



Unintended overexposure of patient Lisa Norris during radiotherapy treatment at the Beatson Oncology Centre, Glasgow in January 2006

Covering note

It was during the final stages of preparation for the publication of this report that I received the tragic news of the death of Miss Lisa Norris. Like people across Scotland, I had followed reports of her progress and shared the widespread admiration of the courage and dignity that she showed. All of those who have assisted me in conducting the incident investigation wish to join with me in expressing our sincere condolences to Lisa's family for their sad loss.

One of the main purposes of my report is to make recommendations aimed at lessening the risk of any similar incident at the Beatson Oncology Centre in Glasgow and elsewhere. It is important, therefore, that the report is available for general distribution and I wish to express my thanks to Lisa's family for their co-operation in allowing this to happen.

The report is the result of a detailed investigation into the nature of the error and how it arose. A change was made to a system of working without adequate analysis of the possible consequences for patient safety. An inexperienced treatment planner therefore failed to identify a critical consequence of this change and a critical error in data passed unidentified to the radiographer responsible for treatment delivery. By the time that the error was identified Miss Norris had received 19 out of the prescribed 20 treatment fractions. The total dose of radiation received was therefore some 58% higher than the dose prescribed.

The general intent of the recommendations arising from this report is to raise awareness of the need for the maintenance and implementation of quality working systems in all areas where patient safety is of concern. Heavy commitments to other areas of work can often deflect attention from this need but it is precisely in these circumstances that the risk for error is greatest and appropriate management intervention is most crucial.

I am conscious of the potential for the content of this report to add to the concerns of those undergoing radiotherapy treatments at the Beatson Oncology Centre. In this regard I should offer my assurance that my investigations have left me in no doubt of the dedication of the Beatson staff and of their commitment to the safety of patients in their care. It would be remiss of me not to acknowledge the many thousands of life-saving radiotherapy treatments that are successfully prescribed, planned and delivered at the Beatson Oncology Centre and, indeed, at the other radiotherapy centres in Scotland every year. Proper attention to the lessons learned from this incident and to the recommendations contained in the report will further enhance the safety of these treatments.

I would urge all of those working in the health services to ensure that the lessons that can be learned from this incident help in ensuring that future risks to patient safety are significantly lessened.

Dr Arthur M Johnston
Warranted Inspector appointed by the Scottish Ministers

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Executive Summary

Introduction

1. Between 5th January 2006 and 31st January 2006, patient Lisa Norris, who was then 15 years old, received a dose of ionising radiation much greater than that intended while undergoing a course of radiotherapy at the Beatson Oncology Centre (BOC) in Glasgow. The incident has been investigated by the Inspector warranted by the Scottish Ministers as regulators for *Statutory Instrument 2000 No. 1059, The Ionising Radiation (Medical Exposures) Regulations 2000* (the IR(ME) Regulations).
2. The Inspector's report records the findings of the incident investigation. It identifies the error that caused this overexposure and includes consideration of the deficiencies that contributed to the error and where responsibilities for these deficiencies lay. It also makes recommendations intended to minimize the possibility of recurrence of any similar error and to enhance patient safety in radiotherapy more generally.

Background

3. When a patient is referred for radiotherapy, a clinical oncologist determines the method of treatment and the total radiation dose. To optimize the safety and effectiveness of this treatment, this total dose is usually delivered in fractions, normally one per day, and careful, detailed planning is needed to ensure that each fractional dose of radiation is properly targeted.
4. Treatment plans vary in complexity, the more complex relying on computer treatment planning systems designed for this purpose. The computer treatment planning system used by treatment planning staff at the BOC is a module called *Eclipse* (registered trade mark). which is a major component of a comprehensive computer system called *Varis* (registered trade mark). The output from *Eclipse* is a Treatment Plan Report that includes treatment delivery parameters.
5. In May of 2005 the *Varis* system at the BOC was upgraded to *Varis 7*. This change allowed the treatment delivery parameters in the *Eclipse* Treatment Plan Report to be transferred electronically to another software module within the *Varis* system. Previously, this transfer was by manual transcription of data to paper forms. However, for some of the most complex treatment plans, including the 'whole CNS' (central nervous system) plan which is the subject of this report, the use of paper forms was retained at the BOC.

The nature and consequences of the error

6. Changing to the new *Varis 7* system introduced a specific feature that, if selected by the treatment planner, changed the nature of the data in the *Eclipse* Treatment Plan Report relative to that in similar reports prior to the May 2005 upgrade. This feature was selected but the critical error was that the treatment planner who transcribed the resulting data from the Treatment Plan Report to the paper form (the planning form) was unaware of this difference and therefore failed to take the action necessary to accommodate the changed data. Further details relating to this feature and the related error are in sub-section 4.2.3 of the report.
7. The outcome was that the figure entered on the planning form for one of the critical treatment delivery parameters was significantly higher than the figure that should have been used.
8. This parameter, the 'Monitor Units' is a number that relates directly to the dose of radiation to be delivered and is set on the console of the treatment unit (the linear accelerator of 'Linac'). This setting is, in turn, transmitted automatically to a monitor within the Linac which measures the amount of radiation delivered to the patient. This monitor then ensures that treatment stops when the prescribed dose of radiation has been received.
9. The error was not identified in the checking process for the treatment plan and the planning form with the erroneous entry was passed to the radiographer who managed treatment delivery.
10. The Monitor Unit setting used for each of the first 19 daily treatments was therefore too high and the cumulative radiation dose received by Miss Norris in these 19 fractions was some 58% higher than the total that was prescribed for the whole of this course of treatment.
11. The error came to light because the same treatment planner made the same error in the next allotted plan of this type for a different patient. On this occasion, however, the error was discovered by a treatment planning colleague and an immediate internal investigation was initiated which subsequently demonstrated the error for Miss Norris. By this time she had received 19 treatment fractions. The investigation confirmed, however, that no other patient at the BOC had been affected.
12. It is important to note that the error described above was procedural and was not associated in any way with faults or deficiencies in the *Varis 7* computer system.
13. Upon discovery, the overexposure was reported promptly by the BOC to the Inspector warranted by the Scottish Ministers for the IR(ME) Regulations. Initial verbal reporting was followed by a written incident report.
14. Because of this overdose, the second phase of the prescribed treatment for Miss Norris that was scheduled to follow the whole CNS procedure, involving targeted irradiation of the tumour region, was abandoned on the instruction of the clinical oncologist.

The circumstances of the error

15. Treatment planning for Miss Norris was carried out by a treatment planner (referred to in this report as 'Planner B') of limited experience under the supervision of an experienced colleague ('Principal Planner A'). In consideration of the circumstances under which the error was made and was carried through undetected to treatment delivery, the report identifies and describes deficiencies in a number of areas including the following:
- i. There were deficiencies in the BOC's compliance with the IR(ME) Regulations.
 - Training records were out of date.
 - Written procedures including working instructions for whole CNS planning were out of date and did not reflect current practice.
 - ii. There was evidence of a general inadequacy of staffing provisions for the proper establishment and maintenance of a suitable system of quality management for radiotherapy treatment planning at the BOC.
 - iii. There was a failure to ensure that the appropriate level of training and experience was brought to bear on planning the treatment for Miss Norris.
 - The training records for Planner B have no indication of formal competence for planning this particular, complex procedure.
 - Planner B had limited experience of 'whole CNS' planning and was not aware that changes associated with the upgrading of the computer system to *Varis 7* had introduced a need for a critical change in the way that treatment delivery data was transferred to the relevant planning form.
 - The supervision provided to Planner B in compiling this treatment plan was insufficient.
 - Checking of the treatment plan was not independent of supervision.
 - iv. The needs for changes to working practices and procedures and for additional training to address any potential implications for patient safety of the change in computer systems in May 2005 were not properly assessed.
 - v. The potential improvements to patient safety following the introduction of new technologies were not properly assessed or implemented.
 - vi. There was a lack of written statements and of common understanding about individual responsibilities.
 - vii. The lessons and recommendations from previous incidents at other radiotherapy centres had not been addressed.

Responsibilities

16. The report concludes that most of the responsibility and hence any blame that can be attributed to treatment planning staff at the BOC falls to the staff member referred to in the report as Principal Planner A. This conclusion is in consideration of Principal Planner A's roles in both supervising and checking the plan in question and in allocating planning duties to an inexperienced colleague and of wider involvement in the management of the BOC's treatment planning provisions. However, the report also concludes that the actual level of attributable blame requires due consideration of the background circumstances at the BOC that contributed to risk of occurrence

for this incident, including general deficiencies in the BOC's quality management systems and deficiencies in staffing resources.

Actions and recommendations

17. The BOC, both as an immediate consequence of the incident and in response to the recommendations made in the subsequent internal incident investigation, has introduced a number of procedural changes aimed at minimizing the possibility of recurrence of any similar occurrences. These are summarized in the report.

18. Additional recommendations for further actions required at the BOC include, in summary:

- A review of the responsibilities of those staff at the BOC with duties related to the IR(ME) Regulations.
- A review of the adequacy of staffing provisions for treatment planning at the BOC.
- Consideration of the need for treatment planning requests to be submitted on a timescale that allows proper distribution of work among treatment planning staff.
- Changes to the treatment planning and delivery systems must be subject to a formal review of possible safety implications by suitably qualified staff.
- Introduction of a written procedure giving clear instruction on the level and nature of supervision required for trainees undertaking planning duties.
- Introduction of procedures to ensure that quality assurance programmes are followed.

19. Recommendations for actions by other parties include:

- A review of treatment planning provisions with regard to regulatory compliance, staffing and quality system working at all five Scottish radiotherapy centres with findings reported to the Scottish Cancer Group.
- Consideration of what measures, in addition to those already identified, are required to safeguard and improve patient safety in the face of predicted increases in the level of demand for cancer radiotherapy and treatment planning in Scotland.
- Consideration of the need to further extend the guidelines currently in preparation by the National Institute for Health and Clinical Excellence (NICE) relating to radiotherapy planning.
- Consideration of how information on incidents involving accidental or inadvertent radiation exposures in medical practice can best be shared among radiotherapy centres in the UK.

20. An Improvement Notice has been served on the BOC giving statutory force to those of the recommendations contained in this report that relate to compliance with the IR(ME) Regulations. Compliance with these requirements will be subject to subsequent inspection.

Acknowledgements

21. The report acknowledges the assistance of staff from the Health Protection Agency, the Health and Safety Executive and the Scottish Executive Health Department in conducting this investigation. It also acknowledges the cooperation of staff at the BOC in responding to questions asked and in providing documents requested during the investigation.

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1. Subject

- 1.1** Between 5th January 2006 and 31st January 2006, patient Lisa Norris, who was then 15 years old, received a dose of ionising radiation much greater than that intended while undergoing a course of radiotherapy at the Beatson Oncology Centre (BOC) in Glasgow. 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 Exposures) Regulations 2000* (the IR(ME) Regulations) [1]. 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

- 2.1** This report records the findings of an incident investigation carried out by Dr Arthur Johnston, Scientific Adviser to the Scottish Executive Health Department (SEHD), 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 Executive Health Department, and Mr Steve Ebdon-Jackson and Ms Carol Nix of the UK Health Protection Agency provided independent expert advice throughout.
- 2.2** 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 BOC and at other radiotherapy centres in Scotland and elsewhere.
- 2.3** Information obtained by the Inspector during the course of this investigation is subject to restrictions on disclosure, particularly those pertaining to Section 28(7) of the Health and Safety at Work Act 1974. Reporting of any information that might be regarded as personal data is further restricted under the provisions of the Data Protection Act of 1998. To address the issues arising from this legislation, the relevant consents were sought from those who provided information and from those for whom it was intended that personal data be included in this report. Consent to disclosure of information under the Health and Safety at Work Act was obtained from all of those asked.

- 2.4** With particular regard to the provisions of the Data Protection Act 1998, the content of this report has been anonymized to the degree considered necessary by the Inspector to accommodate the consents received by BOC staff. Further consideration of anonymity has been necessary to enable BOC staff to consent to disclosure of information provided. In seeking these consents, staff were advised of the need for the titles used in this report to identify individual responsibilities. In general, therefore, individuals are referred to by a title that conveys their relative seniority. The particular titles used for treatment planning staff are, in order of decreasing seniority, 'Principal Planner', 'Senior Planner' and 'Planner'. These titles are not intended to correspond with actual job titles or gradings used at the BOC or in other UK radiotherapy departments. In addition, to avoid gender identification, the pronouns '*his*', '*he*' and '*him*' and '*himself*' are used throughout and are italicised accordingly.
- 2.5** It is the view of the Inspector that the requirement for anonymity of the staff involved and the decision of some members of BOC staff to withhold consent to the inclusion of personal data has not detracted significantly from the principal aims of the report which are those stated in Paragraph 2.2.
- 2.6** 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.
- 2.7** This report makes frequent reference to the computer systems used at the BOC for treatment planning. Particular reference is made to *Varis 7*, *Eclipse* and *RTChart* (registered trade marks). In this regard, it should be noted that at no point in the investigation was it deemed necessary to discuss the incident with the suppliers of this equipment since there was no suggestion that these products contributed to the error.
- 2.8** Staff at the BOC have requested specifically that any Report should again convey to Lisa's family their deep regret for this incident and for the distress that they have suffered as a result.

3. Incident reporting by the BOC

- 3.1 Section 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.'*
- 3.2 In this instance, the 'employer', under the IR(ME) Regulations, is considered to have been the North Glasgow University Hospitals Division of Greater Glasgow Health Board (GGHB).
- 3.3 The treatment error was first identified on 1st February 2006. Details of the incident were reported verbally to the Scottish Executive Health Department (SEHD) on February 2nd 2006 and this was followed on February 3rd 2006 by a copy of an 'initial report' prepared by a member of staff at the BOC. This report included details of three 'immediate changes' implemented by the BOC in respect of this incident.
- 3.4 A separate draft report on the incident by Dr Martin, the Head of Health Physics Section*, was provided to the Warranted Inspector on 10th February 2006 under the title *"Preliminary Report of Investigations on Incident Involving Delivery of a Higher Dose than Intended to the Brain During Treatment of the CNS at the Beatson Oncology Centre, Western Infirmary During January 2006"*. This was followed, on 17th February 2006, by a formal incident report to the Scottish Ministers (the 'appropriate authority'), again by Dr Martin, under the title *"Incident Involving Delivery of a Higher Dose than Intended to the Brain During Treatment of the CNS at the Beatson Oncology Centre, Western Infirmary, Glasgow During January 2006"*.
- 3.5 Initial investigations by the BOC confirmed that no other patients had been similarly affected.

*The Health Physics Section has responsibility for advising on radiation protection issues for the whole of Greater Glasgow Health Board.

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4. Incident description

4.1 Referral

4.1 Lisa Norris, who at the time of this incident was 15 years of age, was referred to the BOC by a consultant clinical oncologist on 13th September 2005 for a course of radiation treatment for a relatively rare brain tumour. Referral was by completion of a Treatment Booking Form (form number BOC 00017). The consultant clinical oncologist prescribed a dose of radiation of 35 Grays* to a treatment volume to include the whole of the central nervous system (CNS); to be delivered in 20 equal fractions of 1.75 Grays, to be followed by 19.8 Grays targeted on the tumour itself in 11 equal fractions of 1.8 Grays.

4.2 Regarding formal duties under the IR(ME) Regulations, the referring Oncologist was therefore acting as both 'referrer' and 'practitioner'.

4.2 Treatment Planning for patient Lisa Norris

4.2.1 General treatment planning provisions

4.3 Treatment planning in cancer radiotherapy is the process whereby patient information is gathered and assimilated, for example by CT scanning, and is used to plan the precise manner in which the dose of radiation prescribed by the clinical oncologist will be delivered. The people who undertake these tasks in UK radiotherapy centres are most commonly in staff categories identified as 'therapeutic radiographers', 'medical physicists' 'medical technical officers' (MTO) and 'medical dosimetrists'.

4.4 The job title 'Therapeutic Radiographer' is a 'protected title', limited to those individuals who are registered as such with the UK Health Professions Council (HPC). Medical physicists can also register with the HPC under the protected title of 'Clinical Scientist'. MTOs are not HPC registered but the Institute of Physics and Engineering in Medicine (IPEM) operates a 'Voluntary Register for Clinical Technologists' for which MTOs are eligible. The term 'medical dosimetrist' is relatively new in the UK and tends to cover radiographers and MTOs who work in treatment planning. However, it is not yet well defined.

4.5 Staffing provisions for radiotherapy treatment planning vary across UK centres. For example, at some centres the bulk of treatment planning is carried out by therapeutic radiographers. At the BOC, all but the simplest of treatment planning is carried out by medical physicists, some of whom (in general the more senior) are HPC registered and by MTOs, some of whom are on the IPEM voluntary register. The division of planning duties between staff in these two groups is mainly in accordance with training and experience rather than by staff category, though responsibilities for checking of treatment plans fall normally to the more senior of the medical physicists. (See also Paragraph 6.6 and Annex 6.) Some of the simplest treatment plans are, however, prepared by the radiographers themselves.

* The 'Gray' is the international unit of 'absorbed dose' that quantifies the amount of energy that is deposited in the tissue of the body by the radiation. One Gray is equal to a radiation absorbed dose of one Joule of energy per kilogram of tissue. This report also quotes absorbed dose in units of centiGrays, where a centiGray is one hundredth of a Gray.

- 4.6 The majority of planning, scheduling and delivery of radiotherapy treatment at the BOC is managed using a computer software package called *Varis*. This comprises a number of individual software modules which deal with different aspects of treatment planning and delivery. The paragraphs that follow describe the general features of the *Varis* system relevant to this Report (including the features of the BOC's latest version, *Varis 7*) and consider specific aspects of its use at the BOC. This includes consideration of the nature of the error that was made. Section 5 of this report then goes on to consider the circumstances that contributed to the error.
- 4.7 Within the *Varis* system, data from the Treatment Booking Form referred to in Paragraph 4.1 is entered into the software modules called *Patient Manager* and *RTChart* by staff in the BOC's Booking Office. These data can include the patient's personal details and the treatment parameters prescribed by the clinical oncologist. The software module that has been used for treatment planning at the BOC since 2003 is called *Eclipse*. The output from the *Eclipse* module is in the form of a 'Treatment Plan Report' which contains detailed information on the beam energy, size and machine settings which determine the position of the radiation fields to be delivered by the linear accelerator (Linac) and the setting, in Monitor Units (MU), that is required on the Linac to deliver the total dose for each treatment field. Several treatment fields may be used to deliver a complete treatment fraction. 'Monitor Units' is the term used for the reading that arises from the monitor on the radiation delivery unit (the Linac) that measures the total output of radiation from the delivery unit during an exposure. The radiographer sets the Linac to terminate the exposure when the pre-set number of MU have been delivered. **The MU setting is therefore critical in achieving the correct dose.**
- 4.8 Prior to the introduction of the latest version, *Varis 7*, in May 2005, a decision had been taken at the BOC to use the *Eclipse* planning system as a stand-alone module within the overall architecture of *Varis* for a number of operational and technical reasons. After the upgrade in May 2005 to *Varis 7*, a decision was taken at the BOC to integrate the *Eclipse* module more fully with the other *Varis* software modules. Following this change, the data entered in the *Patient Manager* and *RTChart* modules, as described in Paragraph 4.7, could be transferred electronically to the forms that were completed within *Eclipse* by the treatment planners using information gathered during the treatment simulation or the CT scanning phase. In addition, the information contained in the Treatment Plan Report created by *Eclipse* could then be transferred electronically back to the *RTChart* module. *RTChart* supports the electronic verification of these treatment parameters by the radiographer and is part of the final check to confirm that these parameters are correct before being transferred to the Linac for delivery of the treatment. It also allows the parameters that were intended and the actual Monitor Units delivered at treatment to be reviewed.
- 4.9 The initial radiation treatment plan that was prescribed for Miss Norris was a 'whole CNS plan'. This comprises separate treatment plans for the radiation exposure of the head and of the spine, generally referred to as the 'head fields' and 'spine fields'. In this case, the treatment plan for the spine was further divided into lower and upper spine fields.

- 4.10 Because of the complexity of whole CNS treatment plans, management of treatment planning considered that electronic data transfer of the Treatment Plan Report from *Eclipse* to *RTChart* was not appropriate for this procedure. The main source of complexity lies in the spine fields. The system that was used prior to the introduction of *Varis 7* was therefore retained, for both the head and the spine fields, whereby the relevant information from the Treatment Plan Report is transferred manually to the BOC's 'Medulla Planning Forms'.
- 4.11 The Medulla Planning Form is then passed to the treatment radiographers to provide them with the information required for final monitor unit calculations and treatment delivery.
- 4.12 Whole CNS treatments of a similar type are performed about six times per year in the BOC. (The total number of new treatment plans at the BOC is advised as being between 4500 and 5000 per year.)
- 4.13 The bulk of the treatment planning for Miss Norris was carried out by a BOC treatment planner referred to in this report as Planner B during the period 16th to 19th December 2005.

4.2.2 Spine fields

- 4.14 Referring firstly to the spine fields, the treatment plan produced initially by Planner B was checked by Principal Planner A, who identified errors in the design of the compensators (shaped wax blocks used to eliminate dose non-uniformity resulting from surface contour irregularities). The compensator designs were amended and the plan was then passed to Senior Planner C, who checked the compensators on the spine fields, looked over the plan, and signed it off.
- 4.15 As a result of this checking process, the spine fields were planned and delivered correctly and no further consideration is given in this report to this aspect of the treatment, except to note that, (i) errors were made by Planner B and (ii) Dr Martin's incident report notes that this was considered the most difficult part of the planning process and speculates that the attention of the treatment planners who carried out the checks may have been distracted by the initial errors in this part of the whole CNS plan.

4.2.3 Head fields

- 4.16 Within *Varis7*, the *Eclipse* treatment planning module allows the user to open the patient file created within *Patient Manager* and then to choose whether to import electronically the relevant data on the prescribed radiation dose (the 'Physician's Intent') entered previously within the *RTChart* module (Paragraph 4.7). For the head fields (but not for the spine fields) this option was selected by the treatment planner and the data that was transferred electronically to the *Eclipse* treatment planning module included the planned total radiation dose and the number of fractions prescribed for Miss Norris by the clinical oncologist. (Both Principal Planner A and Planner B were involved at this stage in the planning process but their recollections could not clarify which of them made the (critical) choice to include the prescribed radiation dose in the treatment planning process.) For reasons that remain unclear, at some point in this process, the number of treatment fractions was changed from 20 to 21. (This change was not in any way a cause of the incident.) The remainder of the planning process for the head fields was carried out by Planner B.

- 4.17 The *Eclipse* treatment planning module then used the values that were transferred electronically for the total radiation dose and the number of fractions to determine the 'Daily Total Dose' (calculated on the basis of 21 fractions as 167 centigrays rather than 175 centigrays) and the setting required for the linear accelerator to deliver this radiation dose to the head in each of the daily treatment sessions. The calculated setting was 91 Monitor Units.
- 4.18 Under their ISO 9000 quality system, controlled document number WI.14.01.01 (Annex 1 to this report) is the BOC's written procedure for 'Medulla Planning'. It includes an instruction to the treatment planner (on completion of the planning process) to 'Write up plan on Medulla Planning Form FM.14.013 or FM.14.014 as appropriate.'
- 4.19 In this case, the Medulla Planning Form used was FM.14.014, for two spine fields. FM.14.014 is also a controlled document under the provisions of the BOC's quality system. A blank copy of the version in use in December 2005, which is dated 11th August 1998, is appended to this report as Annex 2.
- 4.20 The table at the foot of Page 1 on Medulla Planning Form FM.14.014 requires the planner to enter calculated values of the 'Output'. The 'Output' is the intended number of daily MU from the delivery unit 'normalized **' to 100 centigrays (i.e. expressed in units of MU per 100 centigrays). In this case, the normalized 'Output' should have been calculated (for 21 rather than 20 fractions) as 91 MU divided by 167 (centigrays) and multiplied by 100 to give a required 'Output' of 54 MU per 100 centigrays.
- 4.21 **In this case, however, the treatment planner (Planner B) omitted the normalization procedure and erroneously entered an 'Output' figure of 91 MU per 100 centigrays on the Medulla Planning Form instead of the correct figure of 54. This was the critical error and it was not identified by the more senior treatment planners who checked the plan.**

** The term 'Normalization', as used in this report, is the process whereby a parameter is multiplied or divided by a number so that it can be expressed in more convenient or standardized units. For example, the recommended weight of fertilizer to be applied to a lawn might be normalized to a unit of area such as 'grams per square metre'. The actual amount needed is then determined by multiplying this normalized figure by the area of the actual lawn in question.

4.3 Treatment Delivery

4.22 The Medulla Planning form for Miss Norris, containing the erroneous 'Output' figure was passed to the treatment radiographers to provide them with the information required for calculating monitor units for treatment delivery.

4.23 BOC Work Instruction WI 13.26.06 (issued in October 2005 to update WI 13.67, Version 4, dated May 2002 and appended to this report as Annex 3), sets out the procedure to be followed by radiography staff during the pre-treatment processes for 'Medulloblastoma Calculations'. This requires that the number of 'Daily MU' should be calculated by multiplying the intended 'Daily Total Dose' by the 'Output' which (see Paragraph 4.20) is obtained from the Medulla Planning Form that has been completed by the treatment planner.

4.24 In this case, the radiographer, working in accordance with WI 13.26.06, used the erroneous entry (91 MU per 100 centigrays) and calculated the daily number of monitor units, for the 20 dose fractions prescribed, as:

$$\text{Daily MU} = ((175 \times 91) / 100) = 159 \text{ MU.}$$

4.25 The correct calculation should have been:

$$\text{Daily MU} = ((175 \times 54) / 100) = 94.5 \text{ MU.}$$

4.26 The Daily Total Dose equivalent to 159 MU from both the (right lateral and left lateral) head fields is 2.92 Grays (cf. the prescribed dose of 1.75 Grays) and this is the dose that was delivered in each of 19 fractions before the error was discovered. The total dose to Miss Norris was therefore 55.5 Grays (19 x 2.92 Grays), which is 58% higher than the intended total dose of 35 Grays.

4.27 Following discovery of the error, the prescribed, targeted treatment for the tumour region of 19.8 Grays in 11 equal fractions of 1.8 Grays that was scheduled to follow the whole CNS treatment was abandoned on the instruction of the clinical oncologist.

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5. Investigation of the circumstances of the incident

5.1 Summary of the initial investigation

- 5.1 Following receipt by the Inspector of an initial incident report from the BOC, a meeting to discuss the circumstances of this incident was held at the BOC on 10th February 2006. Participants included senior staff from the BOC, staff from the SEHD (including the Inspector) and an adviser from the Radiation Protection Division of the Health Protection Agency.
- 5.2 A draft report on the incident by Dr Martin, under the title "*Preliminary Report of Investigations on Incident Involving Delivery of a Higher Dose than Intended to the Brain During Treatment of the CNS at the Beatson Oncology Centre, Western Infirmary During January 2006*" was made available at this meeting.
- 5.3 A copy of the note of this meeting, which was made by Marianne Cook of the Scottish Executive Health Department, is appended here as Annex 4.
- 5.4 The main findings of this initial meeting can be summarized as follows:
- (i) The principal cause of this incident was identified as a single erroneous entry for the 'Output' on Medulla Planning Form FM.14.014 for Miss Norris, dated 16th December 2005.
 - (ii) The entry was made by Planner B who omitted to carry out the normalization procedure required when entering the 'Output' in monitor units (MU) per hundred centigrays. A figure of 91 was therefore written on the planning form instead of the correct figure of 54.
 - (iii) Checking by more senior colleagues failed to identify the error.
 - (iv) The error was repeated by Planner B subsequently in planning a similar treatment for a new patient but in this case the error was identified by another senior planner (Senior Planner D). It was this discovery that led to investigation of previous treatment plans and to identification of the error in the plan for Miss Norris. No other patients at the BOC were affected.
 - (v) The training records for Planner B indicate no record of competence as either "training", "competent", or "authorised to train" for the 'Spine/Medulla/CNS' (whole CNS) procedure in question.
 - (vi) Planner B had prepared a similar plan, under supervision, in November of 2005, wherein the prescribed radiation dose was input to the *Eclipse* module and normalization of the output was therefore applicable. Planner B was unaware of the need for normalization and did not apply it. In this case, however, the daily radiation dose was 1 Gray (100 centigrays) so the normalization procedure, had it been applied, would not have changed the values of the MU in its transference from the *Eclipse* Treatment Plan Report to the Medulla Planning Form. The correct value for the 'Output' was therefore entered on the Medulla Planning Form.
 - (vii) There is no evidence of the employer's written procedures for 'Medulla Planning' (WI.14.01.01) having been updated annually as required by their own quality assurance procedures. The available procedure thus did not reflect fully the current practice at BOC and contained no specific instruction regarding the normalization procedure referred to above.
 - (viii) The course of radiotherapy for Miss Norris was terminated immediately on discovery of the error and the patient and her family were informed. At this point she had received 19 treatments each of 2.92 Grays, giving a total of

55.5 Grays. The prescribed dose was 35 Grays in 20 equal fractions of 1.75 Grays.

- (ix) The incident was reported promptly to the Scottish Executive Health Department in accordance with the requirements of Regulation 4(5) of the IR(ME) Regulations 2000.
- (x) A number of immediate changes were implemented at the BOC to minimize the possibility of any recurrence of an incident of this type.
- (xi) The Inspector was satisfied that the BOC staff co-operated fully with the inspection team and that all documents requested were made available.

5.5 This initial investigation, together with the BOC incident reports established clearly that the cause of the overexposure was the erroneous 'Output' figure that was entered on the Medulla Planning Form. Further investigation therefore sought to establish (a) the circumstances that caused this error to be made, (b) why the error was not detected earlier and (c) what should be done at the BOC and at other radiotherapy centres to minimize the possibility of recurrence of a similar incident.

5.6 These further investigations included a review of the BOC's written procedures and individual interviews with relevant staff from the BOC and from GGHB. Sections 5.2 and 5.3 of this report, which consider issues (a) and (b) in Paragraph 5.5, include information obtained from individual staff interviews. Annex 5 summarizes the information obtained in these interviews.

5.2 Why was the wrong 'Output' figure entered on the Medulla Planning Form?

5.2.1 The effect of changes to treatment planning procedures in May 2005

5.7 Prior to the introduction of *Varis 7* in May 2005, the actual prescribed treatment dose was not entered into *Eclipse*. Therefore, all BOC treatment plans computed by *Eclipse* were for a 'standardized' dose of 100 centiGrays per treatment fraction and the MU figure in the Treatment Plan Report that was printed by *Eclipse* was always in units of MU per 100 centiGrays.

5.8 For most treatment procedures (in general the simpler procedures) the treatment plan provided to the radiographer was simply the hardcopy 'Treatment Plan Report' from *Eclipse*. For some procedures, however, including the whole CNS procedure, the data from this printout was transcribed to a separate planning form (such as FM.14.014 shown in Annex 2). In either case, since the daily dose fraction that was presented to the radiographer was in units of MU per 100 centiGrays, the actual number of MU for each treatment fraction was always calculated by the radiographer in accordance with the procedure described in Section 4.3 of this report.

5.9 With the introduction of *Varis 7* came the opportunity for electronic transfer of the treatment delivery parameters computed by the *Eclipse* software module to the *RTChart* module.

5.10 To utilise this capability it was necessary for the data input to *Eclipse* to include the prescribed total radiation dose and the number of fractions. Hence, the treatment plans computed by *Eclipse* using this input data were no longer for a 'standardized' dose of 100 centiGrays.

- 5.11** As indicated in Paragraph 4.10, the change to electronic transfer of the calculated data for treatment delivery from *Eclipse* to *RTChart* was not made for all planning procedures. However, the capability of transferring data on the prescribed dose from *RTChart* into the *Eclipse* module was also adopted at the BOC for some (but not all) of those plans where the data continued to be transferred manually from the *Eclipse* Treatment Plan Report back to *RTChart*.
- 5.12** In planning the head fields for Miss Norris, the data that was input to *Eclipse* from *RTChart* did include the prescribed total dose and the number of fractions. For the spine fields it did not. Hence, for the head field treatment plan, the MU figure that was printed in the *Eclipse* Treatment Plan Report was no longer in units of MU per 100 centigrays but was now in units of MU per treatment fraction (in this case MU per 167 centigrays). Therefore, this figure could no longer be transcribed directly to the 'Output' box on the Medulla Planning Form but now had to be normalized back to MU per 100 centigray, as described in Paragraph 4.20 of this report.
- 5.13** Prior to the change in May 2005 therefore, it had never been necessary for treatment planners to normalize the MU figure that emerged from *Eclipse*. BOC work instruction number WI.14.01.01 for 'Medulla Planning' reflected this in that there was no reference to this requirement. (The version of WI.14.01.01 shown in Annex 1 which is dated 11th August 1998 was the latest version available at December 2005.)
- 5.14** More specifically, in planning the head fields for Miss Norris, the input to the *Eclipse* planning module from *RTChart* was chosen to include the consultant oncologist's prescribed dose of 35 Grays but in 21 fractions rather than the 20 fractions prescribed (see Paragraph 4.16). *Eclipse* then calculated that her daily treatment required a Linac setting of 91 MU for a dose of 167 centigrays and printed this number on the Treatment Plan Report. The treatment planner should then have divided the '91' by 1.67 to give a figure of 54 MU per 100 centigrays for the 'Output'. Instead, the treatment planner omitted this normalization procedure and transcribed the figure of 91 directly from the *Eclipse* Treatment Plan Report to the Medulla Planning Form.
- 5.15** Had the potential for error that resulted from the change to inclusion of the prescribed dose in the *Eclipse* input data been identified, then a number of different alternatives could have been implemented:
- (i) The former practice of computing all treatment plans for a dose of 100 centigrays per treatment fraction could have been retained for all of those plans where the data in the *Eclipse* Treatment Plan Report was to be transferred manually back to *RTChart*.
 - (ii) Medulla Planning Form FM.14.014 could have been changed to require an entry in MU per treatment fraction instead of in MU per 100 centigrays and BOC Work Instruction WI13.26.06 for radiography staff (Annex 3 to this report) changed accordingly.
 - (iii) BOC work instruction number WI 14.01.01 for 'Medulla Planning' could have been amended to include instruction on the need for normalization of the MU output figure from *Eclipse* and appropriate training given.
 - (iv) Data for the head fields (planning for which is less complex than for the spine fields) could have been transferred electronically from *Eclipse* to *RTChart*

- 5.16** Had alternative (ii) in Paragraph 5.15 been adopted, then the new practice of entering the prescribed dose into *Eclipse* might have been advantageous in removing the need for radiographers to ‘scale up’ the ‘output’ figure. However, if there remained some planning procedures for which the prescribed dose was not fed into *Eclipse* then the potential for confusion and for critical error would be considerable. Additional potential for confusion would arise from the inclusion of two different conventions (for the head fields and the spine fields) for reporting the ‘output’ within the same CNS plan.
- 5.17** In summary, the introduction of the new procedure involving electronic transfer of data on the prescribed radiation dose from *RTChart* to *Eclipse* was wholly appropriate for and compatible with those plans that involved electronic transfer of the treatment delivery data calculated by the *Eclipse* module back to *RTChart*. However, for plans that continued to employ manual transfer of the treatment delivery data from *Eclipse* to *RTChart*, this change was not essential but, if adopted (for example, for consistency with plans involving electronic transfer of treatment delivery data) should have been accompanied by a comprehensive evaluation of consequences and by changes to the procedures and documents affected, as well as by any necessary re-training.

5.2.2 The role of Planner B in planning this treatment

- 5.18** Paragraph 11(1) of the IR(ME) Regulations requires that: ‘*no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained*’, with the proviso that (Section 11(3)) ‘*Nothing in paragraph (1) above shall prevent a person from participating in practical aspects of the procedure as part of practical training if this is done under the supervision of a person who himself is adequately trained*’.
- 5.19** Paragraph 11(4) of the IR(ME) Regulations requires that: ‘*The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposure or, where the employer is concurrently practitioner or operator, of his own training, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training*’.
- 5.20** In summary, therefore, the IR(ME) Regulations require that any person who participates in practical aspects of the exposure procedure, such as treatment planning, must either be appropriately trained or must do so under the supervision of another person (an ‘operator’) who is properly trained. The policy at the BOC was that employer’s training records should define the training status of the employees involved.
- 5.21** The *Eclipse* Treatment Plan Report for the three planned exposure fields for Miss Norris has the following information:
Head.
Plan created: Thursday December 15, 2005, 3:25:38 PM by [Principal Planner A]
Printed 19/Dec/2005 10:41 AM by [Planner B]
Plan Last Modified Monday December 19, 2005 10:40:32 AM by [Planner B]

Upper spine.

Plan created: Friday December 16, 2005, 10:55:51 by [Planner B]

Printed 21/Dec/2005 3:15 PM by [Principal Planner A].

Plan Last Modified Friday December 16, 2005 12:53:25 PM by [Planner B]

Lower spine

Plan created: Friday December 16, 2005, 11:32:09 AM by [Planner B].

Printed 19/Dec/2005 3:16 PM by [by [Principal Planner A].

Plan Last Modified Monday December 19, 2005 10:40:32 AM by [Planner B]

The data from each of these three forms was transcribed to the Medulla Planning Form by Planner B. Further investigation of relative roles indicates that the bulk of treatment planning for Miss Norris was carried out by Planner B.

- 5.22** In the period between May and December 2005, two whole CNS procedures were planned at the BOC, one in August and one in November. The treatment plan for Miss Norris was therefore the third plan of this type that had been completed following the upgrade to the *Varis 7* computer system. However, for the first of these three plans, the prescribed radiation dose was not included in the data input to the *Eclipse* planning computer. For the second of these plans, in November 2005, the prescribed radiation dose of 3600 centiGrays in 36 fractions was input to *Eclipse* but because the prescribed radiation dose per fraction was 100 centiGrays, the calculated number of monitor units per fraction was precisely the number per 100 centiGrays. Hence the normalization process, whilst applicable, would not have produced any change in the values transcribed to the Medulla Planning Form.
- 5.23** The plan for Miss Norris was therefore the first of its type at the BOC where the calculated number of MU output from the planning computer was anything other than the number per 100 centiGrays. It was, in fact, the first of any type at the BOC, medulla or otherwise, for which there was a need for manual normalization of the number of MU generated in the *Eclipse* Treatment Plan Reports before transcribing to a paper planning form.
- 5.24** Planner B did not participate in the planning of the Spine/Medulla/whole CNS procedure in August. For the November procedure *he* did, under the supervision of Principal Planner A and Senior Planner C.
- 5.25** Inspection of Planner B's training records on 10th February 2006 indicated that these were last signed-off on 28th June 2005 by Principal Planner A. These training records comprise a tabulated list of 'Competences', against each of which are three tick-boxes respectively headed 'L', 'C' and 'T' to indicate that, for each particular competence, the person is deemed to be either *Learning*, *Competent* or *competent to Train*. The competence relevant to the procedure in question is listed as 'Spine/Medulla/whole CNS'. No entries appear in any of the three related boxes, which suggests that, at the time of completion of this record, Planner B had no formal competence in this planning procedure.
- 5.26** However, at interview (see Annex 5) Principal Planner A and Planner B both expressed a view that the training and practical experience received by Planner B in November 2005 was such as to place *him* in the 'Learning' category for planning of the Spine/Medulla/whole CNS procedure. In this

regard, the requirements of Paragraph 11(4) of the IR(ME) Regulations for the employer to keep up-to-date records were not being met. (At Interview (Annex 5) Principal Planner A stated that *he* tried to review training records for treatment planning at six-monthly intervals.)

- 5.27** Therefore, it is the view of Principal Planner A and Planner B that when Planner B undertook planning duties for the Spine/Medulla/whole CNS procedure for Miss Norris, *he* did so as a 'learner' (though not yet recoded as such). However, it is clear that the training that *he* had received was confined to *his* supervised participation in the whole CNS procedure that was planned in November for which (see Paragraph 5.22) failure to apply the normalization procedure prior to transcribing the MU data from the Treatment Plan Report to the Medulla Planning Form had no effect on the number transcribed. At interview (Annex 5) Planner B indicated that no discussion or instruction on the normalization process had been included either in November or subsequently.
- 5.28** A further critical circumstance was that the written procedures that were available to Planner B, in particular BOC work instruction number WI.14.01.01 for Medulla Planning made no reference to the use of a planning computer or the normalization procedure. The latest available version of this document (Annex 1 to this report), is dated 11th August 1998. As discussed in subsection 5.2.1, the need for normalization arose because of the BOC decision taken several years earlier to enter a nominal dose of 100cGy for all computer plans. In 2005 with the introduction of *Varis 7* the BOC decided to implement the full functionality of the software using the actual prescribed radiation doses and number of fractions as an input to the planning computer. Hence, the version of WI.14.01.01 available to Planner B in December 2005 did not reflect current practice. Planner B stated at interview that following *his* supervised participation in planning a previous patient in November 2005, *he* had made *his* own notes on how to carry out the planning. *He* was not aware of the existence of any applicable written work instructions at the BOC.
- 5.29** Taking these circumstances together, the only indication available to Planner B on the need for normalization appears to have been the label on the relevant box in Medulla Planning Form FM.14.014 (Annex 2 to this report) requesting that the entry for the 'Output' should be in units of 'MU/100cGy'.

5.2.3 The role of the Principal and Senior Planners in planning this treatment

- 5.30** Treatment planning for Miss Norris took place between 15th and 19th December 2005. Senior Planner C, who was involved in checking her treatment plan was absent from the BOC for the whole of the week beginning 12th December and was rotated for other duties in the week beginning 19th December. Senior Planner C therefore had no direct initial role in the creation of the treatment plan.
- 5.31** On 15th December 2005, Principal Planner A, using CT images imported into the *Eclipse* planning computer, set up the positions of treatment fields and shielding blocks for the clinical oncology consultant responsible for Miss Norris to approve.

- 5.32** The involvement of Planner B in treatment planning began on 16th December 2005, under the supervision of Principal Planner A. During the interviews that formed part of the incident investigation (between 23rd February and 8th March 2006) the nature of this supervision was discussed. Since no record of their respective roles was made at the time, details given were from recollection.
- 5.33** According to these recollections, Principal Planner A, having set up the positions of treatment fields and shielding blocks, gave Planner B initial direction on the next stages of treatment planning and gave *him* the opportunity to ask for any necessary clarification. Planner B recalls that at each stage in the treatment planning process *he* checked with others to ensure that *he* was following the correct procedure. Principal Planner A was unable to recall what approaches had been made to *him* by Planner B in this connection. Planner B's recollection was that at no stage in planning did *he* recognize the need for normalization and therefore did not raise this as an issue.
- 5.34** It appears therefore, that apart from initial instruction, the process of supervision was largely indirect (or reactive), whereby following initial instruction, Planner B progressed all aspects of the planning process independently but with the opportunity to raise any issues of doubt with appropriate senior colleagues. *His* senior colleagues therefore were not given the opportunity to comment or advise on the normalization process because Planner B did not raise it with them as *he* was unaware that this was an issue.

5.3 Why was the wrong 'Output' figure on the Medulla Planning Form not identified in checking?

- 5.35** BOC Quality System Document QS14.13 'Checking and Issuing of Plans' requires that '*Prior to issuing a plan, calculations and plans will be independently checked and initialled by a suitably qualified member of Physics planning Staff*'. This requirement is in accordance with The Royal College of Radiologists' Clinical Oncology Information Network. *Guidelines for external beam radiotherapy* [2], Recommendation 48 of which states that '*The monitor unit calculation must be rigorously and independently checked*'.
- 5.36** The initials on the completed Medulla Planning Form for Miss Norris indicate that the plan was checked by Principal Planner A and by Senior Planner C. The precise role of each in the checking process is a matter of recollection rather than of record and is therefore difficult to assess. However, it is apparent that Principal Planner A played the more significant part in the checking process and, since *he* was also involved in supervising Planner B during planning, *his* involvement cannot be regarded as wholly independent. Indeed, the degree of *his* independence in checking the plan might be said to correlate inversely with the level of *his* supervision.
- 5.37** Recollections by those involved indicate that initial checking was by Principal Planner A, who identified a number of errors, particularly in the calculation and drawing of the compensators for the spine fields (see Paragraph 4.14). Principal Planner A corrected these errors and passed the amended plan to Senior Planner C for further checking of the corrected spine fields. Both Principal Planner A and Senior Planner C failed to identify the critical error in the 'Output' entry.

- 5.38 As discussed in Paragraph 5.23, the plan for Miss Norris was the first whole CNS plan at the BOC where the calculated number of MU in the *Eclipse* Treatment Plan Report was anything other than the number per 100 centigrays. Therefore, the checkers had no previous experience of checking a plan where normalization had been applied in calculating the 'Output' entry.
- 5.39 In his formal incident report, Dr Martin notes that '*The CNS plan is complex and the checking process is not straightforward. The most difficult part involved relative positioning of the fields, and the attention of the physicists carrying out the checks may have been distracted by errors in other parts of the plan.*'
- 5.40 In summary, there was nothing in either of the checkers' previous experience of creating or checking treatment plans to alert them to the fact that a normalization procedure had been needed in the calculation of the 'Output' entry for the head fields in this plan. The attention of Senior Planner C was directed by Principle Planner A to the spine fields where *he* had already identified and corrected errors. As suggested in Paragraph 5.39 the attention of the checkers might therefore have been focussed on those areas of the plan that they knew from experience to be the most complex, particularly the positioning of the spine fields and aspects of adjustment of the position of the junction between the head and upper spine and between the upper and lower spine fields.
- 5.41 The question that then arises is why was Senior Planner D able to identify the same error made by Planner B in the subsequent plan (Paragraph 5.4(iv))? In this regard, it should be noted that Planner B was unable to recall who had supervised *him* in the preparation of this subsequent plan and to what extent. Formal checking was by Senior Planner C (not by Senior Planner D) who signed-off the plan but at this stage had failed to identify the error.
- 5.42 In principle, the information contained in all Treatment Plan Reports generated by *Eclipse* would be available for electronic transfer to *RTChart*. Therefore, for those procedures where manual transfer of data was required, the system used at the BOC was to set the status of the Eclipse Treatment Plan Report to "*Rejected*". For the 'subsequent plan' referred to in Paragraph 5.4(iv), one of the radiographers in pre-treatment, apparently unaware of this procedure, approached treatment planning staff to ask why the plans in the *Varis 7* database had been set to "*Rejected*" status. Prompted by this enquiry Senior Planner D decided to look at a copy of this patient's planning form to remind *himself* about the relevant working procedures. It was at this point that *he* realised that the monitor units calculated by Eclipse had been based on the prescribed dose of 1.67Gy per fraction rather than 1Gy per fraction. Since this did not appear to *him* to accord with the definition of 'Output' given on the planning form, *he* asked Principal Planner A to double-check this. Principal Planner A confirmed that the number written on the form by Planner B was incorrect and initiated the immediate review of previous plans of this type which identified the error for Miss Norris.
- 5.43 The question of whether this error might have remained un-noticed had it not been for the radiographer's enquiry must remain open. However, the seriousness of the consequences for future patients of this having been the case and hence the importance of Senior Planner D's intervention cannot be ignored.

5.4 A missed opportunity to identify the potential for error from another plan

- 5.44** Between completion of the plan for Miss Norris on 19th December 2005 and identification of the error by Senior Planner D on 1st February 2006, a (manual) medulla procedure for another patient was planned by another treatment planner (Senior Planner E) under the supervision of Principal Planner A. The Medulla Planning Form is dated 12th January 2006. In this case also, the prescribed radiation dose was 35 Grays in 20 equal fractions and this prescribed dose was entered into the *Eclipse* module of the *Varis 7* treatment planning system.
- 5.45** Normalization of the 'Monitor Units' figure appearing on the *Eclipse* Treatment Plan Report was therefore necessary in completing the Medulla Planning Form and this was accomplished successfully. Senior Planner E's recollection of how *he* was able to identify this need indicates that *he* recognized that the units for MU on the Eclipse Treatment Planning report (MU for the full 175 centigray dose fraction) were different from the units for the 'Output' entry on the Medulla Planning Form ('MU/100cGy'). Neither *he* nor *his* supervisor for this plan, Principal Planner A, could recollect clearly their respective contributions to identification of this need but Senior Planner E noted that the extent of *his* experience in the BOC's Treatment Planning Section had allowed considerable familiarity in the manual transfer of information from *Eclipse* Treatment Plan Reports.
- 5.46** This presented an opportunity to identify the potential for error. However, this was the first whole CNS procedure that Senior Planner E had planned and *he* would have been unaware therefore of the change from prior practice. The implications of the change from prior practice also went unnoticed by *his* supervisor. The opportunity was therefore missed.
- 5.47** By 12th January, Miss Norris had received only five of the planned 20 fractions, hence the radiation dose and the related health risk would have been greatly reduced had the error been discovered at this stage in the treatment.

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6. Consideration of background circumstances at the BOC

6.1 Introduction

- 6.1** The primary cause of the overexposure has been identified as omission of the required normalization procedure by the treatment planner and consequent entry of an erroneous 'Output' figure on the Medulla Planning Form. Chapter 5 considered the particular circumstances that contributed to this error and has highlighted (i) the lack of training and experience of the treatment planner, (ii) inadequacy of supervision for this planner, (iii) lack of independence in the checking procedure and (iv) failure to update relevant written working procedures since 1998 and more recently following the introduction of the new *Varis 7* software and the BOC decision to change practice regarding the dose entered into the planning computer. This chapter now considers the broader circumstances that underlie these apparent deficiencies in procedures and practice at the BOC.

6.2 Staffing pressures and workloads

6.2.1 Staffing levels in Scotland

- 6.2** A report published in 2006 by the Scottish Executive on 'Cancer in Scotland: Radiotherapy Activity Planning for Scotland 2011 – 2015' [3] (<http://www.scotland.gov.uk/Publications/2006/01/24131719/9>) states that '*Using current recommendations from IPEM (Institute of Physics and Engineering in Medicine) an establishment of 58.5 WTE radiotherapy physicists is required for Scotland. The current establishment is 42.5 WTE [Whole Time Equivalent], a shortfall of 16 WTE posts. Also 8 WTE posts were vacant as at December 2004 and therefore only 34.5 WTE were in post, less than 60% of the recommended level*' and '*Shortfalls also exist in the establishment of dosimetrists and engineers putting additional pressure on existing staff, particularly during this very busy period of rapid equipment expansion and replacement*'.
- 6.3** The issue of workloads was also raised during the staff interviews that formed part of this incident investigation (Annex 5).
- 6.4** It is therefore relevant to consider the extent to which the relationship between staffing levels and workload caused this error to occur and to remain undetected.

6.2.2 Staffing provisions for treatment planning at the BOC

- 6.5** Annex 6 to this report is a summary of the staffing levels and experience for BOC's Treatment Planning Section as of December 2005.
- 6.6** In February of 2005, Principal Planner A produced a document outlining the structure of duties for treatment planning staff. In essence this divided both staff members and treatment procedures into a number of categories. Staff categories were A (most senior) to C (most junior) with a further division of staff category A into three sub-groups. Categories of treatment plans were A (simplest) to E (most complex). He then apportioned appropriate duties for each category of treatment plan to the appropriate staffing category. For example, staff in Group C were aligned with planning categories A, B and C

with a requirement to 'Focus on routine planning workload: developing expertise'. These provisions are summarized in Table 6.1 where staff category A has been divided into sub-categories A1, A2 and A3.

Table 6.1 A summary of the staffing structures introduced by Principal Planner A in February of 2005. The second column (updated and adjusted from February 2005) shows the estimated number of staff in each category. The third column indicates time allocated to treatment planning (as opposed to other duties) in terms of the approximate number of whole time equivalent staff members in each of the staff categories that were available for treatment planning in December 2005 (absences not included). Column 4 outlines the main assigned duties for staff in each category.

Staff planning category	Number of staff members in each category	WTE* allocation to treatment planning for Dec 2005	Categories of plans
A1	5	3.2	D and E (as checker)
A2	2	1	C, D and E as planner and checker
A3	4	2.3	C and D as planner and checker
B	5	3.3	B, C and D as planner A, B and C checker
C	7	4.7	A, B and C as planner
Totals	23	14.5	

* Whole Time Equivalent

6.7 The intent outlined in this staffing structure was therefore that planning duties for Category E (complex) plans should be assigned to either of the two treatment planners in staff Category A2. These two senior planners were on complementary weekly rotas. Reference to Annex 6 indicates that the first of these (designated A2.1) was assigned to treatment planning for the week beginning 12th December, when treatment planning for Miss Norris was started. The other (designated A2.2) was absent from work for the whole of that week.

6.2.3 Staffing provisions for the treatment plan for Miss Norris

6.8 The question that arises, therefore, is why were the main planning duties for the Category E whole CNS plan under consideration here assigned to Planner B who was in staff Category C rather than to the rotaed senior planner in staff Category A2 or to any of the others in staff Categories A or B?

6.9 The training records for both of the senior planners in staff Category A2 place them in the 'Training' category for whole CNS planning. However, when questioned on the extent of this training, Principal Planner A indicated that as of December 2005, neither of these individuals had had any training or experience of whole CNS planning. Clearly, this lack of any competence for whole CNS planning appears to be at odds with their general assignment to Category E plans as 'planner and checker'. In this regard, Principal Planner A explained that allocation of a 'Training' category to any staff member did not imply any previous experience or training for the procedure in question, nor did it imply that any such training was necessarily expected within the next year. Rather, the allocation of 'Training' status to a member of the treatment planning staff indicated an intention to provide such training should the opportunity present. Training at the BOC normally involves participation in the preparation of actual patient plans. Therefore, access to training opportunities depends on the subsequent availability of plans of the type in question.

- 6.10** Reference to Annex 6 indicates that training records for a total of nine members of staff had some entry for whole CNS planning. Of these, staff members A1.4 and A2.2 were either rotated for other duties or were absent from work for the week beginning 12th December 2005. Two of the remainder (staff members A2.1 and B3) had no previous experience of medulla planning. Of the remainder, only A1.1 and A1.5 had any recent experience of medulla planning and Principal Planner A has stated that both were heavily committed to other duties for the week in question. The remaining three of the nine all had some previous experience of medulla planning but none since 2004, and, of these, A1.2 was not available for planning duties in December of 2005 and A3.2 was only available for one day per fortnight. Staff member A3.3 had been involved with three medulla plans in 2004 and might therefore have been a more appropriate choice than Planner B. However, Principal Planner A has again stated that A3.3 was heavily committed to other duties and therefore not available to plan the treatment for Miss Norris.
- 6.11** When questioned further on this issue, Principal Planner A indicated that most of the work of the treatment planning section is done to very short timescales. *He* stated that around 80% of all planning requests are submitted on the actual date that the plan is required or on the day before (see also Paragraph 9.28). Thus, there is little opportunity for work scheduling to ensure that planning tasks are appropriately allotted.
- 6.12** *He* further indicated that *he* was aware that two of *his* most senior staff would soon leave the Section and *he* was keen therefore to build on Planner B's evident good progress by moving *him* on to more complex work. Planner B had apparently been keen to progress *his* experience in the more complex planning procedures.
- 6.13** Thus, the decision to have Planner B undertake the main planning duties for Miss Norris appears to have been to some extent a forced one, in that *he* was the only staff member with any experience of medulla planning who was available, and to some extent a considered one, in that a conscious decision had been made to expand *his* experience of complex planning.
- 6.14** What is apparent from this analysis, however, is that if the senior planning staff were so heavily committed as to preclude their taking on the main planning responsibilities for Miss Norris, then their availability for the necessary supervision role would have been similarly compromised.
- 6.15** The conclusions that arise are that (a) the level of experience that was brought to bear on creating and on supervising the creation of the treatment plan for Miss Norris was less than that which should reasonably be expected and that which the BOC's own treatment planning structures and procedures would indicate to be necessary and (b) lack of staff availability was at least a contributory factor in causing this deficiency.
- 6.16** These same staffing pressures clearly affected the availability of an independent checker (Paragraph 5.36) and the further extent to which they might have compromised the identification of the error in checking of the treatment plan is a matter of conjecture. However, it should be noted that the fact that the checking process did identify a number of other deficiencies in the original plan (see Paragraph 5.37), indicates that checking had been carried out with some degree of diligence.

6.2.4 The effect of staffing pressures on the general integrity of the treatment planning system at the BOC

- 6.17** Further issues of importance regarding staffing levels include (i) the extent to which this caused the failure of the BOC to keep written procedures up to date (see Paragraph 5.13) and (ii) the level of effort that was committed to evaluating and addressing the potential consequences of the change to *Varis 7* in May 2005.
- 6.18** In relation to issue (i), BOC quality system document QS 03 'Document and Data Control' states that '*All controlled documents are reviewed at least annually...*'. This requirement clearly was not being achieved. Paragraph 44 of the note of the 10th February meeting at the BOC (Annex 4 to this report) notes that quality system audits at the BOC in 2005 had identified that '*Controlled documents are not being reviewed annually for validity via management review or audit*'. Similar concerns for the effectiveness of document maintenance extend to those documents which were not controlled under the BOC's ISO 9000 quality system, such as training records and to employer's procedures required under the IR(ME) Regulations.
- 6.19** The same 10th February meeting note also reports the views expressed by senior BOC staff that the evident failure to maintain these document reviews was due to a general lack of staff resource exacerbated by a number of other unusual demands on departmental staff. These demands included the installation and commissioning of a new radiotherapy facility at Gartnavel Hospital and purchasing and commissioning of new equipment including the *Varis 7* system in 2005. (Previous concerns over staff resource resulted in a restructuring of the entire Radiotherapy Physics Department in 2000 and 2001.)
- 6.20** This view of why quality system procedures at the BOC had not been maintained to the required level was supported in subsequent interviews with Principal Planner A (Annex 5).
- 6.21** Regarding issue (ii) in Paragraph 6.17, guidance from the Royal College of Radiologists on 'The Provision and Replacement of Radiotherapy Equipment' [4] (<http://www.rcr.ac.uk/docs/oncology/pdf/equip.pdf>) says of 'Treatment planning systems', that '*....a comparatively lengthy commissioning period [12 weeks] may be required to acquire and fully test all the data the system requires and hence to establish confidence in the clinical safety of the system before it enters clinical service*'. Whereas a multidisciplinary 'Varis Implementation Team' was established to oversee the technical aspects of the introduction of the new *Varis 7* system, no evidence has been presented by the BOC of any related evaluation of clinical safety having taken place. Had such an evaluation been conducted properly, it seems likely that the potential for the normalization error to occur would have been identified.
- 6.22** In addition, an 'observation' raised in the report on the BOC's internal quality audit for 30th March 2005 (Report number 05 IMK3 BOC) was that '*It is not clear how purchased software updates are controlled. A procedure to clarify this should be looked at.*' Again, no evidence was presented by the BOC of such a procedure having been produced.

6.2.5 How deficient were the BOC's staffing levels for Treatment Planning

- 6.23** Having identified staffing pressures as a significant underlying cause of the errors that led to this incident, the question which then arises is what was the actual level of understaffing for Treatment Planning at the BOC?
- 6.24** Further to the general concerns for staffing levels in Scotland as outlined in Paragraph 6.2, the conclusion of a review of 'Equipment, Workload and Staffing for Radiotherapy in Scotland 1997–2003' [5] (http://www.rcr.ac.uk/docs/oncology/pdf/equipment_scot.pdf) that was published by the Royal College of Radiologists (RCR) in 2005' included a view that *'all departments are well below their minimum recommended level for physicists and dosimetrists, averaging just over 70% of that required. Glasgow has problems with recruiting physicists, as shown by their high number of vacancies.'*
- 6.25** Regarding this latter statement, the BOC's Specialist Oncology Risk Register for October 2005 identifies the need for action in respect of the imminent departure of the Head of Radiotherapy Physics as well as *'Two Clinical Scientist and one MTO vacancy. A further MTO on maternity leave. One MTO on long term sick leave.'*
- 6.26** At interview, the former Head of Radiotherapy Physics at the BOC (who left this post on 31st December 2005) indicated that the required staffing levels for the Radiotherapy Physics Group were assessed in accordance with the relevant guidance from the Institute of Physics and Engineering in Medicine ('Guidelines: The provision of a physics service to radiotherapy. (2002) [7]). The resulting staff establishment (all grades) for the Treatment Planning Section for 2005 was determined to be 18 whole time equivalent (WTE) staff. Against this establishment, figures from the BOC indicate that the number of *available* staff rose from 14.3 WTE in the first quarter of 2005 to 17.6 in the last. These figures include both treatment planners (Table 6.1) and other members of staff within the same Section who were involved in other aspects of patient dosimetry such as equipment calibration.
- 6.27** These figures, in themselves, suggest an ongoing improvement from the position identified in the RCR report [5] and imply that the available staff numbers at the BOC for the last quarter of 2005 were close to establishment levels. They might also suggest that the staffing numbers should have been sufficient to cope with the planning workload. However, it should be recognized that this does not take account of the extra workload imposed by the demands referred to in Paragraph 6.19 or of the evident backlog of deficiencies in quality system documents. The distribution of staff experience is also of importance. In this regard, one member of the treatment planning staff expressed a view that non-availability of senior staff for checking of plans was a frequent issue of concern.
- 6.28** Within the scope of this investigation, it has not been possible to gain a clear overview of the adequacy of the staffing levels for Treatment Planning at the BOC in relation to the requirements placed on the available staff both by routine dosimetry planning and unusual extra demands. However, it is apparent that whether as a consequence of deficient staff numbers and experience or of inefficient use of the staff resource available, the available

staff were not able to maintain properly the relevant parts of the BOC quality system nor to bring the appropriate level of staff experience to bear in the creation of treatment plans for complex procedures.

6.3 Individual responsibilities.

- 6.29** Dr Martin's incident report (referred to in Paragraph 3.4 of this report) includes a recommendation that *'There should be more formal procedures relating to allocation of particular tasks as required by IRMER 2000'*.
- 6.30** In this regard, a recurring theme in the staff interviews that formed part of this investigation was a lack of clarity about who was responsible for what. This extends beyond the requirements of the IR(ME) Regulations to other areas of responsibility such as treatment planning documents, the BOC ISO 9000 Quality System, staffing levels and staff training.
- 6.31** A particular example of this relates to Medulla Planning Form FM.14.014 (Annex 2 to this report). In the completed version for Miss Norris, the box labelled 'Radiotherapist' is initialled by 'XX'. The box labelled 'Physics' is initialled by Planner B/Principal Planner A/Senior Planner C. In addition, on the back of the form is attached a glued label which states *'I have checked this physics plan and treatment may proceed'*. This is initialled by YY (a BOC consultant clinical oncologist).
- 6.32** In this regard, the Clinical Oncology Information Network of the Royal College of Radiologists 'Guidelines for External Beam Radiotherapy', [2] <http://www.rcr.ac.uk/docs/oncology/other/radiotherapy.htm> includes the following recommendations:
- Recommendation 30: One individual clinical oncologist, the planning clinician, is responsible for the whole planning process.
 - Recommendation 45: The planning clinician is responsible for acceptance of the final plan.
 - Recommendation 46: Acceptance of the plan should be indicated by the planning clinician's dated signature.
- 6.33** Adherence to these guidelines would imply that responsibility for the content of the Medulla Planning Form FM.14.014 for Miss Norris lay with either of the clinical oncologists whose initials appear on the form. However, there is nothing in BOC procedures to suggest that this was the case. Indeed, there was general agreement among the BOC staff interviewed that it would be illogical to expect that a clinical oncologist would be able to assess the accuracy of the detailed treatment delivery parameters arising from the treatment planning process.
- 6.34** The situation that emerges, therefore, is that there was no written indication and no common understanding among BOC staff regarding who was responsible for the accuracy of the information on Medulla Planning Form FM.14.014 for Miss Norris.
- 6.35** In other instances, even where BOC documentation does allocate responsibilities, it is apparent that these allocations are not commonly known or acted on. For example, BOC Document QS 10 on 'Training' states that *'The Training Record of each member of staff will be endorsed by the Departmental Heads or their deputies to show that training needs have been reviewed'*.

However, all of the training records for the Treatment Planning staff that were examined as part of this investigation were signed by Principal Planner A (including *his* own record) who is neither a Departmental Head nor a deputy.

- 6.36** A further complication at the BOC, in terms of allocation of responsibilities, is that whereas line management responsibilities for staff in the Radiotherapy Physics Group come under the Head of Clinical Physics and Bioengineering, these same staff are responsible to the Medical Director for the quality of their input to clinical care. In this regard, the Department of Health's 'Manual of Cancer Services 2004' [6] (<http://www.dh.gov.uk/assetRoot/04/08/53/48/04085348.pdf>) recommends that '*Where there is no common line management for medical physics and radiotherapy, a service level agreement should exist between the two.*' (While this document has not been issued in Scotland, this recommendation nevertheless has validity to the situation at the BOC.)
- 6.37** In general, therefore, the situation regarding written allocation and common understanding of responsibilities at the BOC is not conducive to proper maintenance of quality system working. This clearly is an unsatisfactory position.

6.4 Compliance with IR(ME)R procedures

- 6.38** The IR(ME) Regulations [1] which came into force in the UK in May 2000 are made under EU Council Directive 97/43/Euratom. One of the requirements of this Directive is for a system of inspection by a competent authority for compliance with the Regulations.
- 6.39** Between 2001 and 2004, members of the Inspectorate of the Secretary of State for Health for the IR(ME) Regulations were commissioned through the Department of Health in England to undertake a programme of proactive inspection visits for premises in Scotland covered by the IR(ME) Regulations. However, the BOC was not among the premises included in these visits.
- 6.40** Senior management at the BOC had, nevertheless, been concerned that provisions in place in respect of the IR(ME) Regulations were inadequate. In particular, in response to his concerns over a series of reportable incidents in 2004, the Medical Director requested that the Radiotherapy Management Group and other senior managers undertake a review of policies and procedures. This review took place in March 2005 and, at the request of the Scottish Executive Health Department, included representation from Ms Carol Nix from the Radiation Protection Division of the Health Protection Agency (a former member of the Secretary of State's Inspectorate). A result of this review was Ms Nix's clearly stated views on the need for improvement in the BOC's IR(ME)R procedures. Action on this recommendation was ongoing at the BOC at the outset of this investigation.
- 6.41** Annex 7 to this report identifies the particular IR(ME)R requirements for which this incident investigation has found evidence of non-compliance. The findings detailed in Annex 7 are summarized in Paragraphs 6.42, 6.43 and 6.44.

- 6.42** Planner B was not qualified to act as operator under the Regulations and the level of supervision provided by Principal Planner A was not sufficient for *him* properly to adopt and discharge the operator's regulatory responsibilities.
- 6.43** The employer's written procedures and training records were not in compliance with the Regulations.
- 6.44** The requirements of Schedule 1k of the Regulations for employers to have in place '*procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable*' were not being met.
- 6.45** In summary, the contributory factors in this incident with direct relevance to IR(ME)R compliance were (a) delays at the BOC in achieving compliance with employers responsibilities under the IR(ME) Regulations and (b) failure to ensure that all practical aspects of the treatment planning procedure were carried out by someone who was properly qualified to act as an operator under the regulations and was identified as such by the employer.

7. Consideration of the findings of a previous investigation into the conduct of Isocentric Radiotherapy at the North Staffordshire Royal Infirmary between 1982 and 1991

7.1 Introduction

7.1 When incidents such as the one under investigation here occur, it is relevant to ask whether the risk of occurrence might have been reduced by proper attention to the lessons available from previous incidents.

7.2 Between 1982 and 1991 just under 1000 patients who underwent isocentric radiotherapy treatment at the North Staffordshire Royal Infirmary (NSRI) received a dose of radiation significantly *less* than intended. This led to the commissioning by the West Midlands Regional Health Authority of an independent inquiry headed by Sir Peter Baldwin. The first report of this inquiry was published in August 1992 and this was followed by a second report in March 1994. This second report included consideration of the findings of an Independent Clinical Assessment of the affected patients that was commissioned by North Staffordshire Health Authority and published in September 1993.

7.3 While there are some very obvious differences between the circumstances of the North Staffordshire incident and that considered here, the parallels and the extent to which any lessons learned from this previous incident could have affected practice at the BOC are worthy of consideration.

7.2 The causes of the North Staffordshire incident

7.4 'Isocentric' radiation treatment involves rotation of the treatment machine in a plane around the patient whereby the centre of rotation is coincident with the target tumour. The aim is to deliver a predetermined dose of radiation to the target from different angles and treatment planning is complex. Prior to 1982 the absence of a treatment planning computer at NSRI meant that calculations of complete dose distributions for isocentric treatments were not practical.

7.5 One of the difficulties for planning of isocentric treatment is that the beam intensity required to deliver the correct dose to the target depends on the distance between the source and the skin of the patient and this changes on machine rotation. Therefore an appropriate allowance needs to be made.

7.6 Prior to 1982, the Treatment Radiographer at NSRI was familiar with the need to adjust the beam intensity for non-isocentric treatments where the distance between the source and the skin was other than 1 metre. Therefore, when the new computer system was introduced in 1982, the Treatment Radiographer assumed that this adjustment was still required and convinced the Physicist responsible for treatment planning that this was the case. What both failed to recognize was that the new computer software already incorporated an allowance for source to skin distance in its calculation of beam intensity.

7.7 The Treatment Radiographer's concern over the need to make the manual adjustment is understandable in that, had this indeed been needed and omitted, then serious overexposures could have resulted.

7.8 The result of this initial error was that the allowance for distance made by the computer was duplicated manually by the Treatment Radiographer and this duplication continued for all isocentric treatments between 1982 and 1991.

7.3 Findings of the Baldwin Report relevant to the BOC incident

7.9 It is informative to consider what parallels can be identified in the circumstances of the NSRI incident and that at the BOC.

The NSRI incident.

A change was made to the treatment planning software (RT PLAN) but the full implications were not evaluated formally.

The change related to the complex procedure of isocentric radiotherapy.

Following the change, radiotherapy staff continued to use a method of manual adjustment of the MU output from the new software to allow for source to skin distance. The change had rendered this adjustment unnecessary.

The error resulted in the wrong number of monitor units being set on the delivery unit.

The error remained undetected for some 9 years and, as a result, some 1000 patients received doses of radiation much less than intended.

During investigation, treatment planning staff expressed concerns that the staffing arrangements prevalent at the time of the incident left little time for quality assurance measures.

The BOC incident.

A change was made to the treatment planning software (Varis 7) but the full implications were not evaluated formally.

The change had specific implications for certain complex procedures including whole CNS treatment.

Following the change, treatment planning staff continued to use a paper form that required an entry in MU per 100 centigrays. This now required manual normalization of the MU output from the new software but the planner was not aware of this need.

The error resulted in the wrong number of monitor units being set on the delivery unit.

The error was detected in preparation of the next, similar plan and, as a result, only one patient received a dose of radiation much greater than intended.

During investigation, treatment planning staff expressed concerns that the staffing arrangements prevalent at the time of the incident left little time for quality assurance measures.

7.10 There were, therefore, a number of similarities between these two incidents but of principal note is that both stemmed from the introduction of a change to the computer system without formal and detailed evaluation of its full implications. In both cases, had there been a formal requirement for evaluation of significant changes that might affect the dose delivered to the patient, then the incidents might have been avoided.

7.4 Recommendations of the Baldwin Report relevant to the BOC incident

7.11 Part of the remit of the independent inquiry into the NSRI incident was 'To make recommendations for updating and reviewing policies and procedures in the light of the current incident.' The emerging recommendations included the following:

- (i) It should be the duty of the Principal Radiotherapy Physicist to institute such a programme or programmes of tests and checks, recurrent or otherwise, that each Clinical Oncologist in the Department is continually assured that any dose of radiation which he or she prescribes is delivered to the tumour in precisely the manner and the intensity prescribed by the physician.
- (ii) In the event of any new equipment or any new processes being considered for introduction into the work of the Radiotherapy Department, the top management of the Acute Unit should consider what arrangements for training would provide assurance against error, whether on the part of Clinicians, Radiotherapy Physicists, Radiographers or supporting staff; and should draw on resources outside the Acute Unit if there is any reason to believe that those within the Unit would not suffice.
- (iii) No equipment should be allowed to enter into use within the Department without manuals explaining both its operation and the significance in its operation of the scientific understanding which it is the purpose of the equipment to utilise.

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8. Summary of principal findings

- 8.1 The principal findings arising from investigation of this incident both by staff at the BOC and by the Inspector are summarized in the following paragraphs.
- 8.2 In May 2005 an upgrade to the existing computer package to the new *Varis 7* system was installed at the Beatson Oncology Centre. This upgrade overcame previous technical and operational obstacles to allow the data calculated by the *Eclipse* treatment planning module within *Varis 7* to be transferred electronically (rather than manually) to the *RTChart* module which verifies these treatment parameters prior to treatment delivery and records those set at delivery. To optimise the benefit of the change to electronic data transfer, the previous practice at the BOC whereby all treatment plans were computed using a standardized dose fraction of 1 Gray (100 centigrays) was changed so that they were then calculated using the actual prescribed radiation dose per fraction.
- 8.3 This new facility has a number of potential advantages for planning efficiency and for patient safety. For example, the Royal College of Radiologists' Clinical Oncology Information Network 'Guideline for External Beam Radiotherapy' [2] recognizes that '*Manual transfer of data either from planning to treatment units or between treatment units is associated with a high risk of transcription errors*' and recommends, therefore that '*The transfer of treatment data sets should be by local area IT network as far as possible*'.
- 8.4 The 'whole CNS' procedure involved in this incident, comprises separate treatment fields for the head, the upper spine and the lower and spine. Of these, the spine fields are the more complex and it was decided at the BOC that these were not amenable to electronic data transfer within *Varis 7*. For the head fields separate electronic transfer of data would have been possible but for various reasons this was not pursued. Therefore, manual data transfer was retained for all elements of the whole CNS procedure.
- 8.5 Despite the retention of manual data transfer, the change in practice referred to above was applied, whereby treatment parameters for the head fields were calculated using the prescribed radiation dose per fraction instead of a standardized dose fraction of 100 centigrays.
- 8.6 Therefore, the form of the data contained in the paper Treatment Plan Report from the *Eclipse* treatment planning module had changed. Specifically, whereas previously a specific entry on the Treatment Plan Report was always in units of 'Monitor Units per 100 centigrays' the data on the Report for Miss Norris was the number of Monitor Units per treatment fraction. (The prescribed treatment fractions for Miss Norris were each of 175 centigrays.)
- 8.7 Had the potential implications of this change been fully assessed then the potential for this difference in the form of the data output to introduce a critical error into manual planning might have been identified. However, no evidence has been presented of such an assessment having taken place.

- 8.8** Any such assessment would have necessitated a proper review of related written procedures and appropriate training for all staff. However, the last update of the BOC's Work Instruction number WI.14.01.01 for 'Medulla Planning' was in August 1998, and no evidence of any subsequent review of this document has been presented. This is contrary to the requirement of BOC quality system document QS 03 'Document and Data Control' which states that 'All controlled documents are reviewed at least annually...'
- 8.9** The available training records for Planner B who undertook the bulk of the treatment planning give no indication of any formal competence in planning for the whole CNS procedure in question. However, *he* had been involved in planning of one treatment of this type since *his* training records had last been updated and this was considered by Principle Planner A to be sufficient to allow him then to plan similar treatments under supervision (in accordance with the provisions of Section 11(3) of the IR(ME) Regulations).
- 8.10** For this single previous experience, the prescribed radiation dose per treatment fraction happened to be 100 centigrays. Therefore, the number of Monitor Units per treatment fraction written in the Treatment Plan Report from *Eclipse* was already in Monitor Units per 100 centigrays and therefore would not have changed even if the normalization procedure had been applied.
- 8.11** Planner B (in common with the other planners at the BOC) therefore had no experience of dealing with the conversion from MU per treatment fraction to MU per 100 centigrays that was required for completion of the Medulla Planning Form. Further, *he* had no access to any appropriately revised written procedures and, by common agreement among those interviewed, had received no training or instruction on this conversion. Planner B was therefore unaware of the need for this critical normalization step and omitted it.
- 8.12** The choice of Planner B as the main planner for a procedure of this complexity was contrary to the (albeit flexible) staffing structure for treatment planning that was in place at the BOC. This structure (Table 6.1 in this report) allocates planning duties for complex (Category *E*) plans to senior planning staff with appropriate levels of experience. The underlying reason given by the Principal Planner A for allocating this plan to Planner B was non-availability of experienced staff.
- 8.13** The supervision received by Planner B in planning the treatment for Miss Norris was indirect in the sense that, following initial instruction, *he* was left to complete the planning process but with the facility to raise any issues of difficulty with a senior colleague. The use of this form of supervision appears to have been a consequence of the relationship between staffing levels and workload in treatment planning. Had direct supervision been possible, there is a greater likelihood that the more experienced supervisor would have identified the error.
- 8.14** In addition to the critical error for the head fields, Planner B also made other errors for the spine fields which were identified and corrected on checking by senior colleagues.

- 8.15** Checking of the treatment plan by senior colleagues was not carried out according to procedure, in the sense that the principal checker (Principal Planner A) was also involved in supervision and as such should not have undertaken checking. The plan should have been independently checked, as required by BOC Procedure QS.14.13. Again the deficiency appears to have been a consequence of the relationship between staffing levels and workload planning. However, the fact that the checking process did identify a number of other deficiencies in the original plan, suggests that the procedure was correct and that checking of the spine fields had been carried out diligently. The presence of these errors reinforces the need for more direct supervision of plans being prepared by staff in training.
- 8.16** The error was repeated by Planner B subsequently in planning a similar treatment for a new patient and, again, the checker (in this case Senior Planner C) failed to identify the error. However, prior to any treatment being delivered, as a result of a separate enquiry by a treatment radiographer the error for this patient was identified during further checking by Senior Planner D. It was this discovery that led to investigation of previous treatment plans using the same technique and to identification of the error in the plan for Miss Norris. None of the treatment plans for other patients was affected.
- 8.17** This investigation has identified a number of concerns regarding the proper allocation of staff responsibilities and lack of a common understanding about who was responsible for what (Section 6.3 of this report).
- 8.18** There were deficiencies in the BOC's compliance with the IR(ME) Regulations 2000. The decision to use a planning mechanism which did not minimise the risk of error (Schedule 1k), and failure to show particular regard to the maintenance of written procedures and training records contributed to the risk of occurrence for this incident.
- 8.19** The parallels identified in Chapter 7 of this report suggest that had the lessons learned and recommendations made following the previous incident at North Staffordshire Royal Infirmary been properly addressed at the BOC then the risk of occurrence for this incident would have been reduced.
- 8.20** Failure to ensure that the introduction of new technologies and the implementation of related changes in working practices were supported by proper assessment and provision of full written procedures and training have impacted significantly on the causes of this incident.
- 8.21** The main factors that contributed to this error were therefore;
- (i) delays in achieving full compliance with the IR(ME) Regulations,
 - (ii) failure to assess fully and address both the risks and the potential improvements to patient safety following the introduction of new technologies including CT imaging, computer planning and the *Varis 7* upgrade,
 - (iii) failure to keep written procedures and training records properly up to date,
 - (iv) inappropriate over-reliance on the limited experience of Planner B,
 - (v) failure to provide direct supervision in treatment planning,
 - (vi) failure to provide fully independent checking of treatment plans,
 - (vii) lack of written statements and of common understandings about individual responsibilities,
 - (viii) failure to address the lessons and recommendations from previous incidents at other radiotherapy centres.

- 8.22** An underlying cause of most these deficiencies is an evident insufficiency in staff resources which might be attributed to a number of factors including;
- (i) continuing expansion of the service,
 - (ii) difficulties in recruiting and retaining experienced staff,
 - (iii) consequent implications of internal promotion of staff.
- 8.23** The result was that an overriding culture existed such that changes in practice could be made without proper assessment, evaluation and documentation. This culture was founded on reliance on a few well respected, experienced staff who had been employed at BOC for a number of years.
- 8.24** The BOC, both as an immediate consequence of the incident and in response to the recommendation made in the incident report by Dr Martin, has introduced a number of procedural changes aimed at minimizing the possibility of recurrence of any similar occurrences. However, further attention to quality system working is required to ensure that systems of work at the BOC are conducive with the appropriate level of patient safety (Section 9.4 of this report).

9. Actions and recommendations

9.1 Introduction

- 9.1** This investigation has sought to establish what was the precise course of events that led to the series of overexposures for Miss Lisa Norris, what were the contributory factors and who were the BOC staff involved. These findings are summarized in Chapter 8 of this report. The remaining objective is to ensure that appropriate and practical measures are identified that will minimize the possibility of a recurrence of an incident of this type and contribute more generally to the improvement of patient safety.
- 9.2** It should be stressed, however, that the principal responsibility for ensuring that corrective actions are identified and implemented remains with the employers and staff concerned, in accordance with their statutory responsibilities, the provisions of their professional regulation and their general duty of care. In this regard, the BOC's own internal investigations have identified a number of corrective actions. Feedback from the BOC to the Inspector indicates that most of these have already been implemented.
- 9.3** This chapter gives details of the actions already taken at the BOC in respect of this incident and makes further recommendations for improvements in procedures and practice at the BOC. Those recommendations that impinge on the BOC's responsibilities under the IR(ME) Regulations, are subject to separate consideration of enforcement action by the Regulator (Paragraph 9.41).
- 9.4** Consideration is also given (in Sub-section 9.4.2) to how the lessons learned and changes recommended in respect of this incident might extend to other radiotherapy centres in Scotland and the rest of the UK and to other relevant bodies.

9.2 Actions already taken by the BOC

- 9.5** As a result of the initial investigation of this incident by Principal Planner A and subsequent consideration by senior radiotherapy physics staff of the need for further action, management at the BOC has advised the Inspector that a number of changes have been implemented at the BOC. These include the changes summarized below in Paragraphs 9.6 to 9.14.
- 9.6** A list has been compiled of those planning procedures (including the whole CNS procedure) considered to be such as to present a high risk of error. Special provisions for checking plans within this 'high risk' category have been introduced.
- 9.7** A review of all Quality System documents relevant to Treatment Planning at the BOC has been initiated. All documents that do not reflect current practice will be subject to programmed updating with priority given to written procedures for 'high risk' plans. An instruction has been given that no high risk plan will be submitted unless a properly reviewed and suitably revised written procedure is in place.
- 9.8** New planning forms have been introduced which include provisions to identify clearly the roles of all participants, as planner, checker etc.
- 9.9** Reference check lists are being prepared for all planning procedures with priority given to 'high risk' and complex plans. These check lists will include the expected ranges for all critical parameters including the expected range of Monitor Units per treatment fraction.

- 9.10 Advice has been issued to all Treatment Planning staff that any concerns over non-compliances with quality systems procedures should be raised with a Quality Management Representative.
- 9.11 In future, all treatment plans that are created using *Eclipse*, must include the prescribed radiation dose. Quality System Documents referred to in Paragraph 9.7 above have been amended to reflect this change.
- 9.12 Maximal use will be made of the facility for electronic transfer of data from *Eclipse* to *RTChart*.
- 9.13 A thorough review and revision of training records and related documents has been initiated to ensure that the training status of all individuals is properly recorded and verified and that planning duties are allocated appropriately in relation to these records.
- 9.14 Piloting of a new '*Radcalc*' software module which will increase the capability for Monitor Unit checking from the current level of 75% of plans with the extant, internal *QASSUR* system, to all plans, is complete. The *Radcalc* system has been fully implemented.

9.3 Additional actions recommended by the Head of Health Physics

- 9.15 Some of these actions address the recommendations made in Dr Martin's formal incident report to the Warranted Inspector (Paragraph 3.4 in this report). The additional recommendations within Dr Martin's report are summarized in Paragraphs 9.16 to 9.21.
- 9.16 A system should be introduced that ensures that checking of plans is totally independent of their creation.
- 9.17 Consideration should be given to the use of *in vivo* dosimeters to measure the radiation dose delivered in the first fraction for those treatments where an independent check of dose cannot be carried out by other means.
- 9.18 The level of adherence by BOC staff to Quality System procedures needs to be improved.
- 9.19 Consideration should be given to the introduction of a summary planning document to record key information as patients progress through the planning and treatment process. The aim would be to ensure that all parties involved in the treatment planning process have access to all relevant information and thereby to reduce the risk of error.
- 9.20 More formal procedures should be introduced for allocating responsibilities for particular tasks to individual staff members, as required by the IR(ME) Regulations.
- 9.21 An improved multi-disciplinary team approach to treatment planning and delivery should be pursued.
- 9.22 Provisions pursued normally in Scotland for incident reporting and investigation under the IR(ME) Regulations, require the BOC to respond to the Inspector giving details of their approach to Dr Martin's recommendations. A response has been received and the changes indicated will be subject to subsequent review by the Inspector.

9.4 Further recommendations arising from this investigation

9.4.1 Recommendations for action to be taken by the BOC

- 9.23** The actions and recommendations identified in Sections 9.2 and 9.3 of this report represent an appropriate and proportionate response to this incident. However, in consequence of the findings of this investigation, the following additional measures in Paragraphs 9.24 to 9.33 of this Sub-section are recommended for action by the BOC.
- 9.24** A comprehensive review of the responsibilities of all staff at the BOC with responsibilities related to areas covered by the IR(ME) Regulations should be undertaken to ensure that individual responsibilities are well documented and commonly understood. The aim should be to ensure that all areas of responsibility are properly and unambiguously addressed. The outcome should include a clear, written statement of the duties of operators, referrers, practitioners and employers under the IR(ME) Regulations and who is responsible for all elements of the working system including the ISO 9000 Quality System. A single BOC staff member should be made responsible for annual review and redistribution of this written statement or for interim updates. This written statement should be part of the BOC's quality system.
- 9.25** With reference to Paragraph 6.36 of this report, the need for a clearer understanding of the line management responsibilities for staff in the Radiotherapy Physics Group should be addressed. Any related implications of emerging structural arrangements whereby the Head of Clinical Physics and Bioengineering and the Medical Director for Specialist Oncology Services report through different Clinical Directorates should be evaluated carefully.
- 9.26** A comprehensive review of the adequacy of staffing provisions for treatment planning at the BOC should be undertaken, taking account not only of IPEM recommended staffing numbers but also of (a) the distribution of staff training and experience in relation to the annual distribution of plans among the various categories of complexity and risk of error, (b) any extraneous demands on treatment planning staff currently or in the foreseeable future, (c) future developments at the BOC with regard to the projections and recommendations contained in the 2006 report by The Radiotherapy Activity Planning Steering Group on '*Cancer in Scotland: Radiotherapy Activity Planning for Scotland 2011 – 2015*'. The findings of this review should be reported formally to the SEHD.
- 9.27** The current system of rotation of treatment planning staff among different sections should be reviewed with particular regard to the effect of this system on staff training and development.
- 9.28** Principal Planner A informed the Inspector (Paragraph 6.11) that some 80% of requests for treatment plans at the BOC are submitted either on the same day or on the day before the plan is required. Such a position would be contrary to the proper distribution of work among treatment planning staff. Other information received by the Inspector from BOC management indicates that the relevant figure is considerably less than 80%. This position should be clarified and addressed appropriately.
- 9.29** In keeping with the requirements of Schedule 1(k) of the IR(ME) Regulations and with the relevant recommendations of the Baldwin Report on the incident at North Staffordshire Royal Infirmary (Section 7.4 of this report) a written procedure should be introduced within the BOC's Quality System requiring that all changes to the treatment planning and delivery systems must be subject to a formal review of possible safety implications by suitably qualified staff. A formal written report on any such review, appropriately signed, should be kept on record for a specified period.

- 9.30** Consideration should be given to the possible advantages to patient safety of all available technology e.g. electronic data transfer and where appropriate, the use of operator specific electronic passwords in conjunction with the replacement of any paper treatment planning forms requiring handwritten inputs with equivalent electronic data and recording mechanisms. The possible advantages include ensuring completion of mandatory fields, and the ability to set limits on the access of individuals depending on competence.
- 9.31** A written procedure should be introduced within the BOC's quality system giving clear instruction on the level of supervision required for trainees undertaking planning duties and on what form that supervision must take.
- 9.32** All documents relating to IR(ME)R procedures should be produced in an appropriate, common style with clear identification of who is responsible for authorizing and maintaining the content. Wherever possible, such procedures should be incorporated into a single document along with the requirements of the ISO system, but recognising that there are different requirements in these two approaches (for example, the IR(ME)R procedures will need to include a clear statement of duty holder responsibility and how this is demonstrated whereas ISO does not).
- 9.33** In accordance with the requirements of Schedule 1(e) of the IR(ME) Regulations a written procedure should be introduced to ensure that quality assurance programmes are followed.

9.4.2 Recommendations for action by other parties

- 9.34** The lessons and recommendations arising from this incident and the resulting investigations have implications for other radiotherapy centres and for the relevant professional organisations. In addition to the actions and recommendations in Sections 9.2, 9.3, and 9.4.1 the recommendations in Paragraphs 9.35 to 9.40 should be considered for actions by parties outwith the BOC.
- 9.35** A Short Term Sub-Group, of the Radiotherapy Advisory Group (which is current active in Scotland) should be established to review treatment planning provisions at all five Scottish radiotherapy centres and report their findings to the Scottish Cancer Group. The aim should be ensure that all the provisions at all five centres for regulatory compliance, staffing and quality system working are such as to ensure an appropriate level of patient safety.
- 9.36** The Scottish Executive's 2006 report on '*Cancer in Scotland: Radiotherapy Activity Planning for Scotland 2011 – 2015*' [3] predicts that the number of radiotherapy treatment fractions to be delivered in Scotland will increase from 175,954 in 2003 to between 242,384 and 318,422 in 2015. The Short Term Sub-Group should consider what measures might be required for treatment planning, in addition to those identified in the Scottish Executive's 2006 report, to safeguard and improve patient safety in the face of this level of increase in demand.
- 9.37** Particular consideration should be given also to the ways of maximising the uniformity of provisions among the five centres. For example, the provisions described in Paragraph 9.6 of this report could be extended to include unified 'numbering' of each individual planning procedure, under a scheme that identifies its assigned categories of complexity and risk of error. This might then form a basis for agreement between centres on all aspects of the planning requirements for individual procedures including the training and experience required for planners, supervisors and checkers.

- 9.38** The Royal College of Radiologists (RCR) should review the status and content of the 1999 Draft report of the Generic Radiotherapy Working Group of the Clinical Oncology Information Network *Guidelines for External Beam Radiotherapy* [2]. At present, it is not clear whether this document continues to constitute formal RCR guidance and how this guidance might be updated in the future. As indicated in Paragraph 6.32 of this report, some of the recommendations of this guidance seem inappropriate and should be reviewed by the RCR.
- 9.39** The Scottish Executive Health Department should consider the need to extend the guidelines currently in preparation by the National Institute for Health and Clinical Excellence (NICE) to include some of those detailed provisions of The Department of Health's *Manual of Cancer Services 2004* [5] that relate to radiotherapy planning.
- 9.40** National bodies including the Royal College of Radiologists and the recently-formed Medical Practices Sub-Committee of the Committee of Medical Aspects of Radiation in the Environment should consider how information on incidents involving accidental or inadvertent radiation exposures in medical practice can best be shared among radiotherapy centres in the UK.

9.5 Further actions under the IR(ME) Regulations

- 9.41** Those deficiencies identified during this investigation that constitute non-compliances with the statutory requirements of the IR(ME) Regulations will be addressed by the appropriate authority (The Scottish Ministers) in accordance with the relevant regulatory provisions. An improvement Notice has been served on the BOC by the inspector, in accordance with the provisions of Section 21 of the Health and Safety at Work Act 1974.
- 9.42** Satisfactory completion of the required changes to the BOC's IR(ME)R procedures and of any additional requirements specified by the regulator for the IR(ME) Regulations should be subject to a formal IR(ME)R Inspection at an appropriate date.

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10. Concluding remarks

10.1 Introduction

- 10.1** This incident occurred because of mistakes made by BOC treatment planning staff against a background of circumstances that were not conducive to error-free working. Therefore, while it has been relatively straightforward, with the cooperation of BOC staff, to identify who was responsible for making the critical error and for failing to identify it prior to treatment delivery, the issue of levels of blame is more complex.
- 10.2** This question can be looked at in two areas. Firstly, what level of responsibility should be attached to those members of the Treatment Planning staff who were involved directly with the incident. Secondly, who were responsible and at what level for the prevailing circumstances at the BOC that contributed to the risk of occurrence for the errors in question. These two issues are addressed separately in Sections 10.2 and 10.3.
- 10.3** Section 10.4 considers the general lessons to be learned for the BOC and for other radiotherapy centres in Scotland and elsewhere.

10.2 Levels of responsibility for treatment planning staff.

- 10.4** While the critical error was made by Planner B, it is clear from this investigation that *he* was assigned planning functions for preparation of Miss Norris's treatment that were inappropriate at a time in *his* career when *he* was not qualified either by formally assessed competence or by experience to undertake a task of this complexity, other than under close supervision. The appropriate level of direct supervision was not provided. Further, the BOC procedures were clear that Planner B carried no formal responsibility for these functions. In addition the supporting work instruction for medulla planning was out of date and contained no instruction relevant to the normalization procedure that became necessary with the change made to practice following the upgrade of the treatment planning computer system in May 2005.
- 10.5** The person who assigned treatment planning duties to Planner B was Principal Planner A. However, *his* own Treatment Planning Structures document (Sub-section 6.2.2 in this report) indicates that planning duties for procedures of this complexity should be allocated to staff with a much higher level of experience than Planner B. With hindsight, therefore, assignment to Planner B was inappropriate and suggests poor professional judgement on the part of Principal Planner A. However, *he* has explained this decision in terms of (a) the prevalent lack of staff with the experience necessary to create this plan and (b) the consequent need for accelerated training of such junior staff as were available and had demonstrated the necessary aptitude.
- 10.6** Principal Planner A also took principle responsibility for supervising the planning activities of Planner B but the insufficiency of this supervision is evident from the mistakes that were made by Planner B in creating the plan. Again, however, *he* has explained this in terms of the critical demand for *his* input to other treatment planning priorities.

- 10.7** Both Principal Planner A and Senior Planner C were responsible according to BOC procedures for checking the plan produced by Planner B. Whereas this checking successfully identified errors for the spine fields, both failed to identify the critical error for the head fields. Principal Planner A's participation as both supervisor and checker was incompatible with the requirement for independence in these two roles. The same explanation applies.
- 10.8** In summary, although it was Planner B who made the critical error, the circumstances whereby *he* was assigned this task without the appropriate levels of training, experience, supervision or documentary support were such that little blame can be allotted. Senior Planner C became involved when asked by Principal Planner A to check that part of the treatment plan where *he* had already identified and corrected errors in the spine fields. As noted in Paragraph 5.36, the precise role of each in the checking process is a matter of recollection rather than of record and is therefore difficult to assess. Senior Planner C's recollection is that the head fields had already been checked by Principal Planner A. Further, there was nothing in Senior Planner C's training record to indicate that *he* was aware that the 'Output' entry on the Medulla Planning Form was a potential source of error. Senior Planner C was at fault for signing the form to indicate that *he* had checked the plan whereas, in fact, *he* had either (in accordance with *his* recollection) not checked the head fields or had checked and failed to identify the error. Given the circumstances of Senior Planner C's involvement, it is again apparent that little blame can be attributed. (It should be noted also that Senior Planner C was the 'checker' for the similar plan that was prepared subsequently by Planner B and again failed to identify the same error.)
- 10.9** The responsibilities of Principal Planner A can be considered in three different contexts. Firstly, as Planner B's supervisor for this plan and as a checker, *he* was at fault both for failing to provide the level of supervision necessary to prevent the critical error and for failing to identify the error during checking. Secondly, Principal Planner A was responsible for assigning this plan to Planner B. Thirdly, Principal Planner A was fully involved in the decisions made about how different techniques should be planned and should have been instrumental in ensuring that the supporting documentation was in place. Taking these responsibilities together, it must be concluded that most of the blame that can be attributed to staff in the treatment planning section falls to Principal Planner A. However, the actual level of attributable blame requires due consideration of the background circumstances discussed in Section 10.3.

10.3 Levels of responsibility for BOC and GGHB management.

- 10.10** Section 6.3 of this report refers to the lack of written allocation and common understanding of responsibilities at the BOC as a contributory factor in this incident. This lack of clear definition of who was responsible for what makes also makes it difficult to apportion blame appropriately among the senior management staff at the BOC, at North Glasgow University Hospitals Division and at Greater Glasgow Health Board.
- 10.11** This section therefore considers the level of responsibility for this incident that is attributable to management as a whole for their contributory failings. This includes staff at all levels of management from the Head of Treatment Planning at the BOC to the Chief Executive of GGHB. No attempt is made to allot blame for these failings individually.

- 10.12** In addition to the evident lack of definition of management and quality system responsibilities, the further 'corporate' failings that have been identified in this investigation include,
- (i) failure to address the employer's statutory responsibilities under the IR(ME) Regulations for the provision and maintenance of written procedures and adequate training,
 - (ii) inadequacy of staffing provisions in relation to the proper establishment and maintenance of a suitable system of quality management for radiotherapy treatment planning at the BOC,
 - (iii) failure to ensure that flexible staffing provision for treatment planning workload was adopted such that the necessary level of training and experience could be brought to bear on planning for complex procedures,
 - (iv) failure to assess properly the implications of the upgrade to *Varis 7* for working procedures at the BOC, with particular regard to patient safety,
 - (v) failure to learn and apply the lessons available from previous incidents elsewhere, in particular that at the NSRI which is discussed in Chapter 7 of this report.
- 10.13** Compliance with the requirement of the IR(ME) Regulations for maintenance of employers written procedures can be regarded as one element of the BOC's overall provisions for ISO 9000 quality system working and the same concerns apply. However, the general shortcomings relevant to IR(ME)R compliance, had been identified by senior management and a programme of remedial work was in place, with a target date for completion of July 2006. Given the backlog of work required and the level of staff availability, this is considered to have been a realistic timescale. However, the evidence of this investigation suggests that progress towards this target at December 2005 was behind schedule.
- 10.14** Regarding issue number (ii) of Paragraph 10.12, the International Atomic Energy Agency's (IAEA) 2006 report on 'Applying radiation safety standards in radiotherapy' [8], with particular relevance to the maintenance of records, advises that '*When planning and developing an effective QA [Quality Assurance] programme, licensees need to recognize that it demands strong managerial commitment and support in the form of training and time, personnel and equipment resources.*' However, the evidence of this investigation indicates that the general requirements for maintenance of quality system documents at the BOC (see for example Paragraph 6.18) were not being met due to an ongoing shortage of staff allocated to this task.
- 10.15** Regarding issue number (iii) of Paragraph 10.12, it is evident from this investigation that senior management at the BOC was aware of deficiencies in the combined levels of training and experience among treatment planning staff. Staffing levels for Treatment Planning at the BOC had improved during 2005 but the circumstances of this incident indicate clearly that the staffing provision at December 2005 was not sufficient to ensure that the appropriate level of training and experience was brought to bear on planning the treatment for Miss Norris.
- 10.16** Paragraph 6.21 of this report refers to RCR guidance on the commissioning of new equipment and the need for related evaluation of clinical safety. At interview, Principal Planner A stated that '*The schedule for implementation [of Varis 7] was short*' and was '*in addition to the already very high clinical demands*'. He also expressed a view that '*the timescale for implementation, should have been twice as long as we had*' and that '*not enough attention was given to the amount of work involved, the resourcing and the impact on working practices*'. These opinions are in keeping with the lack of evidence of any formal evaluation of the need for changes to working practices and supporting documentation and for training resulting from the upgrade to *Varis 7* or, indeed, of the potential for improved clinical safety.

- 10.17** Regarding issue number (v) of Paragraph 10.12, the importance of ‘lessons learned’, the IAEA’s 2006 report on ‘Applying radiation safety standards in radiotherapy’ [8] advises that *‘Feedback from operational experience and lessons learned from accidents or near misses can help identify potential problems and correct deficiencies, and therefore should be used systematically as part of the QA programme.’* The similarities identified in Chapter 7 of this report between the underlying failures that contributed to both this incident and that at the NSRI indicate that the lessons and recommendations arising from the latter incident had not been adopted at the BOC. This applies particularly to the need for evaluation for the clinical safety of the relevant working procedures at the BOC following the upgrade to *Varis 7*.
- 10.18** Had all of these issues been addressed properly, then the risk of occurrence for this incident would have been reduced significantly. The evident failure to address these issues is due, at least in part, to the absence of a clear definition of management responsibilities referred to in Paragraph 10.10. Therefore, it must be concluded that corporate failings were responsible for creating the conditions under which the mistakes identified in this report were made and that management at all levels must share the blame for these failings.

10.4 Lessons arising from this incident.

- 10.19** The 1992 report of the independent inquiry into the NSRI incident makes a useful and appropriate reference to the ‘barbarian boxer’ of Athenian lore who consistently took heavy punishment because he always placed his guard where he had last been hit. In this regard, whereas those actions already taken by the BOC (summarized in Section 9.2 of this report) relate primarily to prevention of a recurrence of a similar incident, the recommendations in Section 9.4 and in this section are aimed more generally at an enhanced commitment to quality system working.
- 10.20** Those with responsibilities for the clinical safety of patients at radiotherapy centres in Scotland and elsewhere must ensure that the lessons arising from this incident are understood and acted upon within their own organizations. Particular attention should be paid to the considerations in Paragraphs 10.21 to 10.28.
- 10.21** The IR(ME) Regulations came into force in 2000 and should have been implemented fully by January 2001; including provision by the employer of written procedures. For example, failure to indicate that documents issued prior to January 2001 have been reviewed following implementation of these Regulations indicates serious shortcomings in a quality system. Any significant changes in practice such as changing to the use of CT image data rather than orthogonal films and the use of a planning computer rather than hand planning should be incorporated in a planned and systematic way, which includes revision of documentation required under the IR(ME) Regulations.
- 10.22** Management and quality system responsibilities must be clearly and unambiguously assigned and understood by all and must be subject to a proper system of accountability through regular audit of performance.
- 10.23** There must be an appropriate degree of managerial commitment at all levels to the maintenance of an effective quality system.

- 10.24** Staffing of treatment planning and delivery units must be reviewed regularly to ensure that levels are suitable and sufficient in terms of (a) the numbers of staff and (b) the required levels of training, experience and seniority. Such review should take account of routine demands for treatment of patients, research and development and maintenance of quality systems and of any unusual pressures such as the commissioning of new equipment or new systems of working. It is not sufficient to define staffing complements on the guidelines of professional bodies (such as the IPEM) alone.
- 10.25** The introduction of new equipment or new systems of working must be accompanied by a thorough review of the implications for patient and staff safety, both positive and negative. Such reviews should be conducted in accordance with a well defined plan and the outcomes documented formally.
- 10.26** Where systems of working allow for on-the-job training by completion of tasks under supervision, there must be a clear definition of the nature of supervision that is required. In particular, where the task in question has implication for the safety of patients or staff, supervision must be 'direct' in the sense that the supervisor must have direct involvement in overseeing all aspects of the work of the trainee.
- 10.27** Management should ensure that all staff involved in the planning and delivery of procedures involving ionising radiation are appropriately trained and that this training includes a proper understanding of the requirements for quality system working and awareness of the lessons learned from incidents reported previously.
- 10.28** The scheduling of demand for treatment planning (Paragraphs 6.11 and 9.28) must be such as to ensure that sufficient time is allowed for the work to be allocated to appropriately trained staff.
- 10.29** Finally, with due acknowledgement of the seriousness of this incident, attention is redirected to Paragraphs 5.42 and 5.43 of this report which demonstrate the potential for yet wider patient harm to have arisen.

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11 Acknowledgements

- 11.1** In conducting this investigation and in compiling this report, thanks are due to Mr Steve Ebdon-Jackson and Ms Carol Nix of the UK Health Protection Agency, to Ms Marianne Cook of the Scottish Executive Health Department and to Ms Valerie Holland of the Health and Safety Executive.
- 11.2** The co-operation of staff at the BOC in assisting with this investigation and in providing the documents requested by the Inspector is also acknowledged.

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Annex 1: BOC quality system document number WI.14.01.01, written procedures for 'Medulla Planning'.

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

WI.14.01.01

Medulla Planning

Scope: Planning of medulloblastoma or whole CNS treatments by Radiotherapy Physics Treatment Planning Staff.

Documentation:

Medulla Data Tables (DA.15.037, DA.15.038, DA.15.039, DA.15.054, DA.15.055, DA. 15.056, DA. 15.075, DA.15.088)

Medulla Planning Form - 1 Spine Field - (FM. 14.013)

Medulla Planning Form - 2 Spine Fields - (FM. 14.014)

Medulla Head Fields on SLs - Asymmetric Settings (FM. 14.006) Manual of Sample Plans

Set-up Description:

Whole CNS treatments are usually given for medulloblastoma. The patient lies prone on a special 'medulla mattress' and has a BDS.

The brain is treated with lateral opposing beams. The central axis is located at the outer canthus of the eye and asymmetric collimator settings are used. Eyes and mouth are shielded with customized alloy blocks.

The spine is treated from above using one or two beams, at standard or extended SSD as necessary. When using a single spine field, the gantry is set to zero, and the lateral head fields have a collimator rotation to match the divergence of the spine field. When using an upper (Sup) and a lower (Inf) spine field, the upper field is treated with a gantry of zero but the gantry for the lower spine field is angled to Superior (by an angle equal to the sum of the divergences of the two spine fields) so that a geometrical match of the beams is obtained. The lateral head fields have a collimator rotation to match the divergence of the upper spine field.

Compensators are manufactured for spine fields if required to achieve a range of dose of less than or equal to 5%.

Planning Methods:

1. Simulation.

Screen for head fields, centre on outer canthus, ball bearing and washer markers at outer canthii. Asymmetric settings: Sup, Ant and Post borders to cover head; Inf border at junction of C4/C5. Physicist estimates the collimator rotation required to match to spine field. This is based on approximation of spine length, choice of one or two spine fields, SSD. Collimator should be at 180° +/- tilt. Tilt is seldom less than 8° and must not exceed 10°. Mark Inf border (the junction) on Post surface of BDS.

Place medulla marker strip on midline over head and spine, with an identified marker at the junction. Radiograph is taken with 100cm to midline and FFD of 150cm. Other head radiograph is taken. Radiotherapist marks shielding on radiographs.

Overlapping lateral radiographs of the spine are taken (100cm to midline, 150cm S SD). Collimator set at zero, field defining wire set to about 6cm, to provide reference horizontal, line. Inf border is at S2/S3. Mark on radiograph, project back to skin surface (allowing for beam divergence). Using objects from marker strip for guidance, transfer this position onto patient's skin surface for tattooing.

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2. Planning.

Use form Medulla Head Fields on SLs - Asymmetric Settings (FM. 14.006) to convert Simulator settings for the head -fields to those required on the SL75/5 treatment units. Calculate the effective head size and hence the equivalent square at isocentre and at entry point. Measure the separation of the BDS at the centre of the head. Using the entry point equivalent square calculate the midplane depth dose using tabulated data plus a correction for change in SSD. Output factor (with plain tray) is based on the isocentre equivalent square at 100cm SSD and so percentage depth doses also have to be increased by an inverse square law factor to account for this.

As the head fields are isocentric, the T.A.D. at midplane is normalised ie set to 100%. The percentage depth dose figure becomes the normalisation factor.

Radiographs are sent to the Mould Room for manufacture of the shielding blocks and templates for Simulator checks.

Join the radiographs of the spine together. Draw position of spine field(s) and Anterior edge of spinal cord. Select representative points on spinal cord. Demagnify depth, effective SSD and off-axis distance (at depth of COM). From Medulla Data Tables (DA.15.037, DA.15.038, DA. 15.039, DA.15.054, DA.15.055, DA.15.056, DA.15.075, DA.15.088) determine central axis depth doses, off-axis correction factors and SSD correction factors and hence determine % depth dose at each point on the spinal cord.

If the range of dose exceeds 5%, a wax compensator is required. Calculate the percentage dose reduction required at each point to bring the dose down to the lowest value. The wax reduces the dose by 3.8% per cm (at 5MV). Hence the required thickness of wax can be determined for each point. Note: allow for the attenuation of the 3mm thick perspex plate on which the wax is mounted. Draw profile of wax on paper. Scale the off-axis distances from 5cm deep in the patient to the tray distance (69.7cm). Two copies of this are sent to the Mould Room. The wax should normally be 6cm wide.

Calculate the maximum subcutaneous dose. This usually occurs where no wax is required. It is equal to 100% multiplied by the off-axis correction factor multiplied by the effective S SD factor. This is then reduced by 1.14% (to allow for 3mm of perspex).

Write up plan on Medulla Planning Form FM. 14.013 or FM. 14.014 as appropriate.. Scribe position of junction on Post surface of BDS.

3. Treatment.

To minimise the effects and likelihood of dose inhomogeneity at the junctions, field sizes are adjusted twice during treatment.

With a single spine field, its length is increased by 1 cm. and the centre moved 0.5 cm to Sup each time ie the junction point moves 1 cm to Sup. The Inf border of the head field (X2 jaw) moves 1 cm to Sup each time.

With 2 spine fields, the length of the upper spine field is increased by 2cm (centre stays fixed). The lower spine field length is reduced by 1 cm and its centre moved 0.5cm to Inf. Head fields are adjusted as above.

Set-up relies on the accurate alignment of the X-ray field with the light field. Radiation Technology Staff should check these parameters for the field dimensions being used, using X-ray film. If match is acceptable, treatment is set up by matching Inf edge of head fields with Sup edge of (upper) spine field at the scribe mark on the BDS. If there is a mismatch, and recalibration of the machine is not possible, then place a piece of black tape of appropriate thickness at the junction: set the head field to one edge of the tape and the spine field to the other edge. 'Mismatches' of less than 2mm (both fields combined) can be ignored. With 2 spine fields, the Inf border of the upper spine field is marked on the skin, and

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the Sup border of the lower spine field is matched to this point. Again, black tape can be used for any mismatch. Inf border of (lower) spine field should always be set to the tattoo at S2/S3. Small adjustments to field size may be made on a daily basis to achieve this. Compensators should be marked as follows: For a single spine field, mark Inf field border. For two spine fields, mark the Inf field border on the lower spine compensator. Mark the Sup field border on the upper spine compensator. NB: this mark has to be moved each time the junction is moved on the BDS.

Notes:

With a lower spine field, the wax compensator needs to be bolted onto a drilled tray and so slots have to be made in the perspex plate for the bolts.
Sometimes the lower spine requires to be 'spade shaped'. This has to be defined from a PA radiograph. Pb is fixed to the compensator plate with the wax.

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Annex 2: A blank copy of the first page of Medulla Planning FM.14.014 as used for Lisa Norris's treatment plan

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

**MEDULLA PLANNING FORM
TWO SPINE FIELDS**

FM.14.014

Name:	Site:
B.O.C. No:	Unit:
Radiotherapist:	Date:
Physics:	

Setup	Head fields isocentric; asymmetric jaws; customised shielding trays. Physics to move junction after every fractions (see over).			
Site	Head (a)		Upper Spine (b)	Lower Spine (c)
Description	Right Lateral	Left Lateral	Posterior	Post / Sup
Field Size (approx for first fractions)				
Jaw Settings	X ₁ Y ₁ X ₂ Y ₂	X ₁ Y ₁ X ₂ Y ₂		
F.S.D.	ISOCENTRIC		100 cm	100 cm
Gantry Angle	90°	270°	0°° (i.e.° to sup)
Collimators° (i.e.° Sup End Post)° (i.e.° Sup End Post)	90°	90°
Floor Rotation	0°	0°	270°	270°
Beam Modifier	Shielding block tray code =	Shielding block tray code =	Wax compensator (a). tray code 17	Wax compensator (b). tray code 17

Beam Weight (%)	100% (a)	100% (a)	100% (b)	100% (c)
Output (MU/100cGy)				
Dose Information	T.A.D. mid brain = 100%		spinal cord:%	spinal cord:%
	Normalisation = %		max subcut:%	max subcut:%

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Annex 3: BOC quality system document number WI 13.26.06, written procedures for 'Medulloblastoma Calculations'.

BEATSON ONCOLOGY CENTRE – QA CONTROLLED DOCUMENT

WI 13.26.06

**MEDULLOBLASTOMA CALCULATION AND INPUT TO VARIS
GENERATION 7.**

1. Pre-Treatment Staff should be aware that on the prescription page will be Eclipse dose prescription and the status will be unapproved. This will not be used as prescription plan.

2. Check that all data has been co-ordinated e.g.

- Both the plan and the prescription have been signed.
- The dose on the Booking Slip corresponds with the dose on the prescription.
- The Booking Slip has been signed by the relevant IR(ME)R Practitioner.
- The patient has been consented.
- The images/x-rays has been signed by the relevant IR(ME)R Practitioner.
- Check the image or x-ray printout parameters correspond with the plan.
- Check what Treatment Machine the patient is due to attend. Check the plan has been run for the correct machine.

3. Obtain the physics plan and the prescription from the Clinical Oncologist and check that all the information has been completed correctly

4. **The head fields are treated isocentrically** and the information for calculation is given on the physics-planning sheet. ie. weighting, and output – output denoted in MU/100cGy.

$$\text{Daily mu} = \text{Daily T.D.} \times \frac{\text{Output}}{100}$$

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WI 13.26.06

The daily machine units remain the same throughout the treatment irrespective of changing field size.

It may be specified as a 100% incident dose or, more commonly, it is specified as a dose to the spine at depth. In this case the radiographer will have to calculate the 100% incident dose before calculating the daily machine units.

$$\text{Inc. Dose} = \frac{100}{\% \text{ D.D.}} \times \text{daily TD}$$

$$\text{Daily mu} = \frac{\text{daily incident dose} \times \text{output}}{100}$$

The daily machine units remain the same throughout treatment irrespective of changing field size. **Spine fields to be treated at fixed FSD.**

6. Complete the Varis 7 Data Confirmation Sheet. (Note that three separate sheets will be required, specifying the changes in field size as the junctions are moved)

- a) Patient's name and I.D.
- b) Jaw settings
- c) Tolerance (F)
- d) F.S.D
- e) Gantry angles
- f) Collimator rotation
- g) Floor rotation
- h) Daily machine units (in red ink)
- i) Patient position and set up details-including instructions for the use of a wax compensator and shielding
- j) Sign the data sheet

7. Pencil on the appropriate line on the treatment record sheet when the field size should change and the BDS and wax compensator adjusted.

8. In RT Chart, Prescription Page;

This plan will not be downloaded so all treatment data will need to be manually entered.

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9. A new prescription will be required for each site ie. Rename PSI as

MEDULLA1

MEDULLA2

MEDULLA3

SPINE-UPPER1

SPINE-UPPER2

SPINE-UPPER3

SPINE-LOWER1

SPINE-LOWER2

SPINE-LOWER3

It will be necessary to keep the same volume site as medulla throughout for the brain fields and for the spine fields use Spine-Upper and Spine-Lower. For each plan key in the number of fractions to each junction. Key in the daily TD as normal.

10. The following parameters should be entered into **RT Chart**;

- **Parameters**

Field I.D.

Field Name

Technique

Energy/Mode

Dose Rate

M.U's; **as calculated by the Radiographer from physics output.**

Tolerance Table (Tolerance F)

F.S.D.

Gantry Rotation.

Collimator Rotation.

Field X1 and X2.

Field Y1 and Y2.

MLC

Couch Vertical.

Couch Longitudinal.

Couch Lateral.

Couch Rotation.

(Key in any additional data e.g. set-up note, in RT Chart as per W.I 13.26.03).

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- **Reference Points**

Refer to W.I 13.26.03.

The Start Delay will need to be entered for each junction change

i.e. MEDULLA1 start delay is 0

MEDULLA2 (if the junction change is after 7 fractions) start delay is 7

MEDULLA3 start delay is 14.

This will also be the case for the start delay for the Spinal Upper and Spinal Lower.

In the **Dose Contributions** section, the following will be entered;

M.U's

Field Dose

The **Total Dose Limit** is the **total** dose prescribed for the treatment i.e. total dose for all junctions.

(The **Daily Dose Limit** and **Session Dose Limit** will need to be entered as W.I 13.26.03).

- **Scheduling**

Refer to W.I 13.26.03.

(The **Interval Days** and if necessary, a **Sequence Template** will need to be entered as W.I 13.26.03).

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WI 13.26.06

6.The patient's data should be scheduled on Varis 7 Time Planner as W.I 13.26.02.

7.Have the prescription, the VARIS 7 Data Confirmation Sheet and all the data entered on VARIS 7 Patient Manager, RT Chart and Time Planner checked by another radiographer. The radiographer checking the plan must ensure all boxes are 'ticked' on the data confirmation sheet. After checking the plan must be set to **treatment approved**. One of these two must be Senior or Superintendent grade.

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Annex 4: A copy of the Inspector's note of the incident investigation meeting held on 10th February 2006

Note of a meeting to consider a Radiation Incident at Beatson Oncology Centre reported to the Inspector for the IR(ME) Regulations on 2nd February 2006

Location of meeting: Beatson Oncology Centre

Date and time of Meeting: Friday 10th Feb 2006, beginning at 9.50 a.m.

In attendance:

Dr Arthur Johnston,	Senior Principal Scientific Officer, Scottish Executive Health Department
Ms Carol Nix	Senior Clinical Support Officer, Radiation Protection Division, Health Protection Agency (RPD-HPA)
Marianne Cook	Public Health Policy Adviser, Scottish Executive Health Department The Head of Health Physics Section, Greater Glasgow Health Board The Medical Director of Beatson Oncology Centre, Greater Glasgow Health Board The Head of Clinical Physics, Greater Glasgow Health Board The Acting Head of Radiotherapy Physics, Greater Glasgow Health Board The Head of Board Administration, Greater Glasgow Health Board

1. Dr Johnston opened the meeting and distributed a copy of the proposed agenda (Annex A [*not included here*]) together with notes on the scope and purpose of the meeting. All participants agreed to adopt this agenda and indicated also their agreement with the stated scope and purpose.
2. The business of the meeting began with a joint expression of concern by all participants for the distress caused to all of those involved in this incident. It was noted that staff at the Beatson Oncology Centre (BOC) were providing ongoing support to both the patient and the patient's family and that a separate meeting with the patient and family was taking place later that day.

Agenda Item 1: Introductions

3. Introductions were made and employment and line management arrangements were clarified as follows:
 - The Health Physics Section, of the Department of Clinical Physics and Bioengineering, Greater Glasgow Health Board (GGHB) is independent of Radiotherapy Physics and deals with general radiation safety. The Head of Health Physics Section's line manager is The Head of Clinical Physics.
 - The Head of Board Administration reports to the Chief Executive of GGHB
 - The Medical Director of Beatson Oncology Centre reports to the Acting Chief Executive of North Glasgow Acute Division of GGHB.
 - The line manager for the Head of Clinical Physics is the Clinical Director for Imaging.

- The Acting Head of Radiotherapy Physics has been in post since 1st January 2006. His line manager is the Head of Clinical Physics.
- Carol Nix is a Senior Clinical Support Officer, with the Medical Exposures Department of the RPD-HPA. She has extensive clinical experience of radiotherapy treatment and of the legislative requirements governing the use of radiation in medicine. Her attendance was requested by the Scottish Executive Health Department (SEHD) to provide the necessary expert advice
- Marianne Cook deals with radiation policy in the Scottish Executive Health Department and was also in attendance to take this formal note of key points raised during the course of the meeting
- Dr Arthur Johnston has been appointed by the Scottish Ministers as the warranted Inspector for the Ionising Radiations (Medical Exposures) Regulations 2000- "the IR(ME)R Regulations"*. (Details of his responsibilities are attached as Annex B [*not included here*].)

(*A full copy of the IR(ME) Regulations 2000 can be found on the internet at <http://www.opsi.gov.uk/si/si2000/20001059.htm> . Guidance notes on good practice are at <http://www.dh.gov.uk/assetRoot/04/05/78/38/04057838.pdf>)

4. Following introductions, Dr Johnston made both his Inspection Warrant and copies of the powers bestowed on him by that warrant under the 1974 Health and Safety at Work Act (at Annex B) available to all present.

Agenda Item 2: Recording and reporting arrangements

5. Reporting arrangements were agreed. It was agreed that only one note of the meeting would be taken (by Marianne Cook) and that this would provide the basis for this subsequent meeting note and an Inspector's report.

Agenda Item 3: Purpose and scope of the meeting

6. The purpose of the meeting was discussed and agreed as (a) to advise the Inspector of the circumstances surrounding overexposure of this patient at the BOC, (b) to review a draft version of Dr Martin's formal incident report and consider the need for additional information, (c) to give initial consideration to the need for procedural changes aimed at minimising the possibility of recurrence of any incident of this nature at the Beatson Oncology Centre, and (d) to consider implications for other radiotherapy departments in the UK.
7. Dr Johnston noted further that this meeting would form part of a full investigation of the incident in question. A detailed Inspector's report will be produced subsequently, but it should be an aim of this meeting to make such additional recommendations as appropriate for immediate or longer term actions, aimed at minimizing the risk of any recurrence of an incident of this type at BOC and other radiotherapy departments in Scotland (with due regard to the wider implications for the other UK countries).
8. Dr Johnston advised the meeting that, based on legal advice, no discussion with those directly involved in the incident would be entered into at this time. He indicated also that his view of direct involvement extended to those who had written or were responsible for the relevant BOC procedures. However, he also advised that it remained likely that he would wish to interview these people at a later date, under appropriate provisions for legal representation and caution.

9. Having advised all present of the position regarding interview of individuals directly involved, Dr Johnston then asked all GGHB staff present to confirm (a) that they were content with the decision not to include staff directly involved with the incident in this meeting and (b) that they regarded themselves as not being directly involved in the incident. Both were confirmed by all present.

Agenda Item 4: Consideration of the draft incident report prepared by the BOC.

10. It was noted that this incident was reported verbally to SEHD (under the IR(ME) Regulations 2000) on February 2nd 2006 and that this was followed on February 3rd 2006 by a copy of the 'initial report' from the BOC. This report included details of three 'immediate changes' implemented by the BOC in respect of this incident.
11. A separate draft report on the incident was circulated by The Head of Health Physics. This was titled "Preliminary Report of Investigations on Incident Involving Delivery of a Higher Dose than Intended to the Brain During Treatment of the CNS at the Beatson Oncology Centre, Western Infirmary During January 2006". This report will form the basis of the formal incident report to be submitted to the Scottish Ministers (the 'appropriate authority') by the BOC under Section 4(5) of the IR(ME) Regulations 2000. The Head of Health Physics noted that this draft report was erroneously dated '6th Feb 06' and that this should be corrected to '10th Feb 06'. He also noted that a senior person involved in the planning process had yet to be interviewed as part of his report preparation.
12. The Head of Health Physics noted that an earlier draft of this report had been made available to Ms Carol Nix on the evening of February 9th 2006. The Head of Clinical Physics then highlighted verbally the key changes made from this earlier version of this document. He also noted that a corrective action already implemented by the Beatson (and identified in Principal Planner A's earlier report) had been missed from this document in error. This agreed action was that, pending further consideration of changes to operating procedures, two checks will be undertaken for all future 'high-risk cases' and what constitutes a "high-risk" case will be defined clearly.
13. The Head of Health Physics' report included an analysis of the circumstances that caused this incident. Discussion of these circumstances, in the light of the additional documents presented at the meeting, indicated that the causes might be summarized as follows:
 - a. The intent of the referring physician was that the patient should receive a radiation dose of 35 Grays divided into 20 equal fractions of 175 centiGrays.
 - b. This data was input to the Eclipse treatment planning system except that the number of fractions was changed from 20 to 21. The precise reason for the change is unknown. The machine setting required for the delivery unit to deliver the (reassessed) 'Daily Total Dose' (167 centiGrays) was then calculated by the Eclipse treatment planning system. The calculated setting was 91 monitor units (MU). ('Monitor units' (also referred to in BOC Work Instruction WI-13-67 as 'machine units') is the term used for the reading that arises from the monitor on the delivery unit that measures the total output of radiation from the delivery unit during an exposure).
 - c. BOC Work Instruction WI-13-67, Issue 4, dated 15/05/02 sets out the procedure to be followed by radiography staff during the pre-treatment processes for 'Medulloblastoma Calculations'. This requires that the number of 'Daily MU' should be calculated by multiplying the intended 'Daily Total Dose' by a parameter called the 'Output' and dividing by 100. The 'Output' is a figure that is

- calculated by the treatment planner and is entered on the treatment planning form (in this case on Medulla Planning Form FM.14.014). The 'Output' is the intended number of daily MU from the delivery unit 'normalized' to 100 centigrays (i.e. expressed in MU per 100 centigrays). In this case, the normalized 'Output' should have been calculated (for 21 rather than 20 fractions) as 91 MU divided by 167 (centigrays) and multiplied by 100 to give a required 'Output' of 54 MU per 100 centigrays. (Paragraph 17 below considers the need for this normalization process.)
- d. In this case, however, the dose planner omitted the normalization procedure and entered an erroneous 'Output' figure of 91 MU per 100 centigrays on the Medulla Planning Form (FM.14.014, Issue 1, Dated 11/8/98) instead of the correct figure of 54. Subsequent application of the Daily MU calculation by the radiographer, as described in Work Instruction WI-13-67 (and in (c) above), (but in this case for the 20 dose fractions prescribed) led to Daily MU = $((175 \times 91) / 100) = 159$ MU.
 - e. The Daily Total Dose equivalent to 159 MU is 292 centigrays and this is the dose that was delivered over 19 fractions before the error was discovered. The total dose to the patient was therefore approximately 55 Grays, which is 58% higher than the intended total dose of 35 Grays.
 - f. The bulk of the treatment planning was undertaken by a Planner B (see Paragraph 25 below) with supervision from a Principal Planner A. The erroneous entry on the Medulla Planning Form was made by Planner B. Checking of the resulting treatment plan by the two others identified a number of deficiencies but neither of the checkers identified the error in the number of monitor units entered on the Medulla Planning Form.
14. Discussion of these circumstances focussed on (a) the need for manual rather than electronic transfer of data from the Eclipse treatment planning system to the *Varis 7* recording and verification system, (b) the need for the process of normalization of the Total Daily Dose to MU per 100 centigrays and (c) precisely why the wrong figure was entered on the Medulla Planning Form.
15. On the first of these issues, the Head of Health Physics' report indicates that the reason why transfer of data to the *Varis 7* recording and verification system, which was first commissioned by the BOC in May 2005, was not carried out electronically was that it is not yet able to accommodate all the complexity of the medulla and spinal column exposure procedures. BOC representatives suggested that electronic transfer might be technically feasible but that this was an issue best discussed with the Head of the appropriate section.
16. Clarity was sought on whether the data that is entered directly into the *Eclipse* planning computer always included the prescribed dose. It was confirmed that this is the case for all but a very small number of complex cases. Factors which make a case "complex" include type and location of the tumour.
17. In relation to the need for normalization, BOC representatives explained that the need for this process reflected the variability of central nervous system treatments and the frequent need to change the prescribed radiation dose at different stages in the planning process, for example when other patient treatment issues made this clinically necessary. However, it was agreed that the attendant risk of over-exposure, as demonstrated by this incident, was such as to indicate that a detailed reconsideration of the need for this step in any exposure planning procedure (and particularly in Medulla Planning Forms FM 14.013 and FM 14.014 and in Work Instruction WI-13-67) must be reviewed. Meanwhile, it was noted that one of the immediate changes that has been introduced in response to this incident has been to change Medulla Planning Forms FM.14.013 and FM.14.014 and related written

procedures to require that the number of monitor units per fraction will be entered on the planning forms along with the radiation dose per fraction. These modified forms and procedures should be made available to the Inspector forthwith.

[At this stage of the meeting a folder containing specific clinical information relating to the incident was made available to the inspection team by the BOC. Regarding the issue of data confidentiality, it was noted that this folder contains clinical details for a named patient. Pending clarification of the data confidentiality issues, it was agreed that the SEHD will retain a single copy of this folder for the purposes of this investigation. However, checks will be made to consider whether it is appropriate that this information should be held after the investigation has concluded.]

18. The circumstances whereby the wrong figure ('91' instead of '54' MU per centigray) came to be entered on Medulla Planning Form FM.14.014 were then discussed.
19. The original 'Booking Form' (BOC 00017 Version2/116353 dated 13/9/05 and signed by the referring Oncologist) for pre-treatment was referred to. The correct dose (35 Gy) appears on this form, as does the request for 20 fractions. BOC representatives indicated that this booking form was introduced in late 2004 after a pilot period. This booking form and CT data would then have been given to treatment planning staff to create a planning folder for the patient.
20. Additional documentation associated with this procedure (*Varis* Version 7 implementation- 5th revision dated 14.04.05 and various associated flow charts) was shown at the meeting. However, these documents currently are not part of the BOC Quality System, though BOC representatives indicated that it was intended, at the time of drafting, that these documents would become practice and part of the Quality System.
21. It became clear that some questions relating to the procedures in place for planning the treatment of patients of this type, including procedures for planning the treatment of these patients from a CT scan and routine use of the planning computer, could best be addressed by the Head of the appropriate section.

At this point Dr Arthur Johnston, Ms Carol Nix and Ms Marianne Cook broke for independent discussion of the points already raised. They noted their view they were receiving full co-operation from BOC staff present both in terms of their response to questions and provision of relevant information. It was also noted that the incident reports provided to date were both timely and comprehensive.

Agenda Item 5: Review of additional documents.

22. Staff training and competency records for three individuals considered by the BOC to be directly involved in this incident were reviewed. These records indicate a graded approach to training where an entry is made in the appropriate 'check-box' indicating, for each identified competency, whether individuals are "in training", "competent", "authorised to check". The format of these training and competency records is different for each of the three individuals and there are no indications on any of these records that they form part of the BOC's quality system. In addition, BOC representatives indicated that there is no written procedure within the BOC's quality system that defines the structure and requirements of these records or who is responsible for their maintenance and authorization.

23. Current practice for treatment planning staff is that training and competency records are reviewed by Principal Planner A. BOC representatives indicated their belief that assessment of competency is based on a mixture of both discussion and evidence. However, this requires further clarity from Principal Planner A. In this connection, it was further noted that some of the records looked at are initialled and dated but others are not. The initials on Principal Planner A's training record indicate that *his* competencies are reviewed by *himself*.
24. The training records for Planner B indicate no record of competence as either "training", "competent", "authorised to check" for the 'Spine/Medulla/CNS' procedure in question.
25. Within the training records for Senior Planner C, the 'Planning Activities' section suggests (though there is some lack of clarity) that Senior Planner C is (a) 'Training' for the 'medulloblastoma/whole CNS' and 'brain' non-CT procedures and (b) 'Training' for the 'medulloblastoma/whole CNS' but is an authorised 'Practitioner' [not in the sense in which the terms is used in the IR(ME) Regulations] for the 'brain' CT procedures. However, the accompanying record for 'Treatment Planning Training' indicates that Senior Planner C is both 'Competent' and 'Authorised to check' both CT and non-CT plans described as 'Head and Neck – Advanced eg. Medulla, Ho'.
26. The training records for Principal Planner A indicate competence at all levels in the planning of 'Advanced Head and Neck' procedures and competence to check manual plans for 'Spine/medulla/CNS' procedures.
27. BOC procedure QS.14.13- 'Checking and Issuing of Plans', (Issue 1, dated 5.8.96) states that; 'Calculations will be performed by a suitably trained member of the Physics Planning Staff, who will prepare and initial the plan'. The staff training records that were reviewed at this meeting (see Paragraph 25 above) give no indication that Planner B, who prepared the initial plan for this patient, was 'suitably trained' for either the spine or medulla procedures.
28. Principal Planner A's initial report of this incident indicates that planning by Planner B was supervised by both the Principal Planner A and Senior Planner C. The Head of Health Physics' draft report was less clear about the level of supervision provided by the Senior Planner C. [*In this connection it might be noted that Section 11(3) of the IR(ME) Regulations provides for a person in training to participate in 'practical aspects' of the procedure, which would include treatment planning, provided that 'this is done under the supervision of a person who himself is adequately trained'.*]
29. BOC Work Instruction WI.14.13.01- 'Checking/Amending Plans', (Issue 1, dated 5.8.96) states that; 'All physics plans should be checked before they are issued.' and that 'Checking should only be performed by suitably qualified and experienced staff.' The completed Medulla Planning Form (FM.14.014) for this patient is initialled, in the box labelled 'Physics', by Planner B, the Principal Planner A and the Senior Planner C. However, there is no information on this form, nor on any other document provided at the meeting, to indicate in what capacity each of these individuals is initialling the form. Further, as these initials are not dated it is difficult to determine precisely when the form was completed and when it was checked.
30. The initial report of this incident makes it clear that both Principal Planner A and Senior Planner C were involved in checking aspects of the treatment plan. Some errors (unrelated to the incident) came to light at this stage and were corrected. The Head of Health Physics' report suggests that attention to these errors might have distracted the checkers' attention from the erroneous entry for the normalized daily dose.

31. It was noted that, while the treatment planning staff who had checked the plan were deemed competent to check manual plans for the 'spine/medulla/ whole CNS' procedures, this plan was a hybrid of manual-electronic planning for which no specific competency has been defined within the BOC's current procedures.
32. It was noted that the completed Medulla Planning Form (which is an authorized BOC quality system document) was heavily annotated outwith the prescribed boxes. Further, it was apparent that on the photocopy presented at the meeting, one of these annotations had a gap where a change might have been made. BOC representatives therefore sought and produced the original version of the completed form. From this, it was clear that part of this annotation had been erased using correction fluid.
33. BOC Work instruction WI 14.13.01 states that correction fluid should not be used and that any errors on quality system documents should be scored through with a single line and a correction should be initialled and dated. Since this procedure had not been followed it was not clear what the error was or when the changes were made and by whom.
34. It was established on further investigation that that the error in question was a simple misplacement of the word 'multiplied'. The Inspector made clear that, notwithstanding concerns over the misuse of correction fluid, he was satisfied that the data altered did not impact on the radiation dose and that there had been no attempt whatsoever to disguise or deceive.
35. A sticker was also present on the reverse of this form which provides for a signatory to confirm that '*I have checked this physics plan and treatment may proceed*'. This label has been initialled and dated but the provision included under 'CHECKED' had not been signed or dated. There is no indication on Medulla Planning Form FM.14.014 nor on any other document provided to the Inspector to indicate the status of this label nor the responsibility of the persons initialling it under the labels 'SIGNED' and 'CHECKED'. The BOC representatives present indicated a view that this label does not form part of the checking procedures for the plan as the sticker was initialled by a clinician. (BOC representative indicated that it is always a clinician who initials this section of the form.)
36. It was agreed at the meeting that issues related to this label, both in terms of implied responsibilities and its status within the quality system needed to be addressed robustly. As a practical issue it was noted in addition, that stickers can be removed or can fall off and that serious consideration should be given to having their use within any part of the quality system replaced, for example, with the use of a permanent stamp.
37. Ms Nix raised a number of further, detailed issues about the treatment planning and checking procedures, which the BOC representatives present suggested could more accurately be addressed by the Head of the appropriate section. These included –
- How it could be ensured that checking process was independent of the original treatment planning
 - Would the checker ensure that the correct CT scan had been used?
 - Whether the field size was derived from the CT scan.
 - Which elements of the treatment plan are checked by a suitably trained member of staff?
 - Is there a reference checklist available for checking plans?
 - Do specific working instructions exist for different planning procedures?
 - Is there any documentation either within the BOC quality system or elsewhere

that sets out the responsibilities of those involved in the treatment planning process?

- Do the planning staff consider that the term 'suitably trained' as it is used in document QS14.13- is synonymous with the term "competent" used on the training record?
- With regard to this incident, when the checkers identified errors in the compensators for the spine field and subsequent rechecking was done, was this recheck on the spine fields only, or on the whole of the treatment plan?

38. It was noted generally that the dates of issue on several of the Quality System documents, including both procedures and work instructions, indicated that they had not been amended for several years. (The earliest being dated 1996.) This despite the requirement in BOC quality system document QS 03 'Document and Data Control' that '*All controlled documents are reviewed at least annually...*' and evident changes since their last date of issue, including the introduction of new equipment.

39. BOC representatives noted that this issue had already been recognized at Department and Section Head levels and by several internal BOC groups, including the Radiation Protection Group and the Quality System Review Group. Minutes of the April 2005 and September 2005 meetings of the Quality System Review Group at which this issue was discussed were provided as evidence that this problem had been recognized. Both of these documents refer to the visit of Ms C Nix to the BOC in March 2005 and her clearly stated views on the need for improvement in IR(ME)R procedures. Reference was also made to correspondence with the SEHD regarding previous incidents at the BOC which were reported under the provisions of the IR(ME) Regulations. [A previous incident report to the SEHD Inspector in November 2004 was accompanied by a letter indicating that the Medical Director had requested that the radiotherapy Management Group and other senior managers undertake a review of policies and procedures in this area. The Inspector requested that this review should include representation from a former member of the Secretary of State's Inspection Team for the IR(ME) Regulations. The subsequent visit of Ms Carol Nix to the BOC in March 2005 was in support of this review.]

40. When questioned directly as to the reasons why, although identified on several occasions, procedures and documentation had not been updated as required by the BOC quality system, BOC representatives pointed to the following circumstances:

- Part of the difficulty in keeping the BOC quality system up to date relates to resourcing issues, particularly in the Radiotherapy Physics Department where it has been difficult to recruit and retain the full complement of physicists. The Department has drawn up priorities for producing and updating protocols and documentation but considerable expertise is required, including staff from physics, medical and radiography specialties. The issues of understaffing and under-funding at the BOC were acknowledged and an intervention was made by the Health Minister in 2001, whereby additional funding was made available.
- This resourcing issue was exacerbated by a number of other changes and pressures within the department, including; a restructuring of the entire Radiotherapy Physics Department in 2000 and 2001 (in an attempt to ameliorate the difficulties of staff resources); the installation and commissioning of a new radiotherapy facility at Gartnavel Hospital; purchasing and commissioning of new equipment including the *Varis 7* recording and verification system in 2005.
- All of this activity was alongside delivery of treatment to approx 8,000 patients per year in line with current waiting time targets pressures.

41. BOC representatives advised that they have drawn up a detailed plan for full compliance with the IR(ME) Regulations and hoped to achieve the necessary compliance by June 2006.

A break for lunch was taken between 1.30-2.10

42. Ms Carol Nix asked for verification that the correct physician's intent was added onto *Varis 7* recording and verification system for this patient. In seeking to respond, the Acting Head of Radiotherapy Physics left the meeting to review the relevant records and verified on his return that the correct physician's intent was entered onto *Varis* database on 28/11/2005 by Radiographer A as part of the registration process. The records showed that the data entered was 20 fractions of 175 centigrays.

The Head of Health Physics left at approx 2.50pm, after confirming with the inspectorate that there were no further questions for him at this point.

43. Returning to the issue of maintenance of quality system documents, it was noted by the BOC representatives that, in accordance with Quality Standard document QS 03, all Quality Assurance Procedures are authorised by the relevant Head of Department. QS 03 also requires (see Paragraph 39 above) that all quality system documents should be subject to an annual review. No evidence was presented at the meeting of regular review of documentation having taken place. Nor was it apparent from written procedures how evidence of such reviews would be recorded, in particular where the review had indicated no requirement for change.

44. In this regard it was noted specifically that BOC Audit Report Number 05 IMK3 BOC arising from an ISO9000 Internal Quality Audit dated March 2005 had also identified as a 'Corrective Action Request' (CAR 05 BOC1) that 'Controlled documents are not being reviewed annually for validity via management review or audit'.

45. It was noted at the meeting that Quality Standard document QS 03 does not clarify what the signatures that are required in the "Authorised by" and "Issued by" sections of the document footer actually mean in terms of responsibilities for each document. In this regard also, QS 03 states that The Quality Management Representatives (QMRs) have full responsibility for the accuracy, control and issue of all controlled documents. However, there is no indication of how these stated QMRs responsibilities relate those of the aforementioned signatories and these QMR responsibilities do not appear to accord with other parts of the QS 03 document that identify responsibilities for Heads of Department etc. The BOC representatives confirmed that QS 03 was currently being revised and that these points had been noted.

Agenda Item 6: Consideration of actions to be taken at the BOC and implications for other radiotherapy units.

46. The following recommendations, some of which had been enacted prior to this meeting, were noted and agreed by the BOC representatives:

Treatment planning procedures

- (i) Each treatment planning procedure for complex procedures or procedures considered to be within a high risk category (which, in both cases, will be identified and listed in Quality System procedures) will have its own individual written protocol which will be part of the BOC's quality system documentation.
- (ii) All treatment plans for complex or high risk procedures shall be checked by two checkers who were not involved in creating the plan. Checkers must be

identifiable within the BOC quality system as being trained and competent for the procedure in question.

- (iii) Reference check list shall be prepared and these shall include the expected ranges of values for critical parameters such as the minimum and maximum number of monitor units that would be expected for the procedure in question.
- (iv) In future the exact dose per fraction will be input directly into the planning computer and no use will be made of scaling (normalization) factors or calculations. The only exception to this might be in brachytherapy but further discussions with senior Treatment Planning staff will be necessary. An instruction to this effect will be issued to staff and incorporated into the relevant Quality System procedures.
- (v) An immediate review of the practice of manual planning and its relationship to the electronic planning system shall be undertaken with a view to minimizing the need for manual re-entry of dosimetric data to the electronic planning system. The aim will be to optimize the use of the *Eclipse* Treatment Planning System and the *Varis 7* Recording and Verification System and also to extend the use of the new *RadCalc* Monitor Unit Checking System to all suitable plan types.

Training and competency

- (vi) Immediate action will be taken to ensure that only those staff who are identified in an appropriate quality system document as being competent in treatment planning procedures can create plans. Provision will be made, where appropriate, in terms of Regulation 11(3) of the IR(ME) Regulations for trainees to undertake planning activities under strict supervision. The same requirements will apply of those checking plans.
- (vii) Training records must be more robust and procedurally based and should be brought within the BOC quality system. The criteria whereby competency is judged must be documented clearly.
- (viii) For staff under supervision, the supervisor should have documented responsibility for treatment planning and a suitably qualified third individual, not involved in the preparation of the treatment plan must check.
- (ix) Those who are competent to train must be identified clearly and the criteria for attaining such competence must be documented.
- (x) Individuals who can determine competency must be clearly identified and this procedure documented, to include the criteria whereby competencies will be assessed.

Treatment planning forms.

- (xi) The Medulla Planning Form FM.14.014 and any other whose current design requires the addition of annotations should be redesigned to ensure that space exists for all required text to be placed in the properly assigned boxes (rather than the case at present where forms are annotated). This redesign should include consolidation of the label currently stuck to the back of the form together with reconsideration of the text on the current label for improved clarity. The responsibilities of signatories (under 'SIGNED' and 'CHECKED' on the current label) must be identified clearly and clear instruction added to the BOC quality system of the qualifications required for the provision of these signatures.
- (xii) FM.14.014 and those planning forms for other BOC procedures that form part of the quality system should also be amended to require that all individuals involved initial and date at an appropriate place in the form that identifies clearly their involvement, whether it be in dose calculation, checking or adding data to the form.
- (xiii) The use of stickers should cease and should, where necessary, be replaced with stamps. Any use of stamps should be allowed for in quality system documentation and form FM.14.014 and those planning forms for other BOC

procedures that form part of the quality system should be changed to properly accommodate any necessary stamps.

Checking of treatment plans

- (xiv) Clarification is required within the BOC quality system on what information and data those checking treatment plans should check. For example, the checks performed must include a check of the training record to ensure that anyone who initials or signs the treatment planning form as a treatment planner is either identified within the BOC quality system as competent for the procedure in question or was properly supervised in accordance with written BOC quality system provisions.

Other quality system documents

- (xv) The BOC 'Booking Form' (BOC 00017) for pre-treatment radiation exposures should be brought clearly within the BOC's quality system with a robust protocol that describes its use and status and clarifies the responsibilities of signatories. The form should also be redesigned to reflect its status as a quality system document. In redesigning this form, particular attention should be paid to (i) proper accommodation of patient details, (ii) clear definition and identification of 'mandatory fields', (iii) the responsibilities of the signatories (under 'Signed' and 'Countersigned') with particular regard to which of these is responsible for the IR(ME)R requirements for referral, justification and authorisation of the medical exposure.
- (xvi) The relationship between pre-treatment Booking Form BOC 00017 and the 'Radiographer's General Prescription Form' should be established clearly within the BOC's quality system with particular regard to the responsibilities of signatories. In particular, the process whereby the patient is referred for actual treatment should be defined and documented clearly and should include clarity about the purpose and status of related forms as well as the individual responsibilities of signatories for referral, justification and authorisation of the medical exposure. The need to include the 'Radiographer's General Prescription Form' within the BOC quality system should be considered.
- (xvii) These changes to documents should be made with due urgency but should be seen as part of the general plan for compliance with the IR(ME) Regulations by June 2006, referred to in Paragraph 42 above.

Amending quality system documents

- (xviii) No use of correction fluid shall be allowed on any documents that form part of the BOC quality system and all staff must be made aware of the correct procedure for correcting errors.

47. It was agreed that these issues will be addressed urgently by the BOC and that consideration should also be given to whether any of the lessons learned can be applied across other radiotherapy centres in the UK, to ensure no recurrence of this type of incident.

48. Dr Johnston requested that the BOC staff provide him with copies of the following documentation which was not available on the day of the meeting, in the week commencing 13 Feb 2006-

- A chronology of events for this patient, including key milestones such as when planning commenced, when this was checked, when the error was spotted and when the patient was informed
- A departmental accountability structure

- A revised version of the Head of Health Physics' report taking account of the issues discussed at this meeting
- Terms of reference of the Beatson Oncology Centre Radiotherapy Group who oversee the ISO9000 system and IR(ME) Regulations.

49. For the purposes of any immediate need to communicate the purpose and conduct of this meeting externally, it was agreed that the meeting could be summed up as follows;

“This is a very regrettable incident and our concerns are with the patient and the patient’s family.

An initial meeting has taken place between senior staff at the Beatson Oncology Centre and the Inspector appointed by Scottish Ministers, supported by staff from the Scottish Executive Health Department and a radiation expert from the Health Protection Agency.

Further information relating to the incident has been gathered and a number of preliminary actions, in addition to those already identified and implemented by the Beatson Oncology Centre as part of its own investigation, have been agreed upon.

The Inspector was satisfied that the Beatson Oncology Centre co-operated fully with the inspection team and that all materials requested were made available. Senior staff at the Beatson Oncology Centre have stated their willingness to continue to provide any additional information required by the Inspector.

Further steps are currently being discussed”

Annex 5: Staff interviews

A5.1 Introduction

A5.1 A total of seven people who were employed at the BOC or elsewhere in Greater Glasgow Health Board the time when the treatment for Miss Lisa Norris was planned have been interviewed individually by the Inspector. Some of these interviews were carried under caution against the possibility that the information provided might be used as evidence should any legal proceedings arise from this incident.

A5.2 A summary of the principal points emerging from each interview

A5.2 The following is a summary of the principal points emerging from each of these interviews:

Interview 1: Planner B

A5.3 Planner B agreed that it was *he* who had completed and signed the Medulla Planning form FM.14.014 for Miss Morris.

A5.4 *He* accepted that *his* training record gave no indication of any recorded level of competence (either 'learning' or 'competent') for the whole CNS planning procedures. However, since *he* had planned a similar treatment in November 2005, under supervision, *he* was of the opinion that *his* current training record was not up-to-date and that *his* proper training category at the time of planning the treatment for Miss Norris was a 'learner' for the whole CNS planning procedure. *He* therefore considered it appropriate that *he* was asked to plan this procedure under supervision.

A5.5 *He* stated that *he* had received no training in the procedure for normalization of Monitor Units to 100 centigrays and that *his* supervision involved checking with others, at each stage, to establish that *he* was following the correct procedure.

A5.6 In planning the treatment for Miss Norris, Planner B stated that *he* considered *himself* to be acting as an 'operator' under the IR(ME) Regulations*.

A5.7 Planner B stated that, at the time of the incident, *he* was not aware of any quality system procedure having been in place for this particular procedure. *He* prepared a written list of steps in the planning procedure for *his* own reference.

* The IR(ME) Regulations require that employer's written procedures shall include procedures to identify individuals entitled to act as operators. No evidence has been presented by the BOC that *he* was so entitled at the time of the incident.

Interview 2: Senior Planner C

- A5.8** Senior Planner C stated that *he* had been absent from work at the time when the treatment for Miss Norris was being planned and therefore had not been involved in creating the plan.
- A5.9** *He* stated that Principal Planner A had found errors in Planner B's calculations for the spine fields wax compensators and, having made the appropriate changes, had then asked *him* (Senior Planner C) to check them. *He* also stated that *he* had been involved in preparing a list of instructions for Radiography staff, to simulate the lower spine field and had ensured that the correct tray and monitor units had been applied for this particular compensator.

Interview 3: Principal Planner A

- A5.10** Principal Planner A stated that his initial involvement in planning the treatment for Miss Norris was in positioning of the fields on the *Eclipse* treatment planning computer. That process was observed by Planner B. *He* then gave Planner B further directions and the opportunity to ask for clarification about the next steps and process. Planner B then conducted much of the rest of the planning. Principal Planner A had no recollection of whether or not Planner B came back to *him* with further questions.
- A5.11** Principal Planner A stated *his* belief that *he* was responsible for updating of training records for Planner B but acknowledged that, due to pressure of other work, the proper level of updating had not been achieved. However, *he* expressed a view that because Planner B had been involved in one previous plan of this type, *his* training status was 'somewhere between learning and competent'. *He* indicated that *he* was concerned that training records should be of a better standard and that this has been raised through the BOC's quality management group. However, progress in this direction had also been affected by workload and staffing pressures. *He* further indicated that the need for Planner B to become involved in complex planning, such as whole CNS procedures, was the recognised shortage of experienced staff, a situation which, in *his* view, showed no prospect of improvement.
- A5.12** *He* confirmed that when *he* checked Planner B's completed plan initially, *he* identified errors in the spine fields. *He* corrected these then passed the plan to Senior Planner C for further checking.
- A5.13** Principal Planner A expressed a number of related concerns regarding deficiencies in the BOC quality system documents and IR(ME)R procedures and the lack of available staff resources to address these issues.
- A5.14** *He* stated his awareness that within the BOC's ISO 9000 system, there was a requirement for annual review of each document in the system. However, *he* was of the view that no formal process of review and signing-off, of any of the quality system documents was in place.
- A5.15** Regarding staffing pressures, Principal Planner A stated that *he* was the only remaining BOC employee out of the four full time principal staff who had worked in treatment planning two years ago. *He* expressed a view that these staff losses have not been

adequately addressed, but acknowledged that recruitment of Physics staff, particularly experienced staff, is a national problem.

A5.16 Principal Planner A's generally stated opinion was that staffing of Treatment Planning at the BOC has not been compatible with *his* professional view of the quality of service required from this Section. *He* further indicated that representation of this view to senior BOC management through various fora had failed to bring adequate focus to these problems.

Interview 4: Chief Executive of Greater Glasgow Health Board

A5.17 The Chief Executive of Greater Glasgow Health Board has been in post since 1st November 2001.

A5.18 He noted that cancer services at the BOC had been subject to external review in 2001 which resulted in a number of recommendations for service improvement. It had been his responsibility to oversee the implementation of these recommendations.

A5.19 He provided details of the management structure within GGHB including the changes arising from the dissolution of the NHS Trusts in 2004. The four former trusts within GGHB have now evolved into four Divisions and the Chief Executive is now the sole accountable officer for the whole of GGHB.

A5.20 Under GGHB's new management structure there are eight Clinical Directorates within the Acute Services Division. The Medical Director within the BOC is the medical director for specialist oncology services within the Directorate of Regional Services. The Head of Clinical Physics is the most senior physicist within the Physics Department and all physics staff are professionally accountable to him. However, for delivery of clinical care, radiotherapy physics and treatment planning staff are accountable, through the Head of Radiotherapy Physics, to the Medical Director. The Chief Executive's view is, therefore, that the line of accountability for implementation of the employer responsibilities under the IR(ME) Regulations is through the Medical Director.

A5.21 The Chief Executive stated that, prior to this incident, he had received no formal notification of any problems in treatment planning or radiotherapy physics that would affect either patient safety or maintenance of quality systems. He was therefore unaware of the prevailing difficulties in maintenance of written procedures and training records and concluded that insufficient attention had been given to keeping these up to date.

A5.22 He also expressed a view that, if there were any human resource issues, these had not been pursued with rigour and determination or relayed to his level of management. Therefore, given his awareness of staffing numbers and experience, notwithstanding the need for junior staff to be given the opportunity for development, he expressed surprise that principal planning duties for this complex treatment plan were assigned to Planner B.

Interview 5: Head of Clinical Physics, BOC

- A5.23** The Head of Clinical Physics has been Head of the Physics Department In Glasgow since 1989. At the time of this incident, he reported to the Chief Executive of North Glasgow Division of GGHB. Under new organisation arrangements currently under development (whereby North Glasgow Division will cease to exist) his reporting line will be to the new Director of Diagnostics.
- A5.24** The Head of Clinical Physics confirmed that the Head of Radiotherapy Physics reports professionally to him, but for clinical issues reports to The Medical Director.
- A5.25** The Head of Clinical Physics stated that staffing complements for radiotherapy physics were assessed by the Head of Radiotherapy Physics in accordance guidance from the Institute of Physics and Engineering and Medicine. The Head of Radiotherapy Physics also assessed the necessary levels of staff experience. He added that at December 2005, following an aggressive recruitment campaign, staffing of radiotherapy physics was almost full complement and some very experienced staff had been appointed. Prior to 2005 the effect of staff turnover had been identified as a problem but not to the extent that it would compromise patient safety.
- A5.26** Given his understanding of the available levels of staff numbers and experience, he expressed surprise that Planner B was assigned the treatment plan for Miss Norris.
- A5.27** He stated his expectation that, in these circumstances supervision should be 'direct' in the sense that an experienced member of staff would oversee the procedure with the trainee step by step.
- A5.28** The Head of Clinical Physics expressed surprise that written procedures and training records were not up to date.
- A5.29** He stated his view that responsibility for the content of the treatment plan lies with the planner and checker, not the clinician and that the checker is responsible for production of plans as they sign them off before they are passed to the clinician. He further stated that since Principal Planner A acted as supervisor *he* should not also have been the checker.
- A5.30** When asked directly for his view on whether any staff involved had been negligent in their professional duties, the Head of Clinical Physics replied that he did not believe that this was the case and had not taken disciplinary action against anyone involved. However, he added that, following this incident, Principal Planner A's duties had been reassigned away from treatment planning pending the results of the incident investigation.

Interview 6: Medical Director of Beatson Oncology Centre

- A5.31** The Medical Director has been Medical Director of Beatson Oncology Centre since June 2005. At the time of this incident, he reported to the Acting Chief Executive of North Glasgow Acute Division of GGHB. Under new organisation arrangements currently under development his reporting line will be to the new Director of Regional Services.
- A5.32** Regarding his individual responsibilities, he considered that his general responsibility was to work with others to ensure the overall integrity of the whole service. He was uncertain as to who would be regarded as the 'employer' under the IR(ME) Regulations but stated his presumption that this would be GGHB with some responsibility on himself, though he had received no written statement indicating that he was responsible for implementing IR(ME)R requirements. Regarding the quality system and quality management, he considered that he had no written, formal responsibility and had no personal involvement in quality system audits.
- A5.33** Regarding the requirement under the IR(ME) Regulations that employers should have procedures in place to ensure that the probability and magnitude of accidental or unintended doses to patients is reduced so far as is reasonably practicable, his view was that there is no need for a separate document stating how to minimise risk since this should be addressed in other documents within the system. He stated that a lot of work is ongoing in quality system development and that the BOC hoped to be fully compliant with the IR(ME) Regulations by July of 2006.
- A5.34** When asked whether any formal representations had been made to management about staffing resources, the Medical Director responded that he was aware that some members of the treatment planning staff, including Principal Planner A, had raised concerns about workload with their management since at least 2005. However, the details of these concerns were never discussed directly by that individual with the Medical Director. He was not aware of any concerns having been raised that work could not be completed because of a lack of staff resources.
- A5.35** When asked directly for his view on whether any staff involved had been negligent in their professional duties, the Medical Director replied that he was strongly of the opinion that there was no indication of negligence. His view was that the incident was the result of a human error which unfortunately was not identified by an otherwise highly competent supervisor.

Interview 7: Former Head of Radiotherapy Physics

- A5.36** The Head of Radiotherapy Physics at the BOC was in post from October 2003 until he left the organisation on 31st December 2005. Immediately prior to his departure from the BOC, he worked closely with his deputy, who then took over as acting Head of Radiotherapy Physics.
- A5.37** Regarding staffing levels at the time of the incident, the Head of Radiotherapy Physics agreed that a table showing staffing levels 17.6 staff employed against a recommended complement of 18.0 was an accurate representation of the situation at December 2005. He regarded his responsibility as ensuring that required numbers of staff in treatment planning were properly assessed in relation to the relevant guideline levels. He considered that Principal Planner A was responsible for ensuring that the level of experience of treatment planning staff was appropriate. He further stated that he would

have expected Principal Planner A to have made him aware of any issues around staff numbers or experience but had not been made aware of any specific problems within treatment planning.

- A5.38** He stated that he, along with his predecessor, had devised the rota system whereby staff were assigned different tasks on a weekly basis. The purpose had been to broaden the availability of scientific staff for the range of tasks which require to be undertaken by the Department and to increase the variety of work as an aid to recruitment. He considered that the rota system was effective and that staff valued the ability to contribute across the radiotherapy physics field and this gave them improved career prospects.
- A5.39** He stated that he was not aware that at the time when this incident occurred, the relevant training records and written protocols were not up to date and regarded this as Principal Planner A's responsibility. In particular he was surprised that the medulla planning work instruction did not appear to have been reviewed since 1998.
- A5.40** Regarding quality systems at BOC, the Head of Radiotherapy Physics stated that he had been party to BSI inspections and received inspection reports. Following these inspections, he held discussion with Principal Planner A who, as Quality Management Representative, was responsible for maintaining all documentation in the system. However, he noted that since Principal Planner A had been finding it increasingly difficult to allocate time to the quality system, his responsibilities for quality system management were passed to another member of staff in October or November of 2005.
- A5.41** He was of the view that responsibility for the employer's duties under IR(ME)R lay with the Medical Director. He stated that it was the Medical Director who chaired monthly meetings of the radiotherapy management group which was the main forum for I(RM)ER issues
- A5.42** When shown the Medulla Planning Form for Miss Norris, the Head of Radiotherapy Physics considered that it was not clear from the initials what each of the individuals was responsible for what aspects of the plan.
- A5.43** He stated that since this a complex procedure, he would have expected there to have been direct supervision whereby someone explained the process step by step.
- A5.44** Regarding the commissioning of *Varis 7*, the Head of Radiotherapy Physics explained that a multidisciplinary project group had been established to oversee its introduction and that this should have included issues related to identification and management of risks. He stated that Principal Planner A was responsible for treatment planning issues and had been asked during the implementation process to update all relevant documentation as a result of the introduction of *Varis 7*. He further stated that even if a decision was made not to update a particular piece of documentation following the introduction of *Varis 7*, then this decision should have been recorded.

Annex 6. Staffing levels in the BOC Treatment Planning Section at December 2005

Staff Planning Category (see Table 6.1)	Designation of individuals for the purpose of this table	Years' experience in radiotherapy planning (years in planning at BOC)	Time allocated to treatment planning (%)	Rotated dates for treatment planning in Dec 2005 (Weeks commencing)	Documented training status for CNS planning	Periods of absence between 12 and 23 December
A1	A1.1	***	100%.	All	Planner, Checker, Trainer	***
	A1.2	***	20%	Local agreement	Planner, Checker	***
	A1.3	14 (0.5)	100%	All	No record	None
	A1.4	***	50%.	5 & 26 Dec	Planner, Checker	***
	A1.5	***	50%.	12 & 19 Dec	Planner	***
A2	A2.1	***	50%.	12 & 19 Dec	Training	***
	A2.2	4 (4)	50%.	5 & 26 Dec	Training	12-16 Dec
A3	A3.1	14 (4.5)	20%	Local agreement	No entry	14 Dec
	A3.2*	7.5 (5.5)	20%	Local agreement	Training	20 Dec
	A3.3	***	100%.	All	Training	***
	A3.4	***	100%.	All	No entry	***
B	B.1	8 (3)	50%.	5 & 26 Dec	No entry	16 Dec
	B.2	2.5 (2.5)	Local agreement	Local agreement	No record	13 Dec
	B.3	***	100%.	All	Training	***
	B.4*	***	100%.	All	No entry	***
	B.5	***	100%.	All	No entry	***
C	C.1	11 (0.3)	50%.	12 & 19 Dec	No record	None
	C.2	***	50%.	12 & 19 Dec	No entry	***
	C.3	1 (1)	50%.	5 & 26 Dec	No entry	12-13 Dec
	C.4	0.3 (0.3)	100%	All	No record	19-20 Dec
	C.5	***	100%.	All	No entry	***
	C.6	0.5 (0.5)	Local agreement	Local agreement	No record	23 Dec
	C.7	***	100%	All	No record	***

* Part time , 3 days per week.

*** The data in columns 3 and 7 is considered to be personal data in terms of the Data Protection Act An entry '****' indicates that the individual in question has not given the consents necessary for this information to be included.

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Annex 7: Comment on compliance with those requirements of the IR(ME) Regulations that were of particular relevance to this incident

Regulation number	Requirement	Comment on compliance at the BOC
4(1)	<i>The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and shall take steps to ensure that they are complied with by the practitioner and operator.</i>	Many of the employer's written procedures that were inspected during the incident investigation, for example Work Instruction WI.14.01.01 for Medulla Planning, were out of date. No evidence was presented of any steps taken to ensure that written procedures were complied with by the operator.
Schedule 1 (b)	Written procedures for medical exposures shall include procedures to identify individuals entitled to act as referrer or practitioner or operator;	At the time of this incident employer's written procedures to identify individuals entitled to act as referrer or practitioner or operator had been drafted but had not been adopted formally as an authorized procedure.
Schedule 1 (e)	Written procedures for medical exposures shall include procedures to ensure that quality assurance programmes are followed;	At the time of this incident there were no employer's written procedures to ensure that quality assurance programmes are followed. Written procedures were in place within the BOC's ISO 9000 quality system requiring annual reviews of written procedures but this requirement was not being followed.
Schedule 1 (k)	Written procedures for medical exposures shall include) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.	Had such procedures been in place, it might be expected that they would have contained instructions on the measure to be taken at the BOC to ensure that the potential for changes to the treatment planning system (such as the change to Varis 7) to result in unintended doses to radiotherapy patients was properly evaluated. No such procedures were in place and no evidence has been presented by the BOC of such an evaluation having taken place. (Principal Planner A produced documents describing the required 'Changes in Eclipse with Varis Version 7' but these did not include an evaluation of the possible effect on patient safety.).
4(2)	The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment.	Work instruction WI.14.01.01 for Medulla Planning was last updated in 1998 and did not contain the amendments made necessary by the introduction of Varis 7 in May 2005.
4(3)	<i>The employer shall establish quality assurance programmes for standard operating procedures.</i>	Written procedures were in place within the BOC's ISO 9000 quality system requiring annual reviews of written procedures but this requirement was not being followed.

Regulation number	Requirement	Comment on compliance at the BOC
5(4)	<p>The operator shall be responsible for each and every practical aspect which he carries out....</p>	<p>See comments on 11(1) and 11(3) below.</p>
11(1) and 11(3)	<p>Regulation 11(1) requires that: <i>...no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.</i> However, Regulations 11(3) qualifies this in that: <i>Nothing in paragraph (1) above shall prevent a person from participating in practical aspects of the procedure as part of practical training if this is done under the supervision of a person who himself is adequately trained.</i></p>	<p>The regulations require that when Planner B undertook treatment planning for Miss Norris, he did so either as a trained 'operator', recorded as such by his employer, or as a trainee under the supervision of a properly qualified and identified operator. There is nothing in his employers written procedures to identify him as being an operator and his training records give no indication of having been adequately trained to act in this capacity. Therefore, the only person who participated in creating the treatment plans for Miss Norris who would qualify as an operator under the Regulations was Principal Planner A.</p> <p>Regulation 11(3) would therefore require that the level of his involvement as a supervisor should have been sufficient that he could properly assume the responsibilities of an operator. However, the evidence suggests that his supervisory involvement was not to this level. Therefore, Regulation 11(1) was not complied with because practical aspects of the plan were completed by Planner B who was not a trained operator and was not under adequate supervision. Also, Regulation 5(4) was not complied with because the involvement of the operator (Principal Planner A) was not in keeping with his being responsible for each and every practical aspect of the plan.</p>
11(4)	<p>The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures ...showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.</p>	<p>The training records for those involved in the incident were not up to date and had not been properly signed-off as required by BOC written procedures.</p>

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