivalent square
13. Correction factors
14. Reference point depth or reference isodose
15. Calculation points: distance off axis if applicable; changes in beam energy
16. Orientation and position of: reference plane; other planes
17. Normalisation method
18. Planning / simulation remarks, eg “Remarks such as Patient lying on mattress, or, Bladder Empty”
19. Relative output factor for electron fields
20. Record of independent MU check
21. Record of IMRT Fluence map check
22. Responsible planner (printed name, signature & date)
23. Planning checked by (printed name, signature & date)

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

8.3 PRESCRIPTION DATA REQUIREMENTS

1. Diagnosis – indication for treatment & extent/stage (histological type)
2. Technique
3. Patient position and details of simulated reference plane
4. Treatment site (including laterality)
5. Treatment intent – radical / definitive, palliative and adjuvant
6. Total prescribed dose
7. Multiphase Yes / No
8. Reference point depth or isodose
9. Fractions per site
10. Dose per fraction
11. Frequency of treatment (x / day) and interfraction interval when > single treatment / day

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12. Beam type
13. Beam energy
14. Previous radiation treatment Yes / No
15. Previous radiation overlap Yes / No
16. Concomitant treatments: timing with other treatment eg chemotherapy and/or surgery
17. Critical organs at risk and maximum critical organ dose
18. Additional instructions (eg bolus, compensators, special shielding requirements, dosimetry measurements)
19. Verification image instructions
20. Patient monitoring: FBC, weight, pacemaker, infection risk, etc
21. Radiation Oncologist (printed name, signature & date)

Unique Patient Identifier on each page of documentation

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

8.4 TREATMENT DATA REQUIREMENTS

1. Machine identity
2. Beam type and energy
3. Set up details, including location of isocentre, if relevant
4. Set up diagrams, photos and/or images
5. Field identification
6. Either focal or source skin distance or source axis distance
7. Collimator setting including Asymmetric jaws if required and/or applicator size
8. Beam modifiers
9. Collimator angle
10. Couch angle
11. Gantry angle
12. Wedge angle type and orientation
13. Specific blocking tray
14. Shielding / MLC
15. Bolus / Compensator
16. Monitor units
17. Treatment field data: Beam position (site); Beam direction
18. Independent check of treatment sheet by authorised Radiation Therapist or Physicist (printed name, signature & date)

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

Unique Patient Identifier on each page of documentation

8.5 TREATMENT RECORD DATA REQUIREMENTS

1. Date of treatment
2. Initials of two treating Radiation Therapists
3. Daily record of machine identity (if changed from Plan)
4. Daily record of energy (if changed from Plan)
5. Sequential fraction number
6. Daily record of time of treatment (only if multifractions per day)
7. Daily record of monitor units
8. Daily record of dose at isocentre or prescription point
9. Daily record of cumulative tumour dose
10. Treatment comments (including initials of Radiation Therapist) after weekly check

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

8.6 TREATMENT QUALITY CONTROL DATA REQUIREMENTS

1. Image verification instructions
2. Changes to treatment as a result of verification images
3. Final set of verification images reviewed and approved by the Radiation Therapist and / or the Radiation Oncologist (*) either pre or post treatment
(*) Dependent upon the Radiation Oncology Department's imaging policy.
(See note below)
4. Record and verify data entry checks
5. Weekly separation / FSD check
6. Report of dosimetry measurement results (including name and signature of person performing the tests, and date)
7. Dosimetry measurement reports reviewed by Radiation Oncologist (initialled and dated)
8. Changes to treatment as a result of dosimetry measurements
9. Verification that Radiation Oncologist / Registrar has regularly and appropriately seen the patient during the course of treatment

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

Note 8.6, item 3:

With the advent of IGRT, verification images are taken daily and adjustments made to the isocentre position on a daily basis. Of necessity, the Radiation Therapists check these daily images to ensure field position anatomically correct with respect to the plan, with no decision making regarding treatment. Where images are reviewed by Radiation Therapists on a daily basis, adequate protocols, training and processes should be in place to ensure accuracy of treatment.

Unique Patient Identifier on each page of documentation

8.7 TREATMENT SUMMARY DATA REQUIREMENTS

1. * Date treatment started
2. * Date treatment completed
3. Total dose at isocentre or to a prescription point
4. Dose per fraction
5. Total number of fractions

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

* When the treatment commencement and treatment finish dates are entered into the machine, this should trigger a cross-check with the original prescription and the fraction number entered in the machine data.

PART FOUR

Unique Patient Identifier on each page of documentation

9.0 Superficial and Orthovoltage Documentation – Mandatory Data Items

9.1 ADMINISTRATIVE DATA REQUIREMENTS

The items below are inclusive of Client Registration Data items required to be collected and recorded in the Area Health Service-wide client registration database (i) when a booking is made for the first service, and (ii) at the time of service provision, as outlined in the *Client Registration Policy* (PD2007_094). Some of these data items may already have been collected for patients in the Area-wide client registration database prior to data collection processes by Radiation Oncology Treatment Centres.

1. Patient Name:
 - Family name;
 - Given name,
 - Middle name(s);
 - Alias name(s) (including maiden name and any other name used at any time)
2. Unique Patient Identification Number
3. Date of Birth
4. Sex
5. Address of usual residence and Mailing address (if different from Address of usual residence)
6. Mailing address (if different from Address of usual residence)
7. Telephone number(s) – home, work, and/or mobile
8. Preferred language
9. "Interpreter required" Yes / No
10. Country of birth
11. Aboriginal and Torres Strait Islander origin
12. Medicare eligibility and Medicare number, if eligibility for Medicare as a factor in service provision or billing)
13. Department of Veterans Affairs (DVA) file number and card type (if a DVA Card holder)
14. Health fund and health membership number (if the health service intends to make a claim against a private fund for services provided)
15. Person to contact (name, address, telephone numbers, relationship to client / patient) – for clients/patients under 16 years of age
16. Radiation Oncologist
17. Phone number for contacting patient – home, work and/or mobile
18. Patient ID photograph
19. Written consent obtained
20. Accommodation (eg outpatient, inpatient)
21. Transport (hospital or other transport for outpatients, indication of whether the patient walks, requires a chair or stretcher, accompanied by O₂, etc)

9.2 SIMULATION / PLANNING DATA REQUIREMENTS

1. Planning date
2. Responsible simulation Radiation Therapist (printed name, signature & date)
3. Simulation checked by (printed name, signature & date)
4. Responsible planner (printed name, signature & date)
5. Planning checked by (printed name, signature & date)
6. Patient measurements eg templates, landmarks, stand-off
7. Field size / equivalent square / equivalent diameter
8. Correction factors
9. Reference point depth or reference isodose
10. Planning / simulation remarks eg Patient lying on mattress
11. Relative output factor for irregular shaped fields
12. Record of independent MU check

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

9.3 PRESCRIPTION DATA REQUIREMENTS

1. Diagnosis – indication for treatment & extent/stage (histological type)
2. Technique (anterior, oblique, Skin Apposition)
3. Patient position
4. Treatment site (including laterality)
5. Treatment intent – radical / definitive, palliative and adjuvant
6. Total prescribed dose
7. Reference point depth or isodose
8. Fractions per site
9. Dose per fraction
10. Frequency of treatment (x / day) and interfraction interval when > single treatment / day
11. Beam type (HVL,KV and Filter)
12. Previous radiation treatment Yes / No
13. Previous radiation overlap Yes / No
14. Concomitant treatments: timing with other treatment and with other modalities eg chemotherapy and/or surgery, megavoltage
15. Critical organs at risk and maximum critical organ dose
16. Shielding arrangement
17. Additional instructions (eg bolus, special shielding requirements, dosimetry measurements)
18. Patient monitoring: pacemaker, infection risk, etc
19. Radiation Oncologist (printed name, signature & date)

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

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9.4 Treatment Data Requirements

Unique Patient Identifier on each page of documentation

1. Machine identity
2. Beam energy (mA and KV)
3. HVL
4. * Filter
5. * Focal skin distance
6. * Applicator size
7. Set up details
8. Set up diagrams, photographs, templates
9. Positioning devices
10. * Field identification
11. * Field size
12. Shielding instructions
13. * Exposure time / monitor unit
14. Independent check of treatment sheet by authorised Radiation Therapist or Physicist (printed name, signature & date)
15. Bolus

Footnote * - critical treatment parameters that must be checked by a second person before each treatment (as well as initial pre-treatment check).

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

9.5 TREATMENT RECORD DATA REQUIREMENTS

1. Date of treatment
2. Initials of two treating Radiation Therapists
3. Daily record of exposure time or monitor units
4. Daily record of sequential fraction number
5. Daily record of dose at prescription point
6. Daily record of cumulative dose at prescription point
7. Treatment comments (including initials of Radiation Therapist) after weekly check

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

9.6 TREATMENT QUALITY CONTROL DATA REQUIREMENTS

1. Report of dosimetry measurement results (including name and signature of person performing the tests, and date)
2. Dosimetry measurement reports reviewed by Radiation Oncologist (initialled and dated)
3. Changes to treatment as a result of dosimetry measurements
4. Verification that Radiation Oncologist / Registrar has regularly and appropriately seen the patient during the course of treatment

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

Unique Patient Identifier on each page of documentation

9.7 TREATMENT SUMMARY DATA REQUIREMENTS

1. Beam energy (mA and KV)
2. Total dose at prescription point
3. Dose per fraction
4. Total number of fractions
5. * Date treatment started
6. * Date treatment completed

Check all details against the Prescription.

Refer to “General Principles for Developing Prescription and Treatment Sheets”

*: When the treatment commencement and treatment finish dates are entered into the machine, this should trigger a cross-check with the original prescription and the fraction number entered in the machine data.

PART FIVE

Unique Patient Identifier on
each page of documentation

10.0 Optional Data Items

10.1 MEGAVOLTAGE PLANNING AND PRESCRIPTION DOCUMENTATION

10.1.1 Administrative Data

As outlined in the Client Registration Policy, it is highly desirable that the following information is also recorded in the Area Health Service-wide client registration database:

1. Person to contact (name, address, telephone numbers, relationship to client / patient) – for clients / patients 16 years of age or older
2. General Practitioner name, address, telephone, email and facsimile numbers (for the purpose of corresponding with general practitioners about the client's / patient's ongoing care.

10.1.2 Prescription Data Requirements

1. Variation from Protocol Yes No
 If yes, give a reason.
2. Course number delivered to patient (to highlight previous treatment, timeline / order of treatment)

10.2 MEGAVOLTAGE TREATMENT DOCUMENTATION

10.2.1 Simulation, Planning and Treatment Data Requirements

1. Simulation record
2. Table height
3. Cumulative maximum dose to Planning Target Volume (PTV) [Note: This is a progressive review of the dose]

10.2.2 Treatment Summary Data Requirements

1. Total maximum dose to Planning Target Volume (PTV)
2. Mean dose to Planning Target Volume (PTV)
3. Total critical organ dose received
4. Total maximum dose if located outside Planning Target Volume (PTV) (hot spot)
5. Treatment duration (days)

10.3 SUPERFICIAL AND ORTHOVOLTAGE DOCUMENTATION

10.3.1 Prescription Data Requirements

1. Course number delivered to patient (to highlight previous treatment, timeline / order of treatment)

10.3.2 Treatment Summary Data Requirements

1. Total maximum dose
2. Duration of treatment in days