

# **Unintended overexposure of a patient during radiotherapy treatment at the Edinburgh Cancer Centre, in September 2015**

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## Covering note

It is approximately ten years since I was last called upon to undertake a detailed investigation of an incident involving a serious overexposure to ionising radiation for a patient undergoing radiotherapy. That earlier investigation was the overexposure of Miss Lisa Norris at the Beatson Oncology Centre in Glasgow, who was being treated for a pineoblastoma, from which, tragically, she subsequently died at the age of only 16.

To put the incident under investigation here in context, the treatment received by Miss Norris at was a radical radiotherapy treatment, wherein the dose of radiation that she received was 58% greater than the intended dose of 30 Grays. In this case, the treatment delivered at the Edinburgh Cancer Centre (ECC) was a palliative radiotherapy treatment for alleviation of pain and existing disability in an older patient, and the dose received was 100% greater than intended dose of 20 Grays.

In both instances, the extent of the overexposure was such that there was a significant possibility of serious harm to the patient.

Both the detail and the circumstances of these overexposures were very different. In particular, the Glasgow incident arose from a combination of failures in what should have been a robust quality system, whereas this investigation has concluded that the Edinburgh incident was due to a combination of errors made by individuals operating within a well established quality system.

The particular circumstances of this Edinburgh incident were that the treatment was properly prescribed in accordance with the applicable ECC treatment protocol, but errors were made in the subsequent process of planning how the prescribed treatment was to be delivered. These errors remained undetected, such that the treatment planners sent the wrong information to the radiographers who delivered the treatment. The setting used on the treatment machine was therefore twice what it should have been, and remained so for all five 'fractions' of the treatment process.

I am conscious of the potential for the content of this report to add to the concerns of those undergoing radiotherapy treatments at the ECC and elsewhere. In this regard I should note that lessons have been learned and changes implemented at the ECC, and that I have confidence in the dedication and commitment of ECC staff to the safety of patients in their care.

I would again acknowledge the many thousands of life-saving radiotherapy treatments that are successfully prescribed, planned and delivered at the ECC and at the other radiotherapy centres in Scotland every year.

**Dr Arthur M Johnston**

Warranted Inspector appointed by the Scottish Ministers

# Unintended overexposure of a patient during radiotherapy treatment at the Edinburgh Cancer Centre, in September 2015

## Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposure) Regulations 2000

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# Unintended overexposure of a patient during radiotherapy treatment at the Edinburgh Cancer Centre, in September 2015.

## Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposure) Regulations 2000

### Executive Summary

#### Introduction

Between 14<sup>th</sup> September 2015 and 18<sup>th</sup> September 2015, a patient received a dose of ionising radiation much greater than that intended while undergoing a course of radiotherapy at the Edinburgh Cancer Centre (ECC) in Scotland. Since the incident resulted from a procedural error, rather than from equipment failure, it has been reported and investigated under the provisions of *Statutory Instrument 2000 No. 1059, The Ionising Radiation (Medical Exposure) Regulations 2000 (as amended)* [1] (referred to in this report as the IR(ME) Regulations). The regulator for the IR(ME) Regulations (the ‘appropriate authority’) in Scotland is the Scottish Ministers.

This report, by the Inspector warranted by the Scottish Ministers for the IR(ME) Regulations, records the findings of the incident investigation. It identifies the errors that caused this overexposure and includes consideration of the deficiencies that contributed to the errors and where responsibilities for these deficiencies lay. It also makes recommendations intended to minimize the possibility of recurrence of any similar errors and to enhance patient safety in radiotherapy more generally.

#### The nature and consequences the error

Between 14<sup>th</sup> and 18<sup>th</sup> September 2015, a patient diagnosed with multiple myeloma was given palliative radiotherapy treatment at the ECC. This involved irradiation of the vertebrae of the neck to address pain and disability being caused by a bone fragment from complete collapse of the third cervical (‘C3’) vertebra.

The treatment prescribed by the oncologist was a total dose of 20 Grays of X-ray radiation to be delivered in 5 fractions, each of 400 centigrays (hundredth of a Gray normally abbreviated to ‘cGy’). Each of the 400cGy fractions was to be divided into two 200cGy beams, one to be delivered from the left side of the neck, and one from the right. The oncologist wrote this information clearly and correctly in the patient’s ‘Radiotherapy Prescription Sheet’.

The prescribed radiation dose, method of delivery, and fractionation were as expected for treatment of this condition, and in accordance with the relevant ECC Employer’s Written Protocol.

This method of treatment is known as 'lateral parallel opposed fields at 100cm FSD' (focus to skin distance). (The other the form of treatment used at the ECC for the 'cervical spine' is a single (posterior) beam from the back of the neck.)

A Radiographer trained in treatment planning (referred to in this report as Radiographer A) used the information in the Radiotherapy Prescription Sheet to calculate manually (as opposed to using a computer) the dose of radiation that should be delivered to each side of the neck to achieve the prescribed dose to the C3 vertebra. This involves consideration of the attenuation of the beam of radiation as it passes through the skin and underlying tissue. This is generally referred to as the 'depth-dose' calculation.

Radiographer A used the correct ECC treatment planning protocol, but made an error in the depth-dose calculation to the extent that the calculated doses to each side of the neck entered in the 'Radiotherapy Prescription Sheet' were 100% too high.

In accordance with ECC Protocols, a second treatment planner (Radiographer B), carried out a similar manual calculation, but made the same mistake, and got the same wrong answer.

The next step in checking the treatment plan was for patient information, including the result of the manual calculations, to be input to an electronic information management system for radiotherapy called Aria, from where the appropriate information is transferred electronically to a dose calculation programme called RadCalc.

Data input to Aria was carried out correctly by Radiographer C, and this included the (wrong) dose from the manual calculation. RadCalc then calculated the daily dose to each side of the neck independently, and flagged correctly that the manually calculated dose was incorrect.

A fourth Radiographer (Radiographer D) then tried to reconcile the RadCalc calculation with the result of the manual calculation but failed to do so. In accordance with ECC practice, the Radiographers involved therefore sought the assistance of a member of the ECC's Treatment Planning Section (Physicist A). The erroneous belief of the Radiographers at this stage was that the manual calculations were correct, and the computed result was in error. The manual calculation was not rechecked.

For reasons that have not been fully resolved during this investigation, Physicist A achieved an answer from RadCalc that appeared to agree, to within the defined tolerance of 2.5%, with the (erroneous) manual calculations of the number of 'monitor units' (MU) to be set on the treatment machine (the 'Linac') for each treatment.

As a result of these errors the Linac was set to deliver a total of 40 Grays of radiation to the treatment area in 5 fractions of 800cGy, instead of the prescribed 20 Grays in 5 fractions of 400cGy.

The magnitude of this overexposure is such that there was a significant possibility of serious harm to the patient.

The error was first identified at the 'summary/finishing off' stage on 29<sup>th</sup> September 2015, 11 days after completion of treatment.

Upon discovery, the overexposure was reported promptly by the ECC to the Inspector Warranted by the Scottish Ministers for the IR(ME) Regulations, and this initial notification was followed by a written incident report.

### **The circumstances of the error**

Accurate treatment planning in radiotherapy is of critical importance for patient safety, and must be carried out by staff who are appropriately trained, using the correct written procedures, and with appropriate checks and verification of data to ensure that any errors that might arise are clearly identified and corrected. With regard to these requirements, the concerns identified by this investigation include the following.

The approach that is recommended and generally adopted in treatment planning is for the first manual calculation to be checked independently using a different method. In this case, however, two Radiographers used the same method of manual calculation of the MU for this patient and got the same wrong answer.

The method defined in the ECC Employer's Written Procedure for the use of RadCalc for parallel opposed pair treatments, while capable of producing the correct result, was not that which would be recommended by the producers of this software. The description of this method in this Employer's Written Procedure had been changed in February of 2015, but with no retraining of the operators involved.

The Radiographers involved lacked understanding of the defined method of RadCalc usage, and had little confidence in the results arising. They therefore persisted in an assumption, that their erroneous manual calculations were correct and that RadCalc was in error.

Entitlement of radiographers for treatment planning did not include a separate requirement for written evidence of satisfactory completion of initial training in the use of RadCalc, or of any formal provision for maintaining their competence in its use.

## **Responsibilities**

The findings of this investigation are that, in general, the duties of the employer under the IR(ME) Regulations were being implemented appropriately, but with some concerns regarding the provision and recording of operator training. None of the staff involved were found to have acted negligently or to have contravened any requirement of the relevant Employer's Written Procedures. It is also accepted that these operators genuinely believed that they were properly trained and experienced for the duties involved, although the nature of the errors made would suggest otherwise.

## **Recommendations and actions arising.**

As a result of this incident the ECC has made a number of changes details of which are discussed further in the report.

Additional recommendations arising from this investigation include:

- A review of the current ECC procedures for manual calculations.
- A change in the current method of manual calculation to ensure that the second calculation uses a different method from the first.
- A review of the current ECC procedures for the use of RadCalc.
- Retraining of all operators in the use of RadCalc to ensure that they have an appropriate level of understanding of its workings and of confidence in its results.
- A review of the provision, maintenance, and recording of operator training relevant to this incident, and of the relationship between training and entitlement of duty holders.

Serious consideration has been given to the need for an Improvement Notice with regard to the provision and recording of operator training. However, given undertakings by the ECC that these deficiencies are already under review, such enforcement action has been deferred pending consideration of the outcome of this internal review and response to the recommendations of this report.



# Unintended overexposure of a patient during palliative radiotherapy treatment at the Edinburgh Cancer Centre, in September 2015.

## 1. The subject of this investigation

Between 14<sup>th</sup> September 2015 and 18<sup>th</sup> September 2015, a patient undergoing a course of radiotherapy received a dose of ionising radiation much greater than intended at the Edinburgh Cancer Centre in Scotland. Since the incident resulted from a procedural error, rather than from equipment failure, it has been reported and investigated under the provisions of *Statutory Instrument 2000 No. 1059, The Ionising Radiation (Medical Exposure) Regulations 2000* (as amended) [1] (referred to in this report as the IR(ME) Regulations).

The regulator for the IR(ME) Regulations (the 'appropriate authority') in Scotland is the Scottish Ministers.

## 2. The format and scope of the investigation and report

This report records the findings of an incident investigation carried out by Dr Arthur Johnston, as the Inspector warranted by the Scottish Ministers, in accordance with the provisions of the IR(ME) Regulations, for the functions described in Sections 19, 20 and 21 of the Health and Safety at Work Act 1974. The investigation was supported by officials from the Scottish Government Health Directorates, and by Mrs Una Findlay of Public Health England, who provided independent expert advice throughout.

The scope of the investigation and of this report extends beyond consideration of compliance with the statutory provisions of the IR(ME) Regulations to more detailed assessment of the circumstances that caused this incident and of the measures that should be enacted to minimize the potential for adverse incidents at the ECC and at other radiotherapy centres in Scotland and elsewhere.

With regard to the provisions of the Data Protection Act 1998, the content of this report has been appropriately anonymized. ECC staff are referred to in terms of job titles. The particular titles used are, 'Radiographer', and 'Physicist'. In addition, to avoid gender identification, the pronouns '*his*', '*he*' and '*him*' and '*himself*' are used throughout and are italicised accordingly.

Regarding the possibility of legal action arising from this incident, the regulatory powers of the Inspector appointed by the enforcing authority (the Scottish Ministers) extend to issuing of Improvement Notices and Prohibitions Notices under the provisions of Sections 21 and 22 of the Health and Safety at Work Act 1974. Any consideration of additional legal

proceedings in Scotland is a matter for the Crown Office and Procurator Fiscal Service and is not within the scope of this report.

This report makes numerous references to the 'Tumor LOC', 'Aria', and 'RadCalc' commercial software products. It is important to note that the errors described herein were not associated in any way with faults or deficiencies in any of these products.

For reasons of patient confidentiality, no discussion of the condition of the patient following treatment is included in this report. However, the ECC has provided assurance that the patient was properly informed of the incident and of the subsequent investigation, and that appropriate ongoing support and monitoring for potential consequences of the overexposure was provided.

### 3. Incident reporting by the ECC

Regulation 4(5) of the IR(ME) Regulations requires that: *'Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.'*

The treatment error was identified initially on 29<sup>th</sup> September 2015. The first, informal, notification to the 'appropriate authority' was an e-mail from the ECC's Head of Therapeutic Radiography to the Warranted Inspector dated 30<sup>th</sup> September 2015, indicating that an error had been identified and was under investigation. This was followed by a second e-mail, again from the ECC's Head of Therapeutic Radiography, dated 1<sup>st</sup> October 2015, to which was attached a formal notification from the ECC's Associate Medical Director dated 29<sup>th</sup> September 2015, indicating that the error had first been identified that same day, and that *'A report providing details of the incident, and any actions taken by the department to prevent a recurrence, will be forwarded to the Inspector as soon as practicable.'*

An e-mail response to a question from the Inspector on the clinical significance of the incident was received on 22<sup>nd</sup> October 2015, (details not included here on the grounds of patient confidentiality), and a detailed incident report from the 'Radiotherapy Incident Group' (RIG) dated 5<sup>th</sup> November 2015 was received as an attachment to an e-mail from the ECC's Head of Therapeutic Radiography, also dated 5<sup>th</sup> November 2015.

The 'Radiotherapy Incident Group' comprised the Head of Oncology Physics, the Head of Therapeutic Radiography and a Consultant Clinical Oncologist.

Initial investigations by the ECC confirmed that no other patients had been similarly affected.

In all senses, it is the view of the inspector that notification was both timely and comprehensive, and fully in accordance with the requirements of Regulation 4(5).

## 4. The nature of the error

### 4.1 Background to radiotherapy planning and treatment

Radiotherapy involves a series of stages, beginning with clear identification of the size, shape, and position of the tumour (or other region of tissue) to be treated, followed by planning of how best to direct the radiation at the treatment site while minimising damage to healthy surrounding tissue. The resulting plan is then used to direct the treatment machine (the 'Linear Accelerator' or 'Linac') in delivering the prescribed radiation dose.

All ionising radiation, even at the relatively low levels used in the diagnosis of disease or injury can increase the risk of cancer, and it is imperative that all exposures are optimised to minimize this risk. The type of radiation used in radiotherapy treatments is essentially the same as is used for diagnostic X-rays, but the doses delivered in radiotherapy treatments are generally much higher.

At higher doses, X-rays can cause acute tissue damage, and in radiotherapy the intent is to carefully target high doses of radiation so as to inflict such damage on the intended area of treatment. In practice this inevitably means that surrounding, healthy tissue will also receive a high dose of radiation, and this must be kept within tolerable limits. All clinical errors in the use of radiation are taken seriously, but the potential for serious harm to the patient is much greater in radiotherapy than in diagnostic radiology, and special precautions in the planning and delivery of radiotherapy treatments are essential.

Following pre-treatment imaging of the treatment area, the oncologist directing the treatment will prescribe the dose of radiation and the method of treatment delivery. This will normally be recorded on a 'Radiotherapy Prescription Sheet'.

The dose of radiation is measured in units called 'Grays', so, for example, the oncologist might prescribe a total dose to the treatment area of 30 Grays and, for optimal delivery with minimal damage to surrounding tissue, might require that this is delivered in 10 'fractions' of 3 Grays, one per weekday, over a period of two weeks.

The prescribed method of treatment delivery might be by a single beam to one point on the skin, for example, a single beam to the back of the neck, or in multiple beams to more than one point on the skin. In the latter case, by varying the point of delivery, damage to healthy tissue can be mitigated.

The Radiotherapy Prescription Sheet is then passed to the operators responsible for treatment planning, who will undertake the (often complex) task of calculating precisely how the prescribed dose of radiation is to be delivered by the patient by the Linac. This includes

positioning of the patient relative to the source of radiation and calculation of the required radiation output from the Linac in terms of 'Monitor Units'

'Monitor Units' (MU) is the term used for the reading that arises from the monitor on the Linac that indicates the total amount of radiation delivered during an exposure. Once the individually calculated number of MUs for the treatment field have been delivered by the Linac, it terminates automatically. The MU setting is therefore critical in achieving the correct dose.

Complex treatment plans involve the use of sophisticated treatment planning software, but for less complex treatments, MU calculation might be carried out manually. However, manual MU calculations will always be checked independently using a different methodology which usually involves appropriate computer software.

The treatment plan is then provided to the radiographers who deliver the treatment, and data from the treatment planning software is exported electronically to the control systems for the Linac, where it is used for treatment of the patient.

#### **4.2 The prescribed treatment for this patient**

Myeloma is a cancer that develops in the plasma cells found in bone marrow. These malignant myeloma cells produce abnormal proteins that can have a number of serious health consequences, including weakened bones and an increased risk of fractures. This typically occurs in the most active bone marrow, which includes the marrow in the spine, pelvic bones, and hips, and because numerous sites can be affected, the disease is often referred to a 'multiple myeloma'.

In September of 2015, a patient diagnosed with multiple myeloma was prescribed palliative radiotherapy treatment at the ECC involving irradiation of the vertebrae of the neck to address pain and disability being caused by a bone fragment from a collapsed 'C3' vertebra (Figure 1).

This form of treatment is often delivered in a single shot (or 'beam') from behind the neck, but because of concerns that the emerging beam might damage tissues of the mouth, the treatment prescribed for this patient involved the use of two beams, one from each side of the neck. This is generally known as a 'parallel opposed pair' treatment.

The prescription called for a total dose of 20 Grays (usually written as 'Gy') of X-ray radiation to be delivered in 5 fractions, each of 400 centigrays (hundredths of a Gray, usually written as cGy) over a period of 5 consecutive days. Each of the 400cGy fractions was to be divided into two 200cGy beams, one to be delivered from the left side of the neck, and one

from the right. The oncologist wrote this information in the patient's 'Radiotherapy Planning Sheet'.

The oncologist identified the volume for treatment, which included the collapsed cervical vertebra, in a virtual simulation software package ('Tumor LOC'). An appropriate beam to deliver the required treatment from the right side of the neck was then defined by the oncologist in Tumor LOC. This beam was then transferred by the treatment planners to the 'Aria' electronic treatment planning system, where it was mirrored to produce the left lateral beam for treatment. Both the right and left lateral treatment beams were then available in Aria for transfer to other systems as required.

#### **4.3 Positioning the patient for a parallel opposed pair treatment**

For a 'parallel opposed pair' treatment, the 'head' of the Linac from where the X-rays emerge is rotated through 180 degrees between the two treatments (Figure 2). The spacing between the point at which the X-rays are produced within the Linac head (usually called the 'focus' or the 'source') in its left and right position is precisely 200 centimetres.

For this treatment, the patient can be positioned in two different ways. In one of these, the point of treatment within the body of the patient is positioned at the midpoint between the two Linac head positions, i.e. at 100cm from the 'focus', and the patient stays at this point throughout. This is known as an 'isocentric' treatment.

The alternative method (as used here) is to set the patient such that the skin on the right side of the patient is at a fixed distance from the focus for the 'right lateral' beam, and then, when the Linac head is rotated, move the patient on the table sideways so that the skin on the left side is at either the same or a different fixed distance from the focus for the 'left lateral' beam. In this particular case, the patient was moved in such a way that the 'focus to skin distance' (FSD\*) was the same for both positions of the Linac head, and was 100cm. This is known therefore as a 'lateral parallel opposed pair to equal FSD' or as a 'lateral parallel opposed pair to 100cm FSD'.

[\*A frequently used alternative term for the 'focus to skin distance' (FSD) is the 'source to skin distance' (SSD).]

#### 4.4. Manual calculation of the 'depth dose'

The radiation dose that is prescribed by the oncologist is the dose to the point of treatment. However, since radiation is absorbed by the skin and deeper tissues before reaching the point of treatment, the dose at the surface of the skin needs to be higher than the prescribed dose to allow for this attenuation. Therefore, to calculate manually the dose at the skin surface, which will be the dose delivered to this point by the Linac, the treatment planner uses 'depth dose' tables (Appendix 1) that define the level of attenuation according to the depth of the point of treatment below the skin surface. This aspect of the dose calculation is frequently referred to as the 'depth dose' calculation.

Consider, for example, treatment of a tumour the centre of which is 10cm below the skin surface using a single beam, for which the oncologist has prescribed a total of 20Gy to be delivered in 5 equal fractions, on 5 consecutive days.

1. The total dose to be delivered is 20Gy.
2. The level of attenuation (from tables) for 10 cm depth is 30%, which means that only 70% of the dose to the surface of the skin will reach the tumour.
3. The required total dose to be delivered to the surface of the skin (referred to as the 'given dose'), as calculated by the treatment planner, is therefore  $(20/0.7)\text{Gy} = 28.6\text{Gy}$ .
4. Therefore, on each of the 5 days of treatment, the Linac will be set to deliver a 'given dose' of  $(28.6/5)\text{Gy} = 5.71\text{Gy}$  to the surface of the skin.

#### 4.5. 'Depth dose' calculation for a 'lateral parallel opposed pair to 100cm FSD'

For this myeloma patient, the point of treatment at the centre of the neck was taken to be 5.5cm below the skin surface, and the prescription was for 20Gy to be delivered in 5 fractions by 'parallel opposed' beams, as in Figure 2. In this case there are two alternative means of manual calculation whereby the treatment planner can arrive at the same correct answer. These are as follows:

##### Method 1

1. The total dose to be delivered is 20Gy.
2. The level of attenuation (from tables) for 5.5 cm depth is 17.4%, which means that only 82.6% of the dose to the surface of the skin will reach the area of treatment.
3. The required total dose to be delivered to the surface of the skin on each side of the neck, as calculated by the treatment planner, is therefore,  $(20/(0.826+0.826))\text{Gy} = (2000/(1.652)) = 12.1\text{Gy}$ .
4. Therefore, on each of the 5 days of treatment, the Linac will be set to deliver a 'given dose' of  $(12.1/5)\text{Gy} = 2.42\text{Gy}$  to the surface of the skin on both sides of the neck.

## Method 2

1. The total dose to be delivered is 20Gy.
2. The level of attenuation (from tables) for 5.5 cm depth is 17.4%, which means that only 82.6% of the dose to the surface of the skin will reach the area of treatment.
3. The required total dose to be delivered to the surface of the skin on each side of the neck, as calculated by the treatment planner, is therefore,  $(10/0.826)\text{Gy} = 12.1\text{Gy}$ .
4. Therefore, on each of the 5 days of treatment, the Linac will be set to deliver a 'given dose' of  $(12.1/5)\text{Gy} = 2.42\text{Gy}$  to the surface of the skin on both sides of the neck.

Clearly, the only difference between Method 1 and Method 2 is that, in Method 1, double the attenuation has been applied to the total of the doses (20Gy) to both sides of the neck, whereas in Method 2, the dose to be delivered to the treatment point from each side of the neck (10Gy) has been divided by 0.826. The answer is the same.

Critically, therefore, for calculations using Method 1, the treatment planner must ensure that the attenuation is doubled (in this case from 0.826 to 1.652), and for calculations using Method 2, the treatment planner must ensure that the dose is halved (in this case from 20 to 10Gy). Failure to do so will, in either case, result in a doubling of the calculated 'given dose' to the skin surface.

The terminology used to describe the proportion of the 'given dose' that reaches the target is the 'depth dose', and in the relevant ECC Employer's Written Procedure the related calculations expressed in terms of the 'percentage depth dose'. So, for example, the 'percentage depth dose' for the calculation above would be 82.6%.

The relevant ECC Employer's Written Procedure for the manual 'depth dose' calculations involved here is EP2\ECC\3402 'Calculating and Checking Monitor Units of Photon Beam Treatments-Manual Calculations'. The relevant extract from EP2\ECC\3402 is:

### **Parallel opposed fields (equal weightings)**

#### Prescribed to central

*The dose at central will be 1/2 of that of one field. Find the percentage depth dose from one field for half-separation, double it and equate it the prescribed dose. The given dose will equal the 100% for that field*

#### *Example*

<p><b>9 x 9 fieldseparation 20 cm FSD 90 cm</b> Percentage depth dose at centre from one field = 64.8% Percentage depth dose at centre from two fields = 129.6% 129.6% = 2000 cGy <math>100\% = 2000 \times \frac{100}{129.6} = 1543 = \text{given dose.}</math></p>
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#### 4.6 How did the error in the manual calculation happen?

Figure 3 is a copy of the relevant section from the actual Radiotherapy Prescription Sheet for this patient, wherein the radiation dose is expressed in centigrays. These entries were made by Radiographer A.

The first row in this table 'RtLat' and 'LtLat' separates the calculations for the right lateral and left lateral beams (Figure 2).

The numbers in the second row relate to the calibration of the Linac, and give the relationship between the number that the radiographer enters into the Linac at the start of treatment, the 'monitor units' or 'MU', and the Linac output in centigrays. So in this case, the linac will deliver a 'given dose' of 0.983cGy to the skin at 100cm FSD for each monitor unit to which the machine is set.

The 'correction factor' in the third row would apply where, for example, the beam of radiation needed to pass through the Linac table before reaching the patient, and the figure in the fourth row would be modified accordingly. In this case there was no such interruption of the beam, so the 'Final output' in the fourth row remains at 0.983cGy for each monitor unit to which the machine is set.

In the fifth row, Radiographer A has, in accordance with the relevant ECC Protocol (EP2\ECC\3402), used Method 1 above. The entry here is, '82.6% = 2000cGy in 5# at 5.5.cm', wherein '82.6%' is the percentage (assessed from tables) of the dose at the surface of the skin that remains at the treatment site which is 5.5cm below the skin surface, '2000cGy' is the total prescribed dose, and '5#' is a shorthand term, widely used, and meaning '5 fractions'. **However, the critical error here is that, in accordance with this ECC Protocol, the entry should have been '165.2% = 2000cGy in 5# at 5.5.cm'. Because of this, the total dose was divided by 0.826, rather than the correct figure of 1.652. Hence the 'Given dose' in row six, for each side of the neck has been calculated as 2422cGy instead of the intended dose of 1211cGy.**

In the seventh row, the erroneous figure of 2422cGy is divided by the number in the first row (0.983) to give the 'Total monitor units' of 2464, one fifth of which (Row 8) is 493.

The practice within the ECC is for the second treatment planner to use the same method of calculation, but to do so independently. Accordingly, Radiographer B has stated that Method 1 was again used but with precisely the same error, hence giving the same erroneous result.

In accordance with normal ECC practice, this second calculation was done on a random sheet of paper which was immediately discarded. There is, therefore, no way in which documentation of this calculation can be revisited.

#### **4.7. Independent MU Calculation using 'RadCalc'**

Although both of the manual calculations described in Sub-section 4.6 had similarly arrived at the wrong answer, the next step in the process, whereby the monitor units are calculated electronically from the source data, should have made the planners aware of the error and prompted a re-evaluation of the manual calculations. Clearly this did not happen, and this Sub-section seeks to establish why this was the case.

Figure 4 describes the workflow for the various computer programmes used at the ECC for treatment planning and delivery, including RadCalc, the specialist software used for independent MU calculation.

The process begins with manual entry of data from the Radiotherapy Prescription Sheet into the Aria module called RTChart and External Beam Planning. This data includes the prescribed dose, fractionation, the method of delivery, and the result of the manual calculations.

Data input to RTChart and External Beam Planning was carried out correctly by Radiographer C, and this included the (wrong) value for the MU per dose fraction for each of the two parallel opposed fields (493) from the manual calculation.

Within Aria there is an 'export wizard' by which data can be transferred electronically to RadCalc, where the MU are calculated independently using the prescribed dose, fractionation, and method of delivery. The result is then compared to the figure that has been entered into Aria from the manual calculations.

RadCalc was accessed by Radiographer C, and patient data imported from Aria on the basis of patient identifiers, including hospital number and date. This was done correctly, but, again, with inclusion of the erroneous MU from the manual calculation of the 'given dose' per fraction to each side of the neck.

Within RadCalc, there are a number of 'screens' that are available for selection by the user. The first of these to be viewed is the 'Prescriptions' screen, which displays the 'Prescribed dose', entered as 2000cGy, the 'Dose per Fraction', entered as 400cGy, and the number of fractions, entered as 5. All of these numbers are correct for this patient.

The next screen selected is 'Points and off axis assistance'. The version of this screen that would have appeared for this patient, which has been obtained for the purposes of this description by repeating the data transfer from Aria at a later date, is included here as Figure 5. This has two sections, one of which, labelled as 'Calculation Points', includes data that has been imported from Aria for the relevant points on skin at the right and the left side of the neck, labelled respectively as 'IsoCenter\_1' and 'IsoCenter\_2'. This data includes the Radiotherapy Prescription Dose labelled as 'RTP Dose (cGy)', which is the contribution to the prescribed dose at the site of treatment from the relevant (right lateral or left lateral) beam, in this case 200cGy from each of the two beams.

ECC Employer's Written Procedure EP2\ECC\3422 'RadCalc Instructions', (Appendix 2 to this report) then requires the creation of a 'reference point' which in this case is at the centre of the neck, i.e. midway between IsoCenter\_1 and IsoCenter\_2. This new point is labelled RadCalc as either 'IsoCenter\_1\_Copy', or 'IsoCenter\_3'.

The final bullet point in the 'RadCalc Instructions' (Appendix 2) instructs the user to open the 'Photon Beams' screen in RadCalc (recreated here as Figure 6) and change the entries for 'Select Calc Pt' in the 'Beam Setup' section to 'IsoCenter\_3' for both beams.

The 'Points and Off-Axis Assistance' screen that should have appeared at this point in the procedure (recreated for this report) is shown here as Figure 7.

The requirement here is that the MU calculated by RadCalc for each of the two beam entry points (IsoCenter\_1 and IsoCenter\_2) should agreed with the manually calculated MU to within 2.5%. Clearly, as shown in the top right of the screen in Figure 7, this is not the case.

This should have led the radiographers concerned to question their manual calculations. However, as noted in the aforementioned RIG report, there was a perception among the Radiographers that RadCalc '*did not work well for parallel opposed fields at 100cm FSD*'. Therefore, instead of questioning the manual calculations, the Radiographers sought to determine why RadCalc had (in their minds) 'failed', and a fourth radiographer, Radiographer D tried to resolve this discrepancy.

Despite these attempts, the difference remained unresolved, so, in accordance with normal ECC practice, they referred their concerns to the appropriate member of the Treatment Planning Section, who then attended the 'Aria' room and took control of the RacCalc calculation.

On questioning, none of the operators involved could clearly recall the precise entries that were in the various columns in the 'Points and off axis assistance' screen at this point in

time. Both Radiographer C and Radiographer D have accepted that it is possible that, in seeking this resolution, some manual changes to the parameters on this screen could have been made. However neither Radiographer could recall having made any such changes, or could offer any reason for having done so. Physicist A has stated with some certainty that *he* did not change any of this data.

Precisely what happened next regarding the various entries in the relevant RadCalc screen remains unresolved, but actual versions of the 'Points and off axis assistance' screens that were saved finally for this patient are shown here as Figures 8 and 9.

Referring firstly to Figure 8, and comparing the entries in the 'Beam Data for IsoCenter\_1', section with those in Figure 5, it is clear that the 'RTP Dose' entries in Figure 8 have been changed from those that would have appeared initially. In particular, the figure for the '1 RT Lat' beam has been changed from '200' to '400', and figures have been entered for the '2LT Lat beam' where there should be none. (The data here should be for the (selected) 1RT Lat beam only.)

Figure 9 shows that (cf. Figure 7) these same changes in the 'RTP Dose' entries from '200' to '400' have been made for the 'Beam Data for IsoCenter\_3'.

For the purposes of this report, Figure 10 is a recreation of Figure 7, the intention of which is to illustrate the immediate effect of making this change from '200' to '400'. As demonstrated, the immediate result of changing the 'RTP Dose' entries from '200' to '400' is to trigger the appearance of an alert indicating that *'The cumulative dose per fraction for the beams associated with this prescription [now 800cGy] exceeds the prescribed dose per fraction [400cGy] by 100%'*. In this regard, the producers of RadCalc have commented that *'this warning is intended to aid the user in diagnosing the error they made in manually entering information'*.

[The fact that this alert does not appear in either of Figures 8 or 9 could have arisen because the user has ticked the *'Do not show this warning again'* box. However, any change that is made by the user, for example, in moving to and back from the 'Photon Beams' screen also causes this alert to disappear from the screen.]

Regarding this alert, Physicist A stated at interview that :

*'This is something that sometimes comes up if you have more than one isocentre and more than one reference point. So on that basis it didn't ring alarm bells.'*

Whatever the scenario, this alert appears to have been ignored.

Referring again to Figure 9 (cf. Figure 7) the effect of changing the 'RTP Dose' entries in the from '200' to '400' has been to change the entries in the top right hand corner of Figures 9 (for both 1RT Lat and 2LT Lat beams) which are now 'MU = 488, Plan MU =493, % Diff = - 1.0%', indicating apparent agreement within tolerance, and this agreement appears to have been taken as confirmation of the correctness of the manual calculations.

In the (recreated) 'Photon Beams' in Figure 6 the 'Isodose Line at Calc Pt (%)' entry is the total of the entries in the 'Dose at Calc Point (cGy)' for the RLat and LLat beams divided by the total prescribed dose per fraction and express as a percentage. In this case, therefore, the figure is:

$$((200 + 200)/400) \times 100\% = 100\%.$$

This is the figure expected.

Figure 11 is the saved version of the 'Photon Beams' screen for this patient. In this case, the 'Dose at Calc Point (cGy)' copied from the entry for 'RTP Dose' in the 'Beam Data for IsoCenter\_3' section of the 'Points and off axis assistance' screen is now 400cGy for both beams. Therefore, the 'Isodose Line at Calc Pt (%)'

$$((400 + 400)/400) \times 100\% = 200\%.$$

Had the fact that this entry was 200% rather than the expected 100% been noted and had the implication been understood, then this should have given the user a further clear indication that the dose data being used by RadCalc in calculating the Monitor Units for comparison with those calculated manually was 100% too high.

In summary, at this point in the process, as a result of what appears to have been inappropriate manipulation of the on-screen data, the figures in the top right hand box in Figure 9 indicated that the difference between the manually calculated monitor units as entered into RTChart and the figure calculated by RadCalc was within the required tolerance for both the 'Right lateral' and 'Left lateral' beams. It appears, therefore, that the other indicators within RadCalc that the manually calculated MU figure was 100% too high were dismissed because of a perception by the users that RadCalc '*did not work well for parallel opposed fields at 100cm FSD*'. The treatment planning and delivery process therefore proceeded accordingly, using the wrong MU figure.

## 5. Investigation of the circumstances of the incident

### 5.1 Question arising

Having described the nature of the errors in Section 4 of this report, this Section gives more detailed consideration to the circumstances surrounding these errors.

Of particular concern here are the following questions:

- Why did Radiographer A make the error described in Sub-section 4.6 of this report?
- Why did Radiographer B arrive at the same erroneous answer?
- Why did the warning from RadCalc that the manual calculations were 100% too high not lead to a fundamental re-evaluation of the manual calculations?
- How did Physicist A derive figures from RadCalc that apparently agreed with the erroneous manual calculations?
- Is RadCalc, as it is used at the ECC, suitable for calculations of this type
- Why did the experienced treatment radiographers fail to notice that the monitor units on the plan seemed unusually high?

In seeking answers to these questions, formal interviews were held with the duty holders who were involved directly in the treatment planning process. The content of the following sub-sections draws on the information obtained in these interviews.

### 5.2 Why did Radiographer A make the error in the manual calculation?

Simply stated, the mistake made by Radiographer A was that, with regard to Sub-section 4.6 and to the method of manual calculation quoted therein from ECC Employer's Written Procedure 'EP2\ECC\3402 Calculating and Checking Monitor Units of Photon Beam Treatments-Manual Calculations', *he* failed to double the 'percentage depth dose'.

Figures obtained from the ECC indicate that for the four year period 2012 to 2015, a total of 181 cervical spine radiotherapy procedures were planned and delivered, with an even spread over the four years. Of these, 121 were planned and delivered using a single posterior field, 53 were planned and delivered using (as in this case) lateral parallel opposed fields at 100cm FSD, and seven were planned and delivered using lateral isocentric fields (see Sub-section 4.3).

At interview, Radiographer A estimated that, over the past four years, *he* had successfully carried out around 5 cervical spine plans for lateral parallel opposed pair treatments to 100cm FSD.

The concern here is that learning that is not reinforced by regular practice can be forgotten, and the likelihood of this will depend on both the complexity of the process, and the degree to which the steps involved are intuitive.

In this case, the process is relatively simple, in the sense that, starting with the prescribed dose to the target point, the task is to make a relatively straightforward calculation of the (equal) doses to each side of the neck. However, this level of simplicity may have contributed to the error, in that both Radiographer A and Radiographer B stated at interview that they recognized that this was a straightforward calculation that they were confident of undertaking correctly, so neither felt the need to refer to ECC Employer's Written Procedure 'EP2\ECC\3402 Calculating and Checking Monitor Units of Photon Beam Treatments- Manual Calculations'.

For a 'Parallel opposed pair with unequal FSD', both the beam dispersion and (usually) the distances between the skin and the target area are different. It is intuitively obvious therefore (as taught in operator training) that division of the dose into separate beams is required, prior to a different 'depth dose' correction being applied to each (as in 'Method 2 in Sub-section 4.5 of this report).

For a 'Parallel opposed pair with equal FSD', the same intuitive method could be used, but with the same 'depth dose' correction being applied to each of the two beams.

In this regard, it could reasonably be argued that the ECC practice, whereby the treatment planner must ensure that the 'depth dose' correction is doubled and applied to the total dose in both beams, is not intuitively obvious. Further, it could also be argued that the means by which this is described in the ECC Employer's Written Procedure EP2\ECC\3402 (Sub-section 4.5 of this report) and the way in which the calculation is commonly written, as in this case (Figure 3 but corrected):

$$'165.2\% = 2000\text{cGy in } 5\# @ 5.5\text{cm}'$$

does not help to make this method of calculation any more intuitive or robust.

At interview, both Radiographer A and Radiographer B volunteered that there were aware of these different methods whereby this calculation could be done. They also agreed that if the method of calculation had required that the beam be divided between the two opposed beams such that no doubling of the 'depth dose' figure would be required, then they were less likely to have made this mistake. Neither of these Radiographers could offer any other explanation of why both made the same error.

In summary, it clearly is the case that manual calculations for 'Parallel opposed pair with equal FSD' had been infrequent, and far less in number than single posterior field treatments where no doubling of the depth dose is required. Also, the current practice whereby the 'depth dose' correction is doubled and applied to the total dose in both beams, rather than dividing the dose between the two beams, together with the means by which this calculation is expressed, does not help to make the change required from the single posterior field calculation an intuitive one.

A reasonable conclusion would be, therefore, that in making an infrequent change in method to one where the process involved is not intuitively obvious, special precautions should be applied to ensure that any critical changes are applied correctly.

### **5.3 Why did Radiographer B make the same error?**

Clearly, the fact that both Radiographer A and Radiographer B made precisely the same error calls into question the degree of independence between the two calculations.

In this regard, Radiographer A and Radiographer B have stated that, in accordance with normal practice, they took the prescribed treatment parameters from the Radiotherapy Prescription Sheet independently of each other, and with no related discussion. They then seated themselves at different desks within the same room and, again with no discussion, used similar 'depth dose' data tables, and the same method of calculation, to calculate the monitor units per treatment fraction for each of the two opposing beams.

It was only on completion of these calculations that they compared answers.

Nothing has emerged during this investigation to cast doubt on these accounts.

At interview, Radiographer B estimated that, over the past four years, *he* had successfully carried out 'between 3 and 8' cervical spine plans for lateral parallel opposed pair treatments to 100cmFSD.

It seems reasonable to conclude, therefore, that the error made by Radiographer B occurred also as a consequence of the infrequency of the use of this method of calculation and the non-intuitive nature of the change required from the more common posterior single beam treatment.



#### 5.4. Why did the RadCalc result not lead to a re-evaluation of the manual calculations?

At interview, Radiographer A, Radiographer B, and Physicist A all agreed that the difference between the MU as calculated manually and by RadCalc should have prompted a review of the source data and manual calculations. This begs the question of why such a re-evaluation was not pursued.

Historically, in the ECC, the method of treatment for all areas of the body where two lateral beams were involved was to define the required focus to skin distance for each of the two beams and position the patient accordingly (Sub-section 4.3). However, over the years, this had changed to 'isocentric' treatment for all except palliative treatment of the cervical spine and treatment of the 'whole brain'. Therefore, the use of RadCalc by the Radiographers for 'lateral parallel opposed pair at 100cm FSD' treatments was much less frequent than its use for isocentric treatments.

[There is no particular reason why these two procedures could not have been changed to isocentric treatments, and ECC staff have stated that the reason why these two procedures had not been changed over was simply for 'historical reasons'.]

In defining the RadCalc procedure for 'lateral parallel opposed pair at 100cm FSD' rather than for isocentric treatments, the relevant ECC Employer's Written Procedure EP\ECC\3422 'RadCalc Instructions', requires some additional steps involving manipulation of the on-screen parameters by the operator. The relevant extract from this Procedure is annexed here as Appendix 2.

The report from the ECC Radiotherapy Incident Working Group noted that the '*perception within radiography staff is that it [RadCalc] does not work well for parallel opposed fields at 100cm FSD*'. Further to this, at interview Radiographer A commented that:

*'with RadCalc with this particular type of calculation it seems like ... it gets muddled up.'*

and;

*'..it feels more like you have to make the RadCalc fit the calculation than making the calculation be checked by RadCalc'.*

Reference to Figures 8 and 9, and to the discussion of the content of these screens in Sub-section 4.7, suggests also that, whereas all of the operators involved might have known how to run RadCalc, they lacked the fundamental understanding of the RadCalc process and of the significance of the entries appearing in the various fields that would have pointed to the

nature of the error. It might be supposed that this lack of understanding would have contributed further to their lack of confidence in the computed results.

In contrast to their lack of confidence in RadCalc, as noted in Sub-section 5.2, Radiographers A and B stated at interview that they considered that the foregoing manual calculation was a relatively simple one that they were confident of undertaking correctly.

It must be concluded, therefore, that it was this high level of confidence in the correctness of their manual calculations among the radiographers involved, together with their lack of confidence in the use of RadCalc for this infrequent method of treatment, that led to a shared assumption that their manual calculations were correct and the RadCalc MU calculation was wrong. Their interaction following completion of the manual calculation might have reinforced this confidence.

This belief then appears to have permeated all subsequent attempts to reconcile the different means of calculations, and it was therefore the RadCalc rather than the manual calculation process that became the subject of re-evaluation and manipulation until satisfactory final agreement between the computed and manually calculated MUs appeared to have been achieved. However, as illustrated in Sub-section 4.7, had the significance of the entries in the various RadCalc fields been properly understood, there were sufficient indications that this was not the case.

### **5.5 How did Physicist A achieve apparent agreement between RadCalc and the manual calculations?**

As discussed in Sub-section 4.7, the best assessment of what happened is that someone changed the values in the 'RTP Dose' column of both the 'Beam Data for IsoCenter\_1' and the 'Beam Data for IsoCenter\_3' section 'Points and Off Axis Assistance' screen from the correct value of '200' to '400' for both the RLat and LLat beams, resulting in apparent agreement between the computed and manually calculated MU.

However, it should be reiterated that nothing has emerged during this investigation to confirm when this change was made or to clarify who made it.

The question that arises, therefore, is why would the entries in the 'Beam Data for IsoCenter\_1' and in the in the 'Beam Data for IsoCenter\_3' sections of Figures 8 and 9 have been changed as described. Again, no clear answer has emerged during this investigation.

However, one plausible explanation relates to the penultimate bullet point in Appendix 2 which requires that '*With Isocentre\_3 selected, set the SSD for both beams to 100cm and*

*then enter the prescribed dose per fraction in RTP Dose*'. Whereas the intention of this instruction is that the operator should '*enter the prescribed dose per fraction in RTP Dose*' for the beam in question, it does not state this explicitly, and it might have been taken by the operator as relating instead to the total prescribed dose per fraction (400cGy).

Further evidence of operator confusion at this point is the fact the changes to referred to in bullet point 5 of Appendix 2 appear to have been made not only, as intended, to the beam data for 'IsoCenter \_3', but also the that for 'IsoCenter\_1', for which no such changes should be made.

At interview Physicist A commented that having first of all checked that the correct patient had been selected '*I started to do the process and the process that I first of all used was the one that I had used myself when I had been doing these RadCalc sort of investigation, but a few days before I had gone on holiday the work instructions had been updated to include a way of doing it. So I realised that by doing it my own way I had done something wrong and I stopped what I was doing at that point and then went on to the work instructions.*'

In this regard, comparing the earlier version of ECC's Employer's Written Procedure EP2\ECC\3422 'RadCalc Instructions' with the extant version, it is clear that the instructions for 'POP calculation at 100cm FSD' (Appendix 2) had undergone significant change. However, there is no evidence of any resulting retraining of any of the operators involved with this incident.

Physicist A had considerable previous experience in the use of RadCalc, and would therefore have been expected to identify the evident inconsistencies in the on-screen data. It therefore seems likely that the recent changes to EP2\ECC\3422 'RadCalc Instructions' contributed to *his* acceptance of this apparent agreement between the calculated monitor units and the 'plan monitor units' when it should have been clear that this was, in fact, a result of some inappropriate changes to the input data.

## 5.6 The suitability of RadCalc for calculations of this type.

The operators' lack of confidence in the efficacy of RadCalc for parallel opposed fields at 100cm FSD raises the broader question of the suitability of RadCalc for calculations of this type.

With regard to this perception, the producers of RadCalc, 'Lifeline Software Inc.', have commented that '*RadCalc is fully capable and well suited for these types of treatments*'. This, therefore, leads to the further question of whether the issues underlying this perception could have arisen because the procedure used at the ECC for RadCalc calculations for parallel opposed fields at 100cm FSD (Appendix 2) was incorrect, or was not optimal.

Data input to RadCalc is from two different sources, data transfer from the associated treatment planning software, and by direct manual input. When operated in accordance with EP\ECC\3422 'RadCalc Instructions', the data that is transferred from RTChart was the prescribed dose, fractionation, the method of delivery, and the result of the manual calculations.

Data that required subsequent manual input were the 'depth' of this calculation point, the 'focus to skin distance' (referred to in RadCalc and in EP\ECC\3422 'RadCalc Instructions', as the 'source to skin distance' (SSD)). This manual manipulation of RadCalc also included the creation of the 'calculation point' in the centre of the neck.

The view of the producers of RadCalc was sought, therefore, on whether this was considered to be the recommended or optimal method for non-isocentric treatments such as the one under consideration here. Their view was that whereas this method correctly applied would produce the answer required, it is not the method recommended, and a simpler, less error-prone method was available.

In particular, if, instead of copying one of the 'Isocentres' so the coordinates could be changed so as to identify the 'calculation point' ('IsoCenter 3'), this point could simply be identified in the treatment planning system, and imported into the software system, thus avoiding this step. In this way the rest of the process defined in the six bullet points under 'For patients with POP calculation at 100cm FSD' in EP\ECC\3422 'Radcalc Instructions' would become unnecessary, and the likelihood of alerts associated with the sequencing of manual data input would be reduced.

It was also noted by the producers of RadCalc that the terminology used, in particular "IsoCenter\_3" or 'IsoCenter \_1\_Copy' was not helpful and that an alternative label such "Calc Point" or "Mid-Plane" would make this point more easily distinguished from the other points when the "Photon Beams" screen is selected.

## **5.7 Why did the treatment radiographers fail to notice that the MU seemed unusually high?**

Even after completion of treatment planning, there remained one final stage at which it might be expected that the error would be identified. Experienced treatment radiographers who operate the Linacs usually have a feel for the number of MU used for manually calculated treatments, even for treatments that are as infrequent as that considered here.

When questioned on why the error was not identified at this stage, the treatment radiographers indicated that their focus was likely to have been on the difficulties in patient set-up that arose from the condition of the patient, and on the associated daily imaging required to verify correct positioning of the treatment area. It seems likely, therefore, that these were contributory factors in their failure to notice that the MU calculated by the treatment planners were unusually high for this particular treatment.

## **6. Training and entitlement of the operators concerned**

### **6.1 General provisions for training and entitlement of duty holders**

Regulations 4(4) and 11, together with Schedule 1(b) place duties on the employer to ensure that all 'referrers', 'practitioners' and 'operators' are 'identified as entitled to act' in these capacities, and to take steps to ensure that 'no practitioner or operator shall carry out a medical exposure or any practical aspect of a medical exposure without having been adequately trained'. Regulation 11(4) further requires that the employer shall keep appropriate training records for entitled practitioners and operators, and shall make these available for inspection by the appropriate authority, and Regulation 4(4)(b) requires that the employer shall take steps to ensure their continuing education and training.

The ECC provisions for training and for entitlement of duty holders are defined in Level 1 (see Sub-section 7.2.3 for an explanation of 'Levels') Employer's Written Procedures numbers EP1-1 and EP1-2, and in Level 2 Employer's Written Procedures numbers EP2\ECC\0001, and EP2\ECC\0002.

Employer's Written Procedures EP2\ECC\0001, for 'The identification of individuals entitled to act as Referrers for therapeutic exposures, and as Practitioners or Operators for all medical exposures' includes a competency list for Therapeutic Radiographers and a competency list for Oncology Physics. For example, one such Radiographer competence is for the 'Pregnancy status check'.

Employer's Written Procedures EP2\ECC\0002, for 'Induction of new staff and training and training records of entitled Practitioners and Operators' states that for Therapeutic Radiographers, the level of competence must be signed off by the Therapeutic Radiography Senior Manager or Head of Section for that area, and that this signature 'confirms that any relevant certificate of training has been inspected and that the assessor is satisfied that the person meets the competency requirements'. The reference to a 'level of competency', reflects the fact that 'levels' between 0 and 4 might be assigned depending on entitlement to practice unsupervised, to supervise trainees, or to provide training.

### **6.2 Training requirements for the radiographers**

The treatment plans undertaken at the ECC range in complexity from what might be described, for present purposes, as 'simple plans' and 'complex plans' For example, planning for any treatment involving the use of a beam shaping device in the Linac head called a 'multileaf collimator' would fall into the 'complex' category.

All radiographers entering into training as a treatment planner would begin with training in 'simple planning' techniques, for which the ECC training requirements are defined in

controlled document number EP2\ECC\2036 'Training Plan: Radiographer Calculations'. Progression beyond this stage requires highly specialised additional training, and, in practice, only a small proportion of radiographers would pursue such a progression.

The training requirements for the manual calculations undertaken by radiographers relevant to this incident are, therefore, fully covered by EP2\ECC\2036 'Training Plan: Radiographer Calculations', the latest version of which is 'Issue 1.0, dated 18<sup>th</sup> February 2015. This includes a requirement for the trainee operator to undertake '10 (practice) calculations for parallel opposed fields', the 'Pass Criteria' being defined as 'Correct calculation and completion of document'. The 'document' referred to here is the ECC's pro-forma 'Practice Calculations' workbook, and EP2\ECC\2036 includes a 'Signed (trainer)' field to indicate that the trainer is satisfied that the 'Pass criteria' have been met, and a 'Last step completed' field to indicate the date at which all requirements have been satisfactorily achieved.

Radiographers participating in these 'simple plans' should have also undertaken the training defined in ECC controlled document number EP2\ECC\2037 'Training Plan: Data entry', which includes creation of a 'workspace' in the Aria computer programme. The information to be entered by the trainee planner into this workspace would include, (along with other patient data) the various parameters used in their manual calculations.

A further requirement for these radiographers is successful completion of ECC controlled document number EP2\ECC\2038 'Training Plan: Sanctioning', which requires that the trainee demonstrate the ability to correctly check and verify a number of entries in the Radiotherapy Treatment Sheet, prior to this sheet being made available to the operators who deliver the treatment.

EP2\ECC\2036 also includes a requirement for training in 'Export into RadCalc programme (to be within 2.5%)'. Though not stated explicitly, the ECC's Head of Therapeutic Radiography has stated that, in keeping with the documented training provisions for members of the Oncology Physics Department outlined here in Sub-section 6.5, this requirement is for the result of at least 15 manual calculations to have been checked by the trainee using the RadCalc dose verification programme. Each of these 15 computed results must agree with their manual calculation to within 2.5%.

None of Radiographers A, B, C or D had undertaken training in 'complex plans'.

Sub-section 6.3 of this report considers whether these training requirements had been properly completed and recorded for the radiographers involved.

### 6.3 Evidence of initial and continuing training for the radiographers

The training records for Radiographers A, B, and C include evidence of completion of training pro-formas EP2\ECC\2036 'Training Plan: Radiographer calculations', EP2\ECC\2037 'Training Plan: Data entry', and EP2\ECC\2038 'Sanctioning'. Regarding EP2\ECC\2036 the training records for each of these Radiographers also included a completed pro-forma booklet of 'Practice Calculations for Parallel Opposed Treatments' which includes practice calculations for isocentric treatments, and for parallel opposed pair treatments to both equal and unequal FSD.

The pro-forma booklet of 'Practice Calculations for Parallel Opposed Treatments' is not held as a quality controlled document.

In all cases, however, there are deficiencies in record keeping including missing signatures and dates, and records showing a date of completion of training that is some years earlier than the recorded date of last review on the pro-forma in which they appear. This latter anomaly has been explained by the Head of Therapeutic Radiography in terms of development of the document quality system. On replacement of informal training records with quality controlled documents, these informal records were, in many cases, discarded and the dates of completion of training elements were recorded on the new quality controlled pro-formas as the date shown on the discarded document. However, because of this practice, useful evidence of completion of training has clearly been lost, and this issue should be considered in any review of training records arising from the recommendations of this report.

The training records for Radiographer D include evidence of completion of ECC training document EP2\ECC\2055 Training Plan Summary for On-call Entitlement'. For the various training elements listed therein, the 'Date of Completion' is recorded and being between 2006 and 2014.

For Radiographer D, there is no evidence of completion of training pro-formas EP2\ECC\2036 'Training Plan: Radiographer calculations', EP2\ECC\2037 'Training Plan: Data entry', and EP2\ECC\2038 'Sanctioning'. This is explained by the fact that this radiographer qualified before the others, and *his* equivalent training and entitlement preceded the introduction of these documents.

Regarding practice calculations the training record for Radiographer D showed evidence of one such calculation having been completed successfully for an isocentric parallel opposed pair treatment.



There is no written record for any of these four Radiographers of successful checking of 15 (or any) manual calculations using RadCalc.

Regarding the 'competency requirements' referred to in the final paragraph of Sub-section 6.1, there is a lack of clarity in currently in ECC documents about exactly which training should be undertaken, and how this should be followed by actual treatment plans carried out under direct supervision, prior to entitlement for specific competences, and about how that training and experience should be formally recorded and records retained.

In summary, the training records for these operators provide evidence of completion of relevant initial training, and some indication of relevant continuing professional development. However, a number of deficiencies in the keeping of training records have been identified and this is discussed further in Section 9 of this report. Concerns regarding maintenance of competence for these infrequent treatment plans are also discussed in Section 9.

#### **6.4 The scope of entitlement for the radiographers**

The ECC's Level 3 Employer's Written Procedures number EP2\ECC\2000 comprises a set of tables wherein all current Therapeutic Radiography staff are listed in rows and the relevant operator competences for which these staff might be entitled are listed in the associated column headings.

Each cell in the table is completed by the Head of Therapeutic Radiography with a number between 0 and 4, to indicate the level of competence of the operator concerned for carrying out that task, and for training and supervising others. 'Level 0' indicates that the Therapeutic Radiographer is not entitled to undertake any practical aspect of the competence concerned, even under supervision, 'Level 1' indicates authority to undertake practical aspects of the competence under supervision, 'Level 2' indicates authority to act without supervision, and Levels 3 and 4 confer authority for training and supervision.

The total of those competences assigned to the operator by the Head of Treatment Radiography at Levels 1 to 4 comprises the 'scope of entitlement' for that operator.

Among the competences listed in Employer's Written Procedure number EP2\ECC\2000, the one of principal relevance to this particular incident is 'On Call (combined Pre-treatment and treatment preparation/delivery/verification)'. In practice, any operator designated at 'Level 2' or above is thereby entitled to undertake all aspects of pre-treatment imaging, manual treatment planning and checking, data entry to Aria, independent MU checking using RadCalc, final treatment approval, treatment delivery, and verification using on-treatment imaging (whether 'on-call' or during normal working hours). In addition, however, this 'On call' competence has been separated into its individual elements, for example, 'Treatment

Preparation' and 'Treatment Delivery', and the levels of entitlement have been separately assigned and documented in a similar fashion for each.

At the time of this incident each of Radiographers B, C, and D had a documented Level 2 assignment for all of this 'On Call' competence, and for 'Treatment Preparation', which includes manual planning and the use of RadCalc. Hence they were deemed by the Head of Therapeutic Radiography to be competent to undertake all relevant aspects of the manual and RadCalc calculations.

Radiographer A, however, had a Level 1 assignment, which indicates that *he* should have undertaken the manual calculation under direct supervision by an operator at Level 2 or above. However, this has been explained by the by the Head of Therapeutic Radiography as an error in record keeping, and evidence has been provided that, as discussed in Sub-sections 6.2 and 6.3 of this report, Radiographer A had undertaken all the training necessary for a Level 2 assignment for (at least) the manual calculations aspect of this 'Treatment Preparation' competence.

The finding of this investigation is, therefore, that each of Radiographers B, C, and D were properly trained and entitled to undertake the manual and RadCalc calculations. While the training records for Radiographer A, indicate that *he* was adequately trained to undertake manual calculations unsupervised, *his* scope of entitlement did not reflect this, and this is a serious error in record keeping.

Further to this, all operators should have a clear understanding of their own scope of entitlement, which should not be exceeded. At interview, it was clear that Radiographer A lacked a clear understanding of the relationship between training and entitlement by the employer, and of how *his* documented scope of operator entitlement could be accessed.

In summary, this investigation has identified a number of concerns about the current system for assessing and recording of the scope of entitlement for treatment radiographers and for linking entitlement to recorded training. These concerns are discussed further in Section 9 of this report.

## 6.5 Training requirements for the physicist

Physics staff at the ECC come under a different management structure to that for the therapeutic radiographers, and have different training programmes. The principal training document relevant to this incident for Physicist A is EP2\ECC\3030 'Manual Calculations', associated with which are a number of other documents relating to specific area of the overall training provisions required by EP2\ECC\3030.

EP2\ECC\3030 includes a requirement for the trainee operator to successfully undertake a minimum of 15 practice examples, and a minimum of 10 real patient calculations under supervision, using the 'independent monitor unit system' (RadCalc).

## 6.6 Evidence of initial and continuing training for the physicist

The ECC training plan, EP2\ECC\3030 'Manual Calculations', for Physicist "A" was completed in August of 2012 and was signed off by the then Head of the ECC Treatment Planning Section. This includes confirmation that the following training elements have been completed successfully:

- i. EP2/ECC/0050 'External Beam Protocol'; a departmental overview of provisions for identification of the area of treatment, treatment planning, and treatment delivery.
- ii. EP2/ECC/3040 'Treatment Planning' and associated training documentation for trainee planners.
- iii. EP2\ECC\3402 "Calculating and Checking Monitor Units for Photon Beam Treatments-Manual Calculations"
- iv. A minimum 15 practice calculations of various types, including parallel opposed pairs, as laid out in the associated (uncontrolled) document 'Training Progress for Manual Calculations', the results of which are recorded on 'Manual Calculations Record of Evidence'. This includes both manual calculations and verification of the manually calculated Monitor Units using RadCalc.
- v. Ten calculations under supervision for patients undergoing treatment, the results of which are recorded on the associated 'Manual Calculations Record of Evidence' pro-forma'.

Regarding points iv and v above, sign-off by the then Head of the ECC Treatment Planning Section confirms that the various elements required by EP2\ECC\3030 'Manual Calculations' have been completed. However, because of an instruction issued by the Head of Oncology Physics that the associated 'Records of Evidence' did not need to be retained following sign-off, completed versions of these documents for Physicist A were not available. This is discussed further in Section 9.

## 6.7 The scope of entitlement for the physicist

Entitlement for members of the ECC Treatment Planning Section is recorded in quality controlled document EP2\ECC\3002 'Entitled Staff List – Treatment Planning Operators'. This document includes a list of the competences against which staff may be entitled at either of levels '1' or '2'.

Under current provisions either one or both of the required treatment planning calculations for each patient must be carried out by an operator who is entitled at Level 2.

The competence relevant to the role of Physicist A in this incident is listed in EP2\ECC\3002 as 'Manual Calculations, Templates & Finishing Off', for which Physicist A is recorded as having been entitled at Level 1.

Normally, this would mean that the involvement of Physicist A with a plan of this type would be alongside a treatment planner entitled at Level 2. In this case, however, the role of Physicist A was not as a planner of this particular exposure, but as a consultant on the use of RadCalc. The relevance of *his* entitlement is that it demonstrates that Physicist A had successfully demonstrated initial competence in the use of RadCalc. The question that then arises is whether this initial entitlement could be supported with evidence of relevant continuing training and/or experience in the use of RadCalc.

In this regard, Physicist A's record of 'continuing personal development' (CPD) shows considerable experience in the use of RadCalc, including training of radiographers in its use. Indeed, Physicist A has been described by the Head of Oncology Physics in the course of this investigation as the 'go-to' person for advice on the use of RadCalc. The 'Level 1' (rather than Level 2) designation for the 'Manual Calculations, Templates & Finishing Off' competence for Physicist A was explained in terms of the breadth of the tasks included in this competence, in addition to the use of RadCalc.

The finding of this investigation is, therefore, that with regard to Regulation 11(1), Physicist A had been 'adequately trained' for the 'practical aspects' of this exposure in which *he* participated, and was an appropriate person from whom to seek advice. However, there is clear evidence to suggest that the application of the training and expertise of Physicist A had been compromised by recent changes in the Employer's Written Procedure for the use of RadCalc for 'parallel opposed fields', for which no additional training had been given.

The differences between the way that the scope of operator entitlement is defined and recorded for the Physicists and the Radiographers is also of concern, and this is also discussed further in Section 9.

## **7. Responsibilities under the Ionising Radiation (Medical Exposures) Regulations 2000**

### **7.1 General provisions of the Regulations**

The IR(ME) Regulations place duties on a number of 'duty holders'. They are 'the employer', 'the referrer', 'the practitioner', 'the operator' and the 'medical physics expert' (who is considered to be an 'operator'). This Section outlines the particular responsibilities of these duty holders under the IR(ME) Regulations, and considers whether these duties were properly being implemented at the time of this incident

With regard to these duty holders, Regulation 2(1) includes the following definitions:

"employer" means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation'.

"referrer", means a registered health care professional who is entitled in accordance with the employer's procedures to refer patients for medical exposures;

"practitioner" means a registered health care professional who is entitled in accordance with the employer's procedures and whose primary responsibility is justification of the individual medical exposure;

"operator" means a person who is entitled in accordance with the employer's procedures to undertake the practical aspects of the medical exposure;

"medical physics expert" means a person who holds a science degree or its equivalent, and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

### **7.2 The duties of the employer.**

#### **7.2.1 General provisions for implementing employer's duties at the ECC**

The IR(ME) Regulations place a number of statutory duties on the 'employer' which cannot be delegated to others. Therefore, in any such 'trade, business or undertaking', the employer, and the means by which that employer shall implement these duties, must be clearly identified.

In practice, however, there will be many undertakings, (including Health Boards) wherein it would be entirely unreasonable to expect the employer personally to implement these duties, such as providing a clinical protocol for a particular radiotherapy treatment. Therefore, whereas the statutory duties on the 'employer' cannot be delegated to others, it is entirely reasonable that the employer should make others responsible to him for ensuring that these duties are properly implemented, provided that the employer also takes reasonable steps to oversee proper implementation.

In this regard, the NHS Lothian 'Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000' includes the following:

- 'The Chief Executive of NHS Lothian takes overall responsibility for compliance with the duties of the employer under the Ionising Radiation (Medical Exposure) Regulations 2000 (as amended).
- 'The Medical Director of NHS Lothian is responsible to the Chief Executive for implementation of the provisions of this [IR(ME)R] policy across the whole of Lothian NHS Board.'
- 'The Medical Director appoints an Associate Medical Director for NHS Lothian to act as 'IRMER Policy Lead'.
- 'The IRMER Policy Lead authorises, in writing, the Clinical Directors or Heads of Departments of those Directorates or Departments where medical exposures are carried out to discharge particular responsibilities in their respective Directorates or Departments.
- 'The particular duties of the Clinical Directors are;' [*inter alia*):
  - 'To ensure clinical audits are carried out.'
  - 'To provide, maintain and disseminate employer's written procedures'
  - 'To entitle duty holders.'

In summary, the CEO has established and documented a clear chain of responsibilities leading back to *him*, and (as discussed in the following Sub-section) has made appropriate provision to oversee proper implementation of these responsibilities.

### **7.2.2 Clinical Audit**

Regulation 8 requires that 'The employer's procedures shall include provision for the carrying out of clinical audits as appropriate'.

Regulation 2(1) defines 'clinical audit' as: 'a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care, through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, intended to lead to modification of practices where indicated and the application of new standards if necessary'.

Within NHS Lothian these annual clinical audits are the principal means by which the employer maintains oversight of proper implementation of the duties of the employer under

the Regulations. NHS Lothian's Employer's Written Procedure number EP1-10 'Provisions for Clinical Audit' requires that a pro-forma 'IRMER Clinical Audit Form' (EP2\ECC\0064) be completed annually by the Clinical Director of each relevant Directorate, and presented to the NHS Lothian Radiation Protection Committee.

As part of this investigation evidence was provided that the latest clinical audit had been satisfactorily completed on 10 December 2014 and signed-off by the Clinical Director of the ECC. The content of this 2014 clinical audit indicated that the requisite Employer's Written Procedures and Protocols were in place and up-to-date, and that provisions for entitlement of duty holders had been completed.

### **7.2.3 Employer's Written Procedures and Protocols**

Regulations 4(1) and 4(2), require Employer's Written Procedures and Protocols to be in place and (Regulation 3(c)), to be subject to a written system for quality assurance. In practice this means that these documents must be 'controlled documents' within a robust quality system that ensures that they are fit for purpose and are subject to regular review and updating.

Generally speaking, Employer's Written Procedures comprise instruction from the employer on how specific tasks shall be undertaken, for example the procedure that must be applied for proper identification of the patient ahead of treatment, whereas Employer's Written Protocols define clinical practice for specific treatments, and allow for variation according to the clinical judgement of the user.

The NHS Lothian Employer's Written Procedures comprise a set of 13 quality controlled 'Level 1' documents that apply to the whole of NHS Lothian, and nine 'Level 2' documents, which are particular to each directorate, including the ECC. The titles of these nine Level 2 Procedures, for example 'Justification and authorisation of medical exposures' are listed in the NHS Lothian 'Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000'.

The Level 1 Procedures are authorized by the Associate Medical Director (as the NHS Board's 'IRMER Lead'), and Level 2 Procedures are authorized by the Directors of each of the relevant Directorates.

These two sets of Employer's Written Procedures cover all of the requirements of the IR(ME) Regulations, including those of 'Schedule 1'.

Within each of the NHS Lothian Directorates, where a particular Division requires additional Employer's Written Procedures, these are designated as 'Level 3' documents, and are authorized by the relevant Head of Division.

The NHS Lothian 'Policy for the Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000' requires that each of these Employer's Written Procedures and Protocols be reviewed at least biannually.

Within the ECC, the Oncology Physics Division and the Therapeutic Radiography Division each have their own set of Level 3 Procedures.

As part of this investigation, this set of Procedures was reviewed to ensure proper compliance with the IR(ME) Regulations, and with the employer's own document quality assurance requirements.

In this regard, at the time of this investigation, there were a number of inconsistencies between the instructions given by the employer in written Policies and in Level 1 and Level 2 documents, and the content of the Oncology Physics and the Therapeutic Radiography Level 3 Procedures, and the numbering system for these documents appeared to be at odds with stated requirements. However, these are matters of internal consistency, rather than compliance with the Regulations, and in this latter regard no significant deficiencies were identified.

Those ECC Employer's Written Protocols relevant to the radiotherapy treatment for this patient were also scrutinized. Again, all of these documents were found to be up-to-date and, in general, fit for their intended purpose. However, there was evidence of duplication of information in among Procedures and Protocols and, again, of lack of internal consistency. These concerns are discussed further in Section 9 of this report.

#### **7.2.4 Training and entitlement of duty holders**

Regulations 4(4) and 11, together with Schedule 1(b) place duties on the employer to ensure that all 'referrers', 'practitioners' and 'operators' are 'identified as entitled to act' in these capacities, and that 'no practitioner or operator shall carry out a medical exposure or any practical aspect of a medical exposure without having been adequately trained'. Regulation 11(4) further requires that the employer shall keep appropriate training records for entitled practitioners and operators, and shall make these available for inspection by the appropriate authority, and Regulation 4(b) requires that the employer shall take steps to ensure their continuing education and training.



Regulation 11(1) prohibits any operator from carrying out any practical aspect of a medical exposure or without having been adequately trained, but Regulation 11(3) allows that trainees may participate in practical aspects under the supervision of someone who is adequately trained. Regulation 4(4)(a) requires that the employer must take steps to ensure that operators comply with Regulation 11, and Schedule 1(b) requires that the Employer's Written Procedures shall include procedures to identify individuals entitled to act as operators.

Implementation of the duties of the employer for training and entitlement of duty holders at the ECC are described in Section 5 of this report.

A number of deficiencies in the keeping of records of training and entitlement have been identified. The most serious of these concerns was that the employer's record of entitlement dictated that Radiographer A should not have undertaken the manual calculation unsupervised. However, from inspection of the relevant training records for Radiographer A, it is accepted that this was an error of record keeping rather than an example of an operator undertaking a task for which *he* was not adequately trained or experienced

### **7.2.5 Involvement of a Medical Physics Expert**

Regulation 9 requires that 'The employer shall ensure that a Medical Physics Expert (MPE) shall..... be closely involved in every radiotherapeutic practice'.

In this regard, the 'Notes on good practice' issued by the UK Department of Health includes that '*In practice, the level of involvement of the MPE should be determined by the level of hazard and risk associated with the exposure and the amount of benefit expected from their advice. For most radiotherapy, MPEs are likely to be full-time contracted members of staff and will be available on site.*'

Regarding 'the level of hazard or risk', this is one of the least complex of the procedures that treatment planners regularly undertake, and not one in which the MPE would have expected to be involved. Also, although treatment planning for this patient began at the weekend, when the MPE was not available 'on site', the manual and RadCalc calculations referred to here, took place on the Monday morning. The MPE was then available on site for consultation, had the treatment planners and the physicist considered this necessary.

An MPE was also involved in establishing the methodology for the manual calculations, and in initial commissioning of RadCalc.

In this regard, therefore, the employer acted correctly in ensuring that a properly qualified MPE was involved in establishing the treatment planning methodology, and was available for consultation, should the operators involved have considered this necessary.

### **7.3 Findings of this investigation regarding the duties of the employer**

With regard to the duties of the employer referred to in Sub-section 7.2, the findings of this investigation are as follows:

- i. Clinical audit: An up-to-date and satisfactory clinical audit in accordance with NHS Lothian's Level 1 Employer's Written Procedure EP1-10 had been carried out.
- ii. Employer's Written Procedures and Protocols: With some concerns regarding the numbering and content of the Employer's Written Procedures and Protocols relevant to this incident, as discussed in Sub-section 7.2.3 of this report, these documents were in place and up-to-date.
- iii. Training and entitlement of duty holders: A review of training records for Radiographers B, C and D and for Physicist A found that, in all cases, their training records were consistent with the requirements defined in the relevant ECC Employer's Written Procedures. However, some concerns were identified regarding the quality of record keeping and these are reflected in the recommendations in Section 9 of this report. In all cases, these duty holders had been properly 'signed'-off for the operator competences relevant to their role in treatment planning for this procedure. Concerns regarding entitlement of Radiographer A are discussed in Sub-section 7.2.4, but it is accepted that this was a failure of record keeping rather than a deficiency in training that was likely to have contributed to this error.

The need for re-training of all operators concerned in manual calculations and in the use of RadCalc is considered further in Section 9

- iv. Involvement of a Medical Physics Expert: Treatment planning for this patient began over the weekend when an MPE was not available 'on site', and no formal provision had been made for out-of-hours access to an MPE. However, under extant ECC provisions, only the most basic of treatments were planned out-of-hours, with the opportunity to defer treatments where MPE advice was considered necessary.

The finding of this investigation is that, in general, the duties of the employer relevant to this incident had been properly addressed. However, certain areas for improvement and change

of practice have been identified. Of particular concern are the current deficiencies related to training and entitlement of operators, as summarized in Point iv above, which could be regarded as having been a significant factor in the cause of this incident.

#### **7.4 Duties of the practitioner and operator**

With regard to the duties of the practitioner and operators relevant to this incident:

Regulation 5 includes requirements that:

- (1) The practitioner and the operator shall comply with the employer's procedures.
- (2) The practitioner shall be responsible for the justification of a medical exposure and such other aspects of a medical exposure as is provided for in these Regulations.
- (4) The operator shall be responsible for each and every practical aspect which he carries out...
- (6) The practitioner and the operator shall cooperate, regarding practical aspects, with other specialists and staff involved in a medical exposure, as appropriate.

and Regulation 6 includes requirements that:

- (1) No person shall carry out a medical exposure unless –
  - (a) it has been justified by the practitioner as showing a sufficient net benefit...
  - (b) it has been authorised by the practitioner..

and Regulation 11(1) requires that: ... no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.

In practice, justification by a practitioner is a clinical judgement that the exposure will do more good than harm, and authorization by a practitioner is the means whereby the practitioner advises the operator that the exposure is justified and can go ahead, in this case by initialling and dating the space provided on the Radiotherapy Prescription Sheet.

#### **7.5 Findings of this investigation regarding the duties of the practitioner and operators**

With regard to these practitioner duties, the finding of this investigation is that, in all senses, the exposure had been properly justified and authorized by the practitioner, and recorded as such on the Radiotherapy Prescription Sheet. Further, the prescribed radiation dose, method of delivery, and fractionation were as expected for treatment of this condition, and in accordance with ECC Employer's Written Protocol number EP2\ECC\1017 'Clinical Management Guidelines for Myeloma', and were properly described by the practitioner on the Radiotherapy Prescription Sheet.

In summary, therefore, all aspects of the duties of the practitioner were properly and diligently carried out, and in no way influenced the errors in treatment planning.

Clearly, this incident was caused, by errors made by the operators who were responsible for 'practical aspect' of the exposure, in particular for treatment planning. The question arising here is whether any of these errors resulted from failure of any of these operators to comply with the legal duties defined in the Regulations.

In this regard, the finding of this investigation is that methods used by the operators concerned in carrying out their treatment planning duties were in accordance with the ECC Employer's Written Procedures and Protocols (albeit that they made errors in doing so), that the treatment that they planned had been properly authorized, and that, with regard to Regulation 5(6), they co-operated with each other and with the requirements prescribed by the practitioner.

Regarding Regulation 11(1), the question of whether any of the practical aspects undertaken by these operators was outwith the scope of their training and entitlement is considered further in Section 6 of this report. The general conclusion here is that the nature of the involvement of Radiographers B, C, and D and Physicist A was within the scope of both the training that was considered adequate by their employer and of their entitlement. While Radiographer A had also received the training considered adequate by the employer for manual calculations, *he* was not formally entitled by the employer to undertake such calculations unsupervised. However, it is accepted that Radiographer A was firmly of the view that *he* had 'been adequately trained' for this task, and this view is supported by available training records. It is also accepted that Radiographer A was unaware on the status of *his* entitlement in this regard, and that this was due, at least in part, to deficiencies in the structure and accessibility of the scope of entitlement for treatment radiographers.

Concerns regarding the definition and recording of the scope of entitlement for duty holders and the relationship between training and entitlements are discussed further in Section 9 of this report.

With regard to the use of the RadCalc independent MU calculation system, while there was a general belief among the operators concerned and among the senior staff who defined the training requirements that all concerned were adequately trained, the evidence that has emerged in this investigation suggests otherwise. While this might be due in part to lack of re-training following the changes to ECC's Employer's Written Procedure EP2\ECC\3422 'RadCalc instructions' referred to in Sub-section 4.7 of this report, there are clear indications that the operators concerned lacked a general understanding of the RadCalc process and that this contributed to their lack of confidence in its outputs.

In carrying a 'practical aspect without having been adequately trained', the operators concerned were in breach of Regulation 11(1). However, it is accepted that this insufficiency

in training has been identified mainly by the hindsight provided by this incident, and that those operators concerned did not knowingly act in breach of this Regulation.

Notwithstanding the concerns regarding entitlement of Radiographer A and the adequacy of training relevant to the use of RadCalc, the finding of this investigation is that all of the actions taken by the operators involved in planning and delivering this treatment were properly in accordance with their legal duties under the IR(ME) Regulations.

## 8. Summary of principal findings

The principal findings arising from investigation of this incident are summarized in the following paragraphs.

Between 14<sup>th</sup> and 18<sup>th</sup> September 2015, a patient at the ECC diagnosed with multiple myeloma was given a palliative radiotherapy treatment of the vertebrae of the neck to address pain and disability being caused by a bone fragment from a collapsed 'C3' vertebra.

The prescribed total dose of ionising radiation to be delivered to the patient and the method of delivery were fully in keeping with the ECC's treatment protocol for this condition, and this treatment was correctly described by the oncologist on the patient's 'Radiotherapy Prescription Sheet'. In all senses, therefore, and with particular regard to Regulation 7(2) on the optimization of radiotherapy treatment, the duties of the practitioner under the Regulations were fully met.

On the morning of Monday 14<sup>th</sup> September a treatment planner (Radiographer A), used the correct ECC treatment planning protocol, to carry out a manual calculation of the dose of radiation to be delivered to each side of the neck for each day of treatment, but made an error in calculation. As a result of this error, the dose calculated by this Radiographer was double what it should have been.

A second treatment planner (Radiographer B), carried out a similar manual calculation, but got the same wrong answer.

Data input to the 'Aria' electronic information management system was carried out correctly by Radiographer C, and this included the (wrong) dose from the manual calculation. The associated dose calculation programme called RadCalc then calculated the daily dose to each side of the neck independently, and determined correctly that the manually calculated dose was 100% too high.

Believing that the RadCalc calculation was in error, the Radiographers involved sought assistance from a member to the ECC's Treatment Planning Section (Physicist A).

For reasons that remain unclear, Physicist A achieved an answer from RadCalc that appeared to agree with the (erroneous) manual calculations of the number of 'monitor units' to be set on the Linac for each treatment.

As a result of these errors the Linac delivered a total of 40Gy of radiation to the treatment area in 5 fractions of 8Gy, instead of the prescribed 20Gy in 5 fractions of 4Gy.

Regarding compliance with the duties of the employer under the IR(ME) Regulations, the finding of this investigation is that the structures in place at Lothian NHS Board for implementation of the duties of the employer, and for proper oversight of implementation of these duties were robust and, with minor concerns, were being applied properly. However, concerns have emerged regarding the adequacy of training provided to the operators involved, and these are considered likely to have contributed significantly to this incident.

Regarding compliance with the duties of the operators concerned, the finding of this investigation is that all of the practical aspects of the treatment undertaken by Radiographers B, C and D and by Physicist A were in keeping with their entitlement by the employer, and were in accordance with the relevant Employer's Written Procedures and Protocols. Concerns regarding recording of the entitlement of Radiographer A to carry out manual calculations unsupervised are discussed in Sections 6 and 7 of this report, but there is documented evidence that Radiographer A had completed the training considered by the employer to be adequate for this duty.

Section 9 of this report considers the 'concerns' mentioned in the three previous paragraphs in more detail, and the recommendations arising. Section 11 considers the need for these recommendations to be supported by formal enforcement action.

## 9. Recommendations arising

### 9.1 Recommendations concerning manual calculations

Regarding the ECC procedures for manual calculations, 'Towards Safer Radiotherapy' [2] recommends that :

*'Calculations should be checked by a different entitled operator, preferably using a different method and a separate data set. Reverse checking is an example of the use of a different method.'*

Prior to the autumn of 2013, in-house computer programs called 'T' and 'Check' were used as part of the treatment planning calculation and checking process. However, due to some lack of certainty about the applicability of the 'T' program for treatments using the new 'true beam' linear accelerators, a memo was circulated to the radiographers informing them that both the first and second calculations were to be done using the data tables.

Clearly, had a 'different method and a separate data set' been used, then it is highly unlikely that both manual calculations would have given the same wrong answer.

**Recommendation 1:** Relevant Employer's Written Procedures for manual calculations should be changed to ensure that the first and second calculations are carried out independently using a different method, and entitled operators should be appropriately retrained.

Further to this, the practice at the ECC was to carry out the two manual calculations using plain paper, check that the answers matched, and then transcribe the results of these manual calculations to the Radiotherapy Prescription Sheet (Figure 3). Since there is no formal procedure for subsequently checking the accuracy of this transcription, this allows that transcription errors might arise.

**Recommendation 2:** The practice of carrying out manual calculations using plain paper, and then transcribing the results to the Radiotherapy Prescription Sheet should be reviewed. In particular, the results of the second manual calculation should be checked or rechecked against the data that had already been transcribed to the Radiotherapy Prescription Sheet.

As discussed in Sub-section 4.5 of this report, the method of manual calculation for 'parallel opposed pair with 100cm FSD' as currently documented in ECC Employer's Written Procedure EP2\ECC\3402 'Calculating and Checking Monitor Units of Photon Beam Treatments-Manual Calculations' lacks clarity.



**Recommendation 3:** Review the description of the current method of manual calculation for parallel opposed pair treatments in ECC Employer's Written Procedure EP2\ECC\3402 and the way in which this calculation is laid out on the Radiotherapy Prescription Sheet. In particular, consider defining a method of calculation that divides the prescribed dose between the two beams, and modifying the layout of the manual calculation tables in the Radiotherapy Prescription Sheet to offer greater clarity about the entries required. An example of this is shown here in Figure 12. Any resulting changes should be followed by appropriate re-training of operators.

## 9.2 Recommendations concerning RadCalc calculations

The producers of the RadCalc software, Lifeline Software Inc., have advised that the method currently described for 'lateral parallel opposed pair at 100cm FSD', treatments in ECC Employer's Written Procedure EP\ECC\3422 'RadCalc Instructions', is not optimal.

**Recommendation 4:** A review of all Employer's Written Procedures and Protocols relevant to the use of RadCalc should be undertaken, with appropriate input from Lifeline Software Inc., to ensure that the methods used are in keeping with those recommended. This should include reconsideration of the terminology used (such as 'Isocentre\_3') and steps to ensure that consistent terminology is used in RadCalc and all related Employer's Written Procedures and Protocols.

From the interviews referred to in Sub-section 5.1 of this report, it is clear that whereas the Radiographers concerned considered themselves capable of operating RadCalc in accordance with the relevant ECC procedures and protocols, their understanding of the electronic calculation process was limited. This, coupled with their lack of confidence in the use of RadCalc for this particular form of treatment, led to failure to notice and take proper account of what should have been clear on-screen indications that, not only was their calculation out of tolerance, but since it was approximately 100% out, they had in all likelihood failed in their manual calculation to divide the prescribed dose of radiation between the two opposing fields.

**Recommendation 5:** Following a review of all relevant Employer's Written Procedures and Protocols, appropriate retraining of everyone involved in the use of RadCalc should be undertaken, and this should seek to ensure that all users have a clear understanding of the calculation process, and a high level of confidence in its results.

As discussed in Section 6, documented provisions for training in the use of RadCalc differ between the two Divisions involved, and there is no separate competence within the scope of entitlement of either the Radiographers or the Physicists for the use of RadCalc.

**Recommendation 6:** Training requirements for use of RadCalc should be formally documented within the ECC quality system and should be consistent for all Divisions involved. This should include pro-forma training records with provision for 'sign-off' by appropriately qualified and entitled trainers. In addition to an appropriate number and range of 'practice calculations', consideration should be given to the need for 'real patient' calculations carried out under supervision.

**Recommendation 7:** Appropriate competences that provide a clear separation between any other aspects of the calculation and checking procedures should be added to the list of authorized competences for operators in the Divisions involved. For example 'Competent to undertake RadCalc calculations for non-isocentric treatments to unequal FSD'.

**Recommendation 8:** The relevant Employer's Written Procedure should include an instruction that where the difference between the monitor units calculated manually and those calculated by RadCalc is out of tolerance for reasons that are not immediately evident, then the source data, its input to Aria, and the manual calculations must be re-visited.

Towards Safer Radiotherapy [2] recommends when new or changed treatment techniques or processes are to be introduced, a risk assessment should be undertaken and consideration given to additional verification procedures for the initial cohort of patients.

**Recommendation 9:** Following the introduction of any changes arising from these recommendations or otherwise, a risk assessment should be undertaken and appropriate verification procedures implemented for, at least, the initial cohort of patients.

**Recommendation 10:** Regarding the RadCalc programme itself, consideration should be given by Lifeline Software Inc. to the mistakes made by these operators and to whether any additional safeguards could be added to prevent or highlight inappropriate data entry or manipulation. For example, whereas at present the alert referred to in Sub-section 4.7. of this report [*The cumulative dose per fraction for the beams associated with this prescription exceeds that prescribed dose per fraction by 100%*] disappears following any change between screens, it might be more appropriate that this should persist.

### 9.3 Recommendations concerning the recording of training and entitlement of duty holders

This investigation has identified deficiencies in the current provisions for holding of operator training records and inconsistencies between the two Divisions involved. Concerns have also arisen about the linkage between training of operators and definition of their scope of entitlement.

**Recommendation 11:** Provisions for operator training for Radiographers and Physicists should be reviewed to ensure consistency in the training provided and in the means of recording satisfactory completion of training. Pro-forma training plans that include a number of elements that must be completed should include provision for identification of the person confirming satisfactory completion of that element, and the date.

**Recommendation 12:** The current instruction for staff in Treatment Planning Section that they need not retain evidence of training should be rescinded, and, in accordance with Regulation 11(4) and related guidance, training records that show clear evidence of 'the nature of the training' should be retained. Where possible, pro-forma documents intended to record evidence of training should be held as quality controlled documents.

**Recommendation 13:** Each member of staff should have a personal record of their scope of entitlement comprising a list of competences for their Division that has been authorised by the Division Head. The competences among those listed for which the duty holder is entitled should be clearly indicated by means which includes identification of the person conferring the entitlement and the date. This 'sign-off' should also clarify whether the duty holder concerned is also authorized to supervise trainees in this competence, and to provide and 'sign-off' the relevant training.

**Recommendation 14:** Where possible, there should be a clear linkage between each of these authorized competences and the training required prior to entitlement. For example, with regard to Sub-section 5.1 of this report, the prerequisite for sign-off of an operator competence 'Competent to carry out data entry to Aria for all treatment plans for which the operator is entitled' would be completion of the training defined in ECC controlled document number EP2\ECC\2037 'Training Plan: Data entry'.

**Recommendation 15:** Where a particular competence within the scope of entitlement of a duty holder is undertaken infrequently, consideration should be given to defining a separate requirement for maintenance of that competence. For example, where an operator has been deemed 'Competent to carry out manual calculations for all parallel opposed pair treatments

to unequal FSD', it might be appropriate to require that evidence should be recorded of at least three such actual or practice calculations having been undertaken in the previous year.

#### 9.4 Recommendations concerning Employer's Written Procedures and Protocols

This investigation has identified inconsistencies between the content of the Employer's Written Procedures and Protocols for the two Divisions involved, and with the content of the ECC's Level 1 and Level 2 Employer's Written Procedures.

**Recommendation 16:** A joint review of those Employer's Written Procedures and Protocols for treatment planning held by the Oncology Physics and by the Treatment Radiotherapy Divisions should be carried out to ensure that these are consistent in terms of the instructions given and the terminology used, and that, as appropriate, they are fully in keeping with the ECC's Level 1 and Level 2 Employer's Written Procedures. This should include due consideration of the need to avoid duplication of instructions, and to ensure that all such documents are freely available to staff in both Divisions and are compatible with their training and entitlement. For example Employer's Written Procedures EP2\ECC\0050, EP2\ECC\2200, EP2\ECC\2201 and EP2\ECC\3402 each describe the manual calculation process.

#### 9.5 Further measures to reduce the risk of overexposures

Towards Safer Radiotherapy [2] recommends that all centres should have protocols for in-vivo dosimetry monitoring for most patients at the beginning of treatment. *In vivo* and transit dosimetry, which can be described as being the use of detectors to measure the amount of radiation delivered, can detect some significant errors, and, if carried out at an early stage in the course of treatment, might allow corrective action to be taken.

**Recommendation 17:** The use of an in-vivo dosimetry tool should be considered for palliative patients.

While there were clear differences between the circumstances of the incident considered here and those of the Glasgow incident [3], a fundamental similarity is that in both cases the MU used were much higher than the figure normally expected for the treatment in question. This would suggest that if the prescribed MU could have been compared with an appropriate stored list of expected MU values for particular treatments, then the Radiographers would have been alerted to the fact that the MU figure was unusually high at some point prior to delivery of the first fraction of the treatment.

In this regard, Towards Safer Radiotherapy [2] notes that *'For some commonly delivered treatments, ... the range of monitor units per fraction falls within a predictable range for the*

*majority of patients' and recommends that 'Centres should consider which kinds of treatment fit into such categories and draw up lists of ranges of expected monitor units for certain beam configurations to assist staff in establishing familiarity with standard protocols'.*

The simplest form of such a check might be comparison of manually calculated MU with locally listed expectation values. However, an additional possibility is that this comparison could be carried out electronically. The optimal point for such an electronic comparison would be immediately prior to delivery of the first fraction of the treatment so that any foregoing errors in the MU calculation whether in the prescription, manual planning, transcription of data, or in electronic planning could be identified.

**Recommendation 18:** For those treatments for which 'the range of monitor units per fraction falls within a predictable range for the majority of patients' consideration should be given to how the prescribed MU can be compared to appropriate stored data, both manually and electronically, so that significant departures can be flagged ahead of treatment delivery.

## **10 Actions already taken by the ECC**

Treatment planning for this patient was started, but not completed, during the weekend 'on-call' period. Internal consideration of the circumstances of this incident has therefore led the ECC to review on-call staffing provisions and relevant on-call procedures. This has led to a number of changes including strengthening of on-call staffing, changes to on-call procedures, and the introduction of an additional calculation check for patients who commence their radiotherapy treatment during an on-call period.

The ECC has also undertaken a review of current practice in accordance with the 'Self Assessment Tool' in 'Towards Safer Radiotherapy'[2]

## **11 Consideration of the need for enforcement action**

### **11.1 Blame attributable to the employer**

This investigation has identified a number of areas for improvement in the means of implementation of the employer's duties under the Regulations, and these are the subject of the Recommendations in Section 9 of this report. Of particular concern among these is the quality and consistency of current arrangements for provision and recording of training and the linkage between training and entitlement of duty holders.

However, notwithstanding these concerns, no areas have been identified where the employer failed clearly to comply with the requirements of the Regulations. The general finding is, therefore, that the provisions that were in place for compliance with the employer's duties under the IR(ME) Regulations were robust and were being properly implemented and overseen.

### **11.2 Blame attributable to duty holders**

In considering the degree of fault or blame attributable to any of the operators involved with this incident, it is important to draw a distinction between wrongdoing, negligence, and making a mistake.

In this regard, this investigation has identified a number of mistakes made by the operators concerned in both the manual and electronic calculations involved. Given the combined level of experience of these operators, it could reasonably be expected that the errors involved should have been identified prior to treatment, particularly in light of the alerts and indications that arose during the independent monitor unit calculation in RadCalc.

However, no instances have been identified where it could be said clearly that these mistakes were as a result of wrongdoing by those involved, such as failing to follow documented procedures, or knowingly carrying out tasks for which they were neither trained nor entitled by the employer. Equally, nothing has emerged to suggest that any of these operators were negligent in their approach to their duties.

The general finding is, therefore, that the operators concerned acted in accordance with the Regulations in carrying out duties for which they believed themselves to be appropriately trained and experienced, albeit that the findings of this investigation indicate that this was not the case.

### **11.3 Consideration of the need for an Improvement Notice**

A previous investigation of the overexposure of Miss Lisa Norris at the Beatson Oncology Centre in Glasgow, reported in 2006, [3] identified a number of areas where the employer had failed to comply with the provisions of the IR(ME) Regulations. This resulted in the issue of an improvement notice to the employer under the provisions of Sections 21 and 22 of the Health and Safety at Work Act 1974.

For the incident under consideration here, no areas have been identified where the employer failed clearly to comply with the requirements of the Regulations. Nevertheless, serious consideration has again been given to the need for an Improvement Notice with regard to the provision and recording of operator training. However, given undertakings by the ECC

that these deficiencies are already under review, such enforcement action has been deferred pending consideration of the outcome of this internal review and the response of the ECC to the recommendations of this report.

The need for an Improvement Notice regarding training or any other aspect of the Recommendations of this report will be reviewed by the Inspector three months after the date of publication of this report.

## 12 Acknowledgements

In conducting this investigation and in compiling this report, thanks are due to Mrs Una Findlay of Public Health England, and to David Leslie and Dan Curran of the Scottish Government Health Directorates.

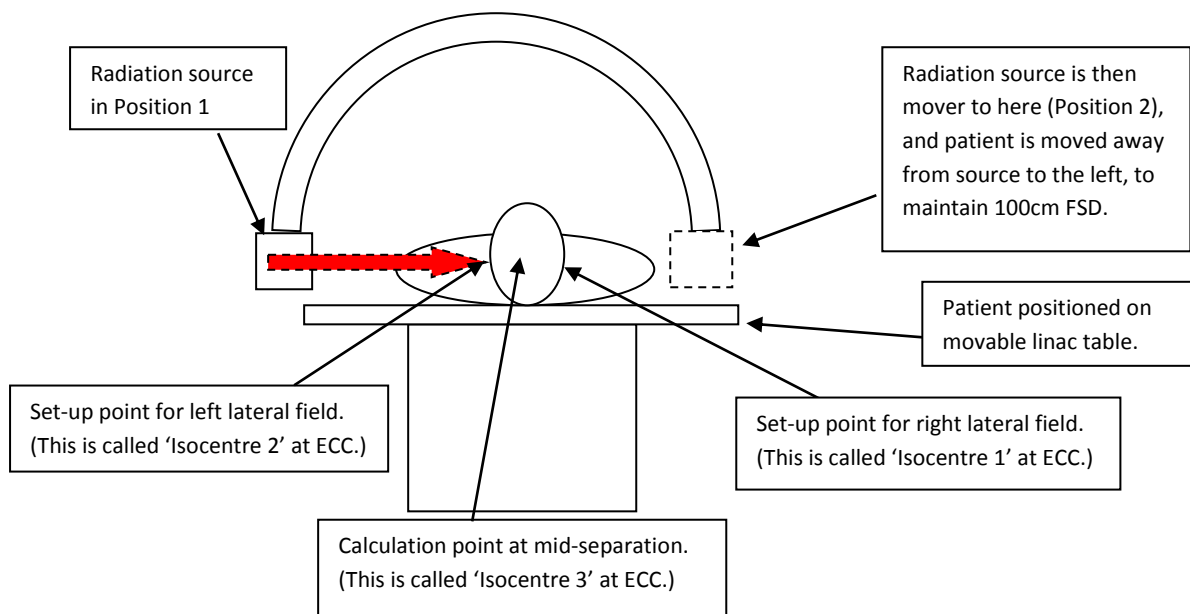
The co-operation of staff at the ECC in assisting with this investigation and in providing the documents requested by the Inspector is also acknowledged. In particular, those operators involved have been forthcoming in acknowledging and describing the errors made, and in helping to identify the underlying circumstances.

## 13 References:

1. *Statutory Instrument 2000 No. 1059, The Ionising Radiation (Medical Exposure) Regulations 2000*. HMSO, London. <http://www.opsi.gov.uk/si/si2000/20001059.htm>
2. 'Towards Safer Radiotherapy' (2007) London: British Institute of Radiology, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, Society and College of Radiographers, The Royal College of Radiologists.  
([https://www.rcr.ac.uk/sites/default/files/publication/Towards\\_saferRT\\_final.pdf](https://www.rcr.ac.uk/sites/default/files/publication/Towards_saferRT_final.pdf))
3. Johnston, A. M. (2006) Report of an investigation by the Inspector appointed by the Scottish Ministers under the Ionising Radiation (Medical Exposure) Regulations.  
(<http://www.gov.scot/Resource/Doc/153082/0041158.pdf>)



**Figure 1:** Showing the position of the C3 vertebra. This shows that had the treatment been prescribed as a single beam incident from behind the neck, the proportion of this radiation not absorbed in the region of the spine would have exited via the area of the mouth with possible damage to sensitive tissues such as salivary glands. Hence the decision to use a 'lateral parallel opposed pair' treatment.

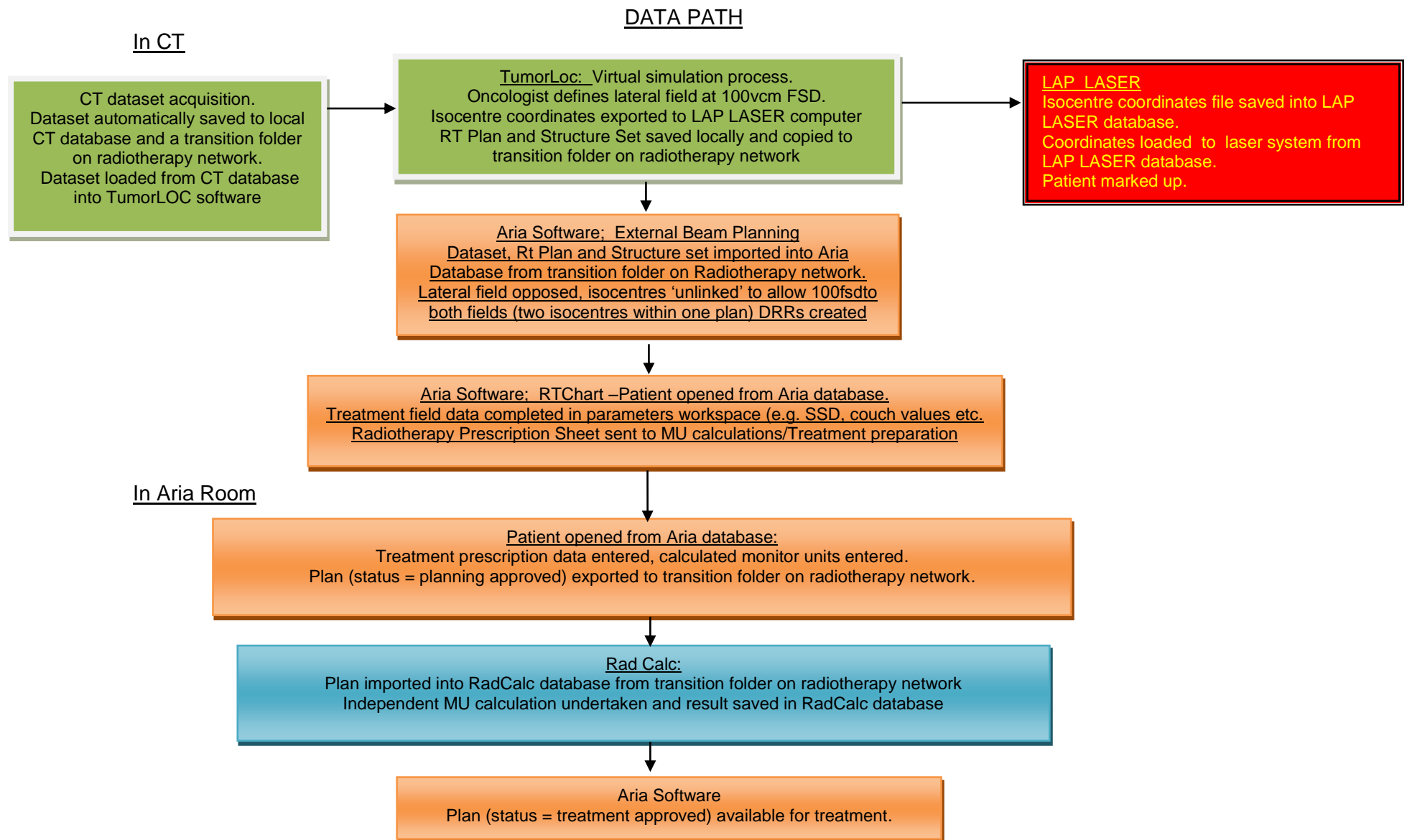


**Figure 2 :** Showing the 'reference points' and how the patient is positioned relative to the Linac head (the radiation source) for a 'parallel opposed pair' treatment. In this case, the distance between the linac head and the side of the neck was set to 100cm for both sides of the neck.

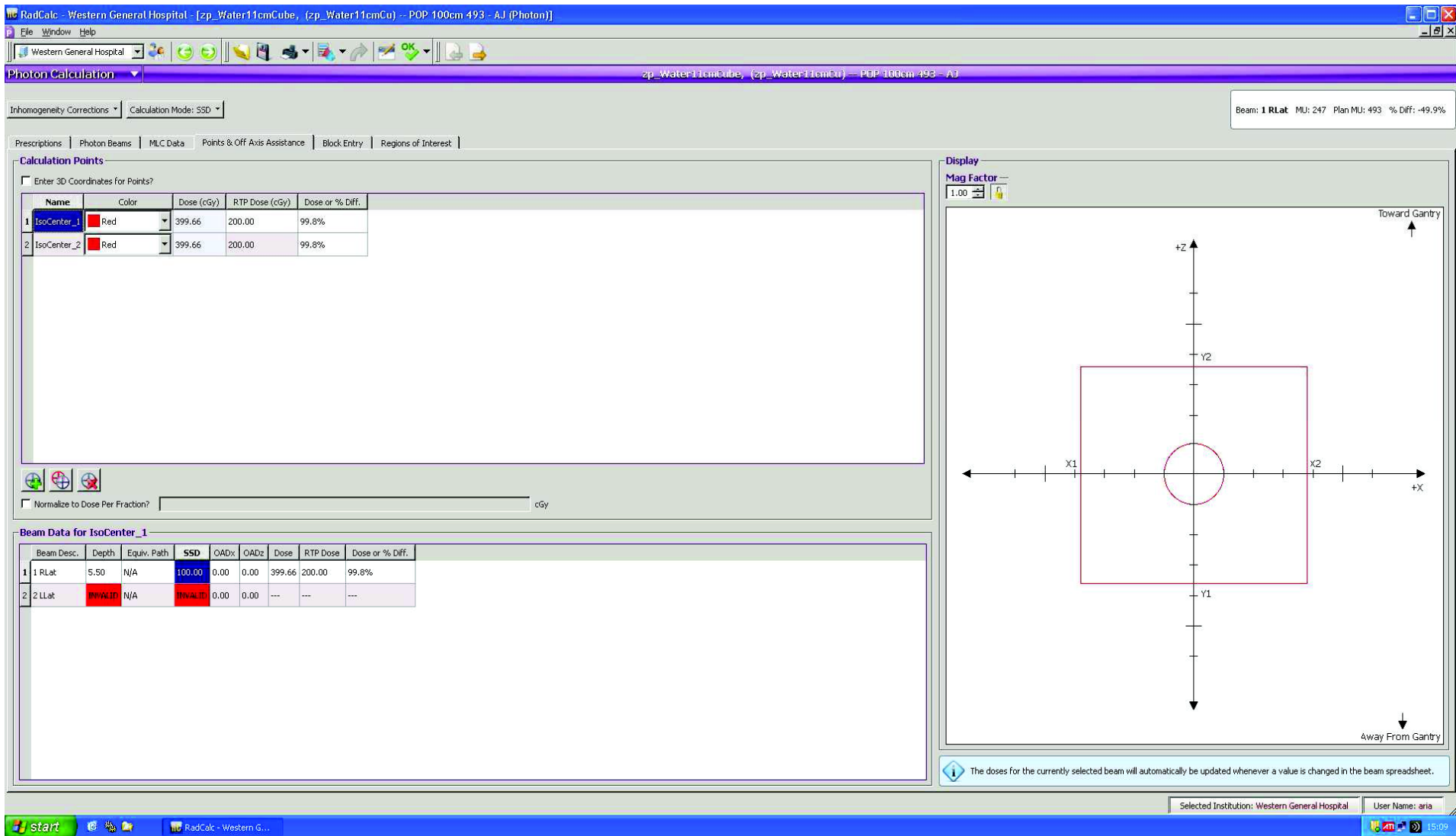


PLANNING CALCULATION			
FIELD	Rt Lat	Lt Lat	
OUTPUT	.983	.983	
CORRECTION FACTOR	-	-	
FINAL OUTPUT (cGy/mu)	.983	.983	
DEPTH DOSE DATA	82.6% in 5# @ 5.5 cm	2000 cGy	
GIVEN DOSE (cGy)	2422	2422	
TOTAL MONITOR UNITS	2464	2464	
MONITOR UNITS PER#	493	493	
BU PLAN REQ Y / N	BU MACHINE		

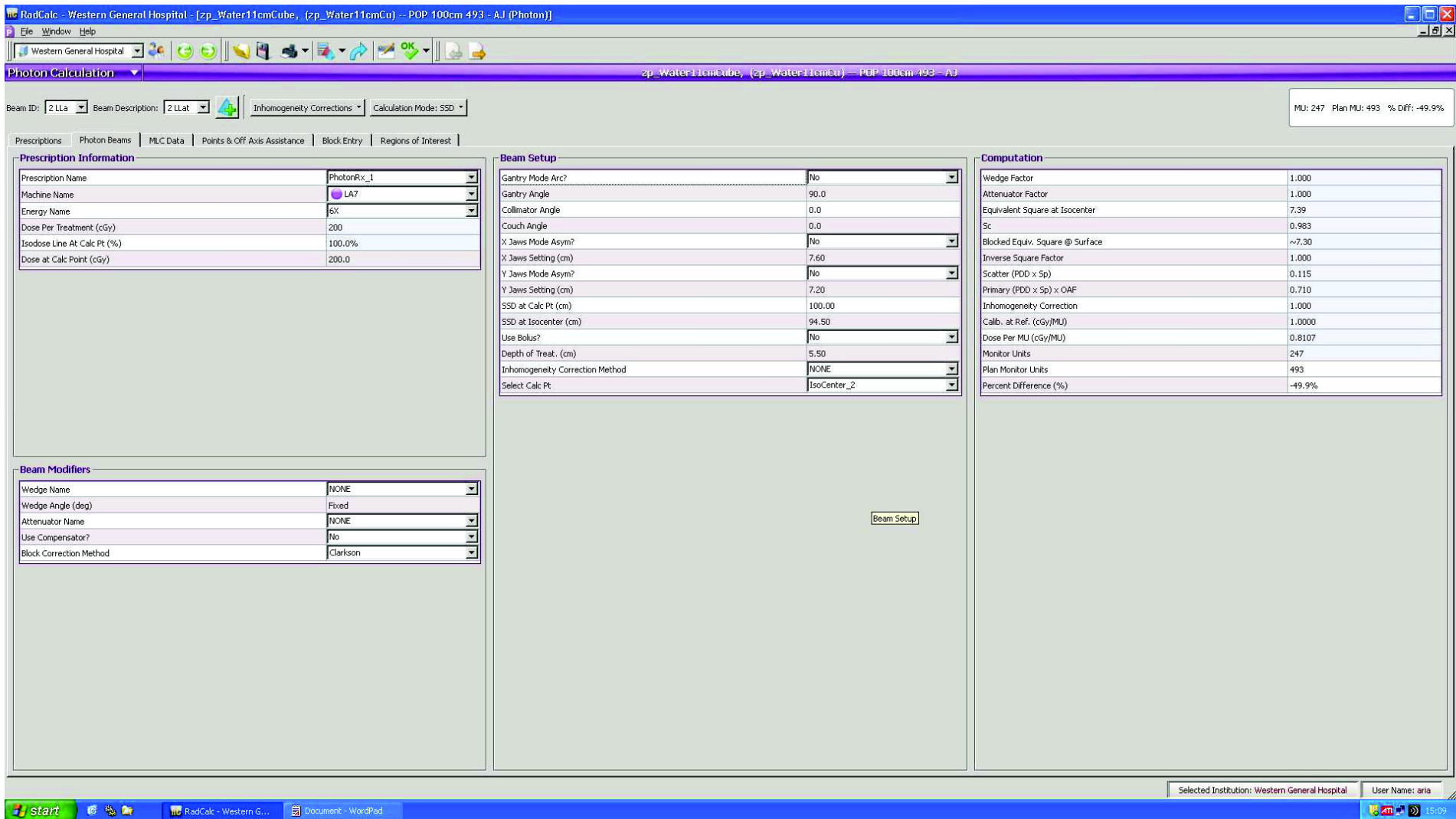
**Figure 3:** A copy of the section from the 'Radiotherapy Prescription Sheet' for this patient showing the erroneous 'Depth Dose Data' calculation



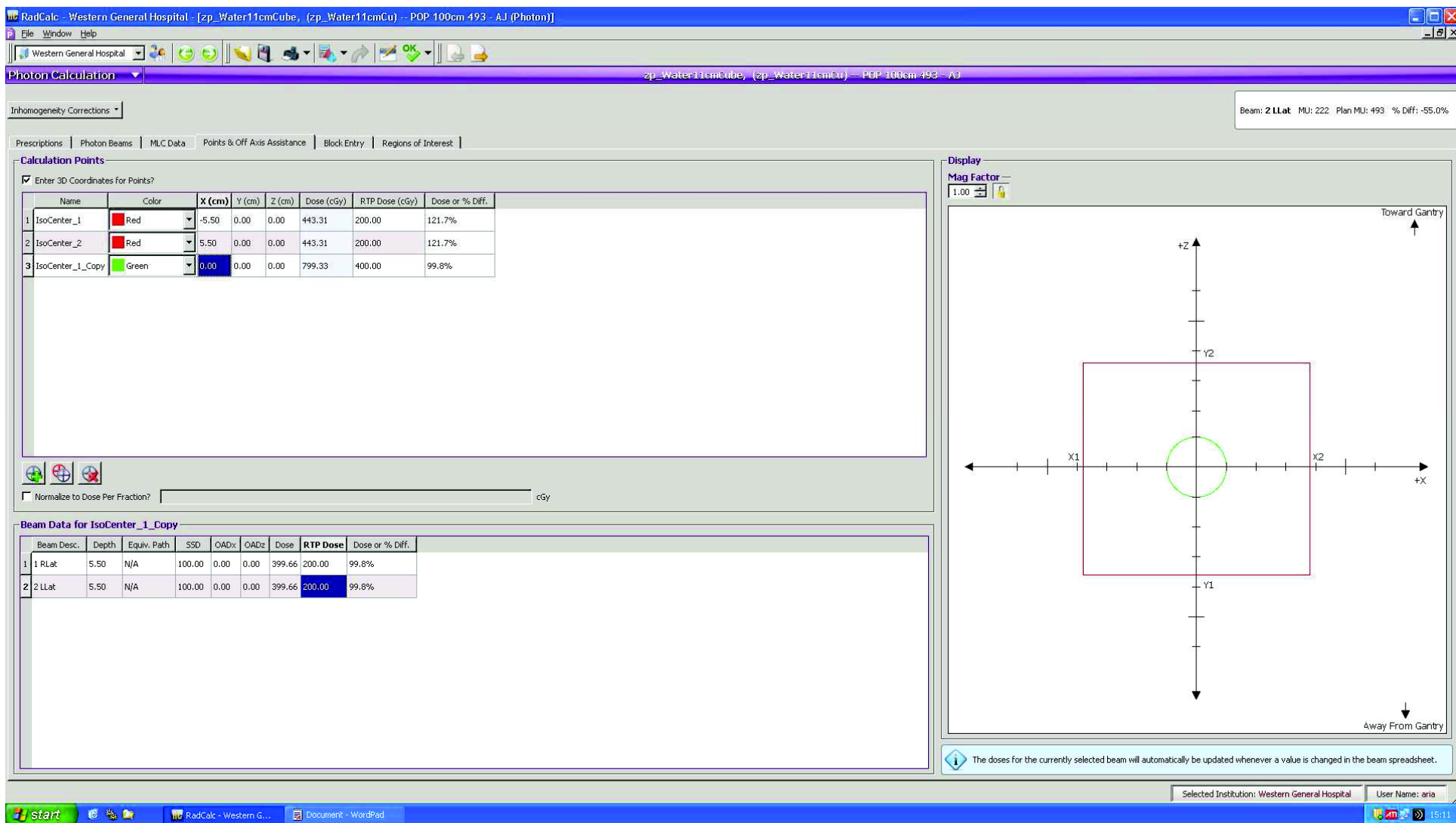
**Figure 4:** Showing the workflow for the various computer programmes used at the ECC for treatment planning and delivery, including the specialist software (RadCalc) used for independent MU calculation.



**Figure 5:** A 'screenshot' from RadCalc showing the first 'Points and Off-Axis Assistance' screen that would have appeared for this patient. The point highlighted in the 'Calculation Points' screen 'IsoCenter\_1' is the right side of the neck, hence the information in the 'Beam Data' section is for the '1Rt Lat' beam (the beam from the right hand side) only, and data for the 2Lt Lat beam is correctly shown as being 'invalid' for this point.



**Figure 6:** A 'screenshot' from RadCalc showing the first 'Photon Beams' screen that would have appeared for this patient. The data shown (top left) is for the '2Lt Lat' beam (the beam from the left to 'IsoCenter\_2'), and, at this point in time, the point selected in the 'Select Calc Pt' field of the 'Beam Setup' section is 'IsoCenter\_2'.



**Figure 7:** A 'screenshot' from RadCalc showing the first 'Points and Off-Axis Assistance' screen that would have appeared for this patient on correct completion of all of the steps defined in Appendix 2. The box at the top right shows that the difference between the calculated MU for the Lt Lat beam (as selected at the top left) and the manually calculated figure that was entered into Aria (493) is well out of tolerance.

Inhomogeneity Corrections | Calculation Mode: SSD

Beam: 1RT LAT MU: 488 Plan MU: 493 % Diff: -1.0%

Prescriptions | Photon Beams | MLC Data | Points & Off Axis Assistance | Block Entry | Regions of Interest

Calculation Points

Enter 3D Coordinates for Points?

Name	Color	Dose (cGy)	RTP Dose (cGy)	Dose or % Diff.
1 IsoCenter_1	Red	807.97	800.00	1.0%
2 IsoCenter_2	Red	3470.59	200.00	1635.3%
3 IsoCenter_3	Green	807.97	800.00	1.0%

Display  
Mag Factor: 1.00

Normalize to Dose Per Fraction? cGy

Beam Data for IsoCenter\_1

Beam Desc.	Depth	Equiv. Path	SSD	OADx	OADz	Dose	RTP Dose	Dose or % Diff.
1 1RT LAT	5.50	N/A	100.00	0.00	0.00	403.98	400.00	1.0%
2 2LT LAT	5.50	N/A	100.00	0.00	0.00	403.98	400.00	1.0%

The doses for the currently selected beam will automatically be updated whenever a value is changed in the beam spreadsheet.

Selected Institution: Western General Hospital | User Name: aria

**Figure 8:** A 'screenshot' from RadCalc showing the saved 'Points and Off-Axis Assistance' screen for this patient. Comparing this to Figure 5, the RTP Dose for the '1Rt Lat' beam has been changed from 200 to 400 and data entered for the '2Rt Lat' beam where clearly there should be none.

Inhomogeneity Corrections | Calculation Mode: SSD

Beam: **IRT LAT** MU: 488 Plan MU: 493 % Diff: -1.0%

Prescriptions | Photon Beams | MLC Data | Points & Off Axis Assistance | Block Entry | Regions of Interest

**Calculation Points**

Enter 3D Coordinates for Points?

Name	Color	Dose (cGy)	RTP Dose (cGy)	Dose or % Diff.
1 IsoCenter_1	Red	807.97	800.00	1.0%
2 IsoCenter_2	Red	3470.59	200.00	1635.3%
3 IsoCenter_3	Green	807.97	800.00	1.0%

Normalize to Dose Per Fraction? \_\_\_\_\_ cGy

**Beam Data for IsoCenter\_3**

Beam Desc.	Depth	Equiv. Path	SSD	OADx	OADz	Dose	RTP Dose	Dose or % Diff.
1 IRT LAT	5.50	N/A	100.00	0.00	0.00	403.98	400.00	1.0%
2 2LT LAT	5.50	N/A	100.00	0.00	0.00	403.98	400.00	1.0%

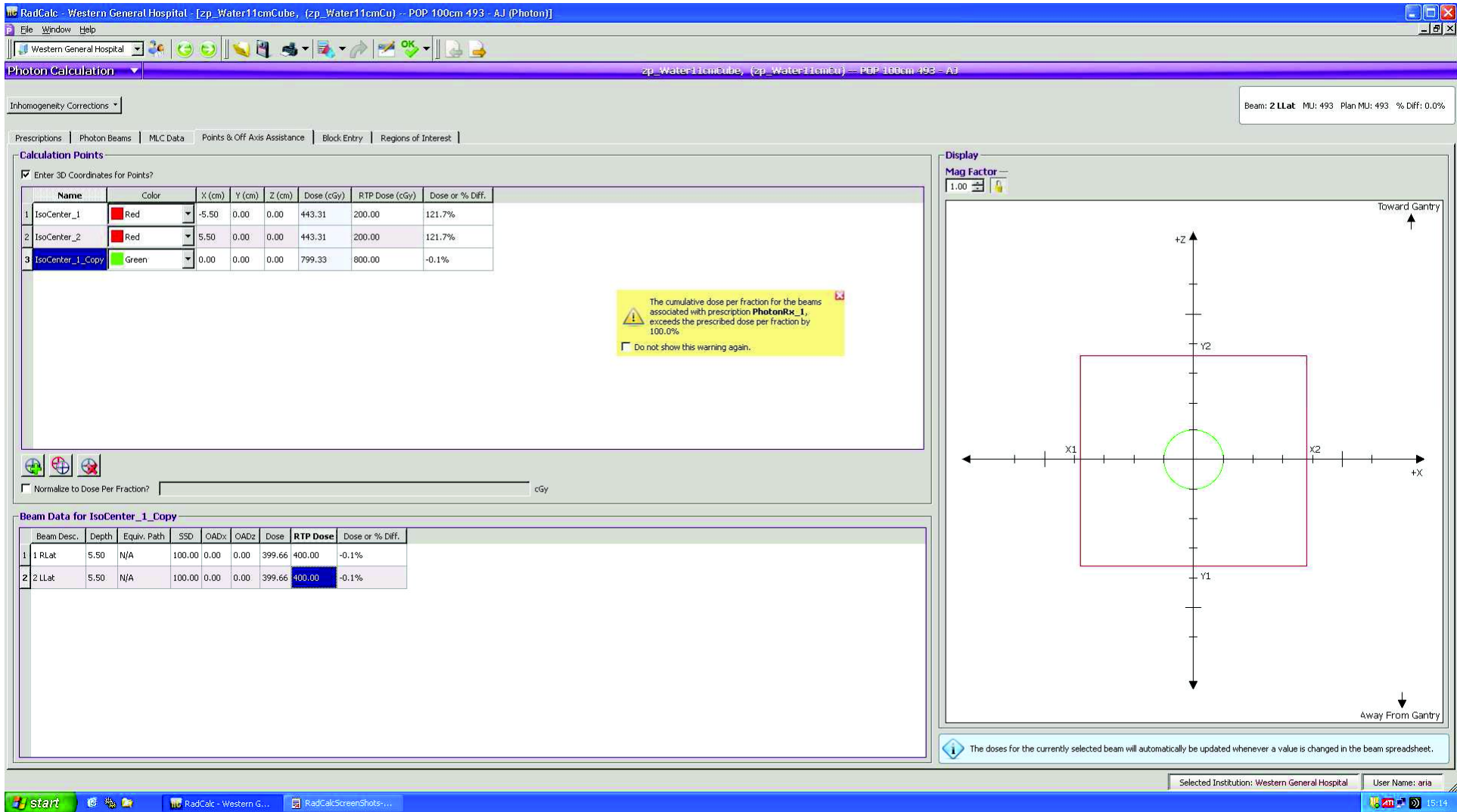
**Display**

Mag Factor: 1.00

The doses for the currently selected beam will automatically be updated whenever a value is changed in the beam spreadsheet.

Selected Institution: Western General Hospital | User Name: aria

**Figure 9:** A 'screenshot' from RadCalc showing the saved 'Points and Off-Axis Assistance' screen for this patient. Comparing this to Figure 7, the change in the RTP Dose from 200 to 400 has led to apparent agreement between the MU as calculated manually and by RadCalc, to within 1%. (The 'Dose cGy' figure appearing the 'Calculation Points' screen for 'IsoCenter\_2' has no validity here because the 'Depth' for this beam in the 'Beam Data' section has not been set.)



**Figure 10:** A 'screenshot' from RadCalc showing the same 'Points and Off-Axis Assistance' screen as in Figure 7 except that in this case the original RTP Dose entries (200) have been changed to '400', as in Figure 9, to demonstrate that this causes the appearance of the yellow alert box.



Beam ID: IRT L Beam Description: IRT LAT Inhomogeneity Corrections Calculation Mode: SSD MU: 488 Plan MU: 493 % Diff: -1.0%

Prescriptions Photon Beams MLC Data Points & Off Axis Assistance Block Entry Regions of Interest

**Prescription Information**

Prescription Name	PhotonRx_1
Machine Name	LA7
Energy Name	6X
Dose Per Treatment (cGy)	200
IsoDose Line At Calc Pt (%)	200.0%
Dose at Calc Point (cGy)	400.0

**Beam Setup**

Gantry Mode Arc?	No
Gantry Angle	270.0
Collimator Angle	90.0
Couch Angle	0.0
X Jaws Mode Asym?	No
X Jaws Setting (cm)	8.00
Y Jaws Mode Asym?	No
Y Jaws Setting (cm)	8.00
SSD at Calc Pt (cm)	100.00
SSD at Isocenter (cm)	94.50
Use Bolus?	No
Depth of Treat. (cm)	5.50
Inhomogeneity Correction Method	NONE
Select Calc Pt	IsoCenter_3

**Computation**

Wedge Factor	1.000
Attenuator Factor	1.000
Equivalent Square at Isocenter	8.00
Sc	0.968
Blocked Equiv. Square @ Surface	~7.86
Inverse Square Factor	1.000
Scatter (PDD x Sp)	0.120
Primary (PDD x Sp) x OAF	0.710
Inhomogeneity Correction	1.000
Calib. at Ref. (cGy/MU)	1.0000
Dose Per MU (cGy/MU)	0.8194
Monitor Units	488
Plan Monitor Units	493
Percent Difference (%)	-1.0%

**Beam Modifiers**

Wedge Name	NONE
Wedge Angle (deg)	Fixed
Attenuator Name	NONE
Use Compensator?	No
Block Correction Method	Clarkson

Selected Institution: Western General Hospital User Name: ariah

**Figure 11:** The saved 'Photon Beams' 'screenshot' from RadCalc for this patient. Comparing this to Figure 6, the Dose at Calc Pt (cGy) for the selected '1Rt Lat' beam has changed from '200' to '400' and, consequently, the 'IsoDose Line at calc Pt (%)' entry has changed from 100% to 200%.

<b>A</b>	<b>Field</b>	<b>Rt Lat</b>	<b>Lt Lat</b>
<b>B</b>	<b>Contribution to prescribed dose from this field (cGy)</b>	1000	1000
<b>C</b>	<b>Depth dose correction</b>	0.826	0.826
<b>D</b>	<b>Given dose at skin (cGy) (B/C)</b>	1211	1211
<b>E</b>	<b>Output from Linac (cGy/mu)</b>	0.983	0.983
<b>F</b>	<b>Correction factor</b>	1	1
<b>G</b>	<b>Final output (cGy/mu) (ExF)</b>	0.983	0.983
<b>H</b>	<b>Total monitor units (D/G)</b>	1232	1232
<b>I</b>	<b>Number of fractions</b>	5	5
<b>J</b>	<b>Monitor units per fraction (H/I)</b>	246	246

**Figure 12:** A possible alternative layout to that in Figure 3 for the manual calculation table in the 'Radiotherapy Planning Sheet' for this patient, where the prescribed dose is divided between the two beams and entered into this table, and the labelling and ordering of the rows has been changed for greater clarity.

**Appendix 1:**  
Depth dose tables.

**LA4/5**

Varian **8MV** linear Accelerator

Percentage Depth Doses at 90 cm FSD for use between 80 and 100 cm FSD

AREA (sq cm)	DEPTH (CM)																					
	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.5	13.0
20	98.3	96.1	94.0	91.8	89.5	87.2	85.0	82.6	80.3	78.0	75.7	73.4	71.6	69.6	67.6	65.7	63.9	62.1	60.3	58.6	57.0	55.4
40	98.3	96.3	94.2	92.1	90.0	87.8	85.6	83.4	81.2	79.0	76.8	74.6	73.0	70.9	69.0	67.1	65.2	63.5	61.7	60.0	58.4	56.8
60	98.3	96.4	94.3	92.3	90.2	88.1	86.0	83.8	81.7	79.5	77.4	75.2	73.7	71.7	69.7	67.9	66.0	64.3	62.5	60.9	59.2	57.6
80	98.4	96.4	94.4	92.3	90.3	88.2	86.2	84.1	82.0	79.9	77.8	75.7	74.2	72.2	70.3	68.4	66.6	64.8	63.1	61.5	59.8	58.3
100	98.4	96.4	94.4	92.4	90.4	88.3	86.3	84.2	82.2	80.1	78.0	76.0	74.5	72.6	70.7	68.8	67.0	65.3	63.6	61.9	60.3	58.7
120	98.4	96.4	94.4	92.4	90.4	88.4	86.4	84.4	82.3	80.3	78.3	76.2	74.8	72.9	71.0	69.1	67.4	65.6	63.9	62.3	60.7	59.1
140	98.4	96.4	94.5	92.5	90.5	88.5	86.5	84.5	82.5	80.5	78.4	76.4	75.0	73.1	71.2	69.4	67.6	65.9	64.2	62.6	61.0	59.4
160	98.4	96.4	94.5	92.5	90.5	88.5	86.6	84.6	82.6	80.6	78.6	76.6	75.2	73.3	71.5	69.6	67.9	66.2	64.5	62.9	61.3	59.7
180	98.4	96.4	94.5	92.5	90.6	88.6	86.6	84.6	82.7	80.7	78.7	76.8	75.4	73.5	71.7	69.9	68.1	66.4	64.7	63.1	61.5	60.0
200	98.4	96.4	94.5	92.5	90.6	88.6	86.7	84.7	82.7	80.8	78.8	76.9	75.6	73.7	71.8	70.0	68.3	66.6	64.9	63.3	61.7	60.2
220	98.4	96.4	94.5	92.6	90.6	88.7	86.7	84.8	82.8	80.9	78.9	77.0	75.7	73.8	72.0	70.2	68.4	66.7	65.1	63.5	61.9	60.4
240	98.4	96.4	94.5	92.6	90.6	88.7	86.8	84.8	82.9	81.0	79.0	77.1	75.8	73.9	72.1	70.3	68.6	66.9	65.3	63.6	62.1	60.6
260	98.4	96.4	94.5	92.6	90.6	88.7	86.8	84.9	82.9	81.0	79.1	77.2	75.9	74.1	72.2	70.5	68.7	67.0	65.4	63.8	62.2	60.7
280	98.4	96.4	94.5	92.6	90.7	88.7	86.8	84.9	83.0	81.1	79.2	77.3	76.0	74.2	72.3	70.6	68.9	67.2	65.5	63.9	62.4	60.9
300	98.4	96.4	94.5	92.6	90.7	88.8	86.9	84.9	83.0	81.2	79.3	77.4	76.1	74.3	72.5	70.7	69.0	67.3	65.7	64.1	62.5	61.0
350	98.4	96.4	94.5	92.6	90.7	88.8	86.9	85.0	83.2	81.3	79.4	77.6	76.3	74.5	72.7	70.9	69.2	67.6	65.9	64.4	62.8	61.3
400	98.4	96.4	94.5	92.6	90.8	88.9	87.0	85.1	83.2	81.4	79.5	77.7	76.5	74.7	72.9	71.1	69.4	67.8	66.2	64.6	63.1	61.6
450	98.4	96.5	94.6	92.7	90.8	88.9	87.0	85.2	83.3	81.5	79.7	77.8	76.6	74.8	73.0	71.3	69.6	68.0	66.4	64.8	63.3	61.8
500	98.4	96.5	94.6	92.7	90.8	88.9	87.1	85.2	83.4	81.6	79.8	78.0	76.8	74.9	73.2	71.5	69.8	68.1	66.5	65.0	63.5	62.0
550	98.4	96.5	94.6	92.7	90.8	89.0	87.1	85.3	83.5	81.6	79.8	78.1	76.9	75.1	73.3	71.6	69.9	68.3	66.7	65.1	63.6	62.1
600	98.4	96.5	94.6	92.7	90.9	89.0	87.2	85.3	83.5	81.7	79.9	78.1	77.0	75.2	73.4	71.7	70.1	68.4	66.8	65.3	63.8	62.3
650	98.3	96.5	94.6	92.7	90.9	89.0	87.2	85.4	83.6	81.8	80.0	78.2	77.1	75.3	73.5	71.8	70.2	68.5	67.0	65.4	63.9	62.4
700	98.3	96.5	94.6	92.8	90.9	89.1	87.2	85.4	83.6	81.8	80.1	78.3	77.1	75.4	73.6	71.9	70.3	68.7	67.1	65.5	64.0	62.5
750	98.3	96.5	94.6	92.8	90.9	89.1	87.3	85.5	83.7	81.9	80.1	78.4	77.2	75.4	73.7	72.0	70.4	68.8	67.2	65.6	64.1	62.7
800	98.4	96.5	94.6	92.8	90.9	89.1	87.3	85.5	83.7	81.9	80.2	78.4	77.3	75.5	73.8	72.1	70.5	68.8	67.3	65.7	64.2	62.8
850	98.4	96.5	94.6	92.8	91.0	89.1	87.3	85.5	83.7	82.0	80.2	78.5	77.3	75.6	73.9	72.2	70.5	68.9	67.4	65.8	64.3	62.9
900	98.4	96.5	94.6	92.8	91.0	89.2	87.4	85.6	83.8	82.0	80.3	78.5	77.4	75.6	73.9	72.3	70.6	69.0	67.4	65.9	64.4	63.0

**Appendix 2:**

The relevant section from the ECC's Employer's Written Procedure EP2\ECC\3422 'RadCalc instructions' for parallel opposed pair at 100cm FSD calculations

**For patients with POP calculation at 100cm FSD:**

- A new calculation point must be created that sits midway between the 2 isocentres.
- In Points & Off Axis Assistance, copy the IsoCenter\_1 point by clicking on the middle button "copy point".
- Tick "Enter 3D coordinates for point" and look at the x, y, and z coordinates for Isocentre\_1 and Isocentre\_2 to find out which value differs. If they are lateral fields, the x value will be different. If they are ant/post fields, the y value will be different.
- Set whichever value differs to zero for IsoCenter\_3.
- With IsoCenter\_3 selected, set the SSD for both beams to 100cm and then enter the prescribed dose per fraction in RTP Dose.
- On the photon beams tab, select Calc Pt as IsoCenter\_3 for both beams.



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