
■ The Unintended Radiotherapy Overexposure of
Scottish Patient Lisa Norris: Synopsis,
Recommendations, and Lessons Applicable to USA
Radiotherapy Centers

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

Report of an investigation by the Inspector appointed by
the Scottish Ministers for The Ionizing Radiation (Medical
Exposures) Regulations 2000

<http://www.scotland.gov.uk/Publications/2006/10/27084909/0>

<http://www.scotland.gov.uk/Resource/Doc/153082/0041158.pdf>

Report Components

- Covering Note – 1 Page
- Table of Contents – 2 Pages
- Executive Summary – 4 Pages
- Report Body – 48 Pages
- Acknowledgements – 1 Page
- References – 1 Page
- Annex 1 – Quality Systems Docum.; Written procedures for “Medulla Planning” (11/8/98) – 3 pages
- Annex 2- First page of Medulla Planning Form – 1 Page
- Annex 3 - Quality Systems Document. - Written procedures for Medulloblastoma Calculations – (5/10/05) – 5 Pages
- Annex 4 – Inspector Notes (2/10/06) – 11 Pages
- Annex 5 – Staff Interviews – 6 Pages
- Annex 6 – Staffing Levels – 1 page
- Annex 7 – Compliance with IR (ME) Regulations – 2 Pages
- 86 Pages Total

■ Why give this talk?

- “Those with **responsibilities** for the clinical safety of patients at radiotherapy centers in Scotland and elsewhere must ensure that the **lessons** arising from this incident are **understood** and **acted upon** in their own organizations” P. 46, ¶ 10.20
- IAEA 2006 Report “..Safety Standards...” : “**Feedback** from operational experiences and lessons learned from accidents ...can help **identify** potential **problems** and **correct deficiencies** and should be **used** systematically as part of **QA** program”

■ What was the *exact* error? (Part 1)

- **Prior** to adoption of VARIS 7, all *Eclipse* "Outputs" for VARIS were manual (paper form) and for a **normalized output**, the monitor units (MU) to delivery 100 cGy. There was never a form that simply stated the MU needed for a particular dose. At the linac, therapeutic radiographers calculated the MU needed for a prescribed tumor dose (Total Daily Dose) other than 100 cGy
- **After** adoption of *VARIS 7*, *electronically* transferred files required Total Prescribed Dose and number fractions and used MU for the prescribed tumor dose (Total Daily Dose); use of the **normalized outputs** (and paper forms) were abandoned, *except* for complex cases (CNS with spinal fields, moving junctions, etc.)

■ **What** was the *exact* error? (Part 2)

- For reasons unclear, Planner B , at *Eclipse*, worked with 21 fractions, not 20. Rather than 3500 cGy/20 fxs = 175 cGy, the prescription became 3500 cGy/21 fxs = 167 cGy (**Dosimetrists**: Beware Fx Changes!)
- The *Eclipse* calculated MU setting for 167 cGy was 91 MU, the MU for the Total Daily Dose (Not MU for 100 cGy!). Planner B transcribed 91 MU into box (paper form) that was for MU for 100 cGy. (**Dosimetrists**: Know definitions on forms!)
- The therapeutic radiographer scaled the 91 MU assuming 20 fxs, as $(175 \text{ cGy}/100 \text{ cGy}) \times (91 \text{ MU}) = 159 \text{ MU}$, which gives 292 cGy. The patient received 55.5 Gy in 19 Fxs. **Dosimetrists**: Avoid others modifying your calculations!)

■ **Factors** Contributing to the Incident

- **Inexperienced** personnel (Planner B) inappropriately assign responsibility beyond level of training
- Written procedures and forms **out-of-date** and incorrect for current practices
- **Inadequate** (casual, not direct) supervision of Planner B by Principal Planner A
- Adoption of new planning/verification software with **inadequate testing** to understand functionality
- **No annual** Quality System reviews
- **Mixed procedures** (manual data transfer retained when electronic data transfer was available) lead to confusion
- “Independent” check process **not independent**; failed!
- **Failure to comply** with Guidelines & Regulations
- **Inadequate training; lack of documentation** of training

Contributing **Organization** Factors

- Medical Director **unaware** of need to comply with applicable regulations
- Medical Director **unaware** of status (poor) of Quality System program and lack of annual audits
- **Lack** of written delineation of roles and responsibilities
- Medical oncologist's role in reviewing the chart **unclear** and not mentioned in the report
- Redundancy checks never seems to address **who checked therapeutic radiographer's work** (the final calculation!)

Administrative Entities

- Scottish Ministers – Overall governmental responsibility
- Scottish Exec Health Dept
- North Glasgow University Hospital Div'n of Greater Glasgow Health Board (Employer)
 - Head of Board Adm'n
 - Chief (Act) - Acute Div'n
 - Dept Clin Physics & Biomedical Engineering
 - Health Physics Sec
 - Head Clin Physics
 - Head Radiotherapy Physics

Beaston Oncology Centre (BOC)

Medical Director – Reports to Acting Chief - Acute Div. of Greater Glasgow Health Board

- Head Clinical Physicist (Same)
- Head Radiotherapy Physics (Same)
- Physics Planners (Senior, Principal, Planner)
- (Dosimetrists: Note your absence!)

International Organization for Standardization (ISO) 9000 Quality System Requirements

- Apparently, an ISO 9000 **Quality System Program** was implemented at BOC in or around 1998
- **Quality System Documents** (Annex 1, 2, & 3) were prepared in 1998 as part of the ISO 9000 Program
- ISO 9000 requires annual reviews and updates of written procedures; this apparently was not done once ISO 9000 certification was achieved.
- ((Dosimetrists: Are there Quality (Assurance? System? Controls?) for your work in your current facility?))

Administrative Personnel (Named)

- Dr. Arthur M. Johnston – Warranted Inspector & Report Author; Scientific Advisor to Scottish Executive Health Department
- Marianne Cook - Radiation Policy - Scottish Executive Health Department
- Carol Nix -- UK Health Protection Agency
- Steve Ebdon-Jackson – UK Health Protection Agency
- Dr. Martin – Head - Health Physics Section – Greater Glasgow Health Board

■ Staff Categories (Not Specific Job Titles - BOC)

- Clinical Oncologist – Physician
- Medical Physicist- Registered with UK Health Professions Council as Clinical Scientist - Physics Planner Staff further denoted as:
 - Senior Planner - Most experienced
 - Principal Planner – Trained
 - Planner – “Learner; In training!”
- Medical Technical Officer (MTO) –Voluntary Registration with Institute of Physics and Engineering in Medicine
- **Medical Dosimetrist** – New; radiographers & MTOs who treatment plan; not yet well-defined
- Therapeutic Radiographer - Protected Title – Registered with UK Health Professions Council

Responsibilities

- **Clinical Oncologist** – Prescribed the treatment; Initialed chart form “**I have checked** this physics plan and treatment may proceed.”
- **Medical Physicists** – “Planners” – At BOC all but the simplest treatment plans performed by medical physicists; Responsibility for checking treatment plans performed by one “planner” fall normally to one of the more senior medical physicist “planners”
- **Medical Technical Officer** – No role identified in this report; in some centers performs dosimetry as dosimetrists.
- **Therapeutic Radiographers** – Performs any “final” monitor units calculations at linac; treats patients. In some centers, performs simplest treatment plans.

Equipment & Documents

- **Written Procedures** for Medulla Planning (Prepared 11/8/98 & never revised) (Annex 1)
- **Medulla Planning Form** (Prepared 11/8/98 & never revised) (Annex 2)
- **Medulloblastoma Calculation Form** (Prepared 5/10/05)(Annex 3)
- Eclipse –Installed 2003
- VARIS Software prior to May, 2005
- VARIS 7.0 Software after May, 2005
 - Patient Manager Module/Eclipse Software Module/RT Chart Module
- **Training Records** – (6/28/05 - Principal Planner A reviewed Planner B Training)
- **Treatment Booking Form** (9/13/05 - Dose Prescription Form used by Clinical Oncologist)

The **CNS** Patients

- Patient #1 (Un-named) – 8/05 -Prescribed radiation dose not included input to *Eclipse*; **treated correctly**
- Patient #2 (Un-named) – 11/05 - 36 Gy/36 Fxs; 100 cGy/100 MU = 1.0 cGy/MU; Normalization not required; Inadvertently **correctly planned** by Planner B;
- **Lisa Norris** -#3 –15 Yr Old – **Incorrectly planned** by Planner B during 12/05; First instance of calculated MU other than for 100 cGy. Treated 1/5/06 – 1/31/06; Treatments discontinued after discover of error on 2/1/06.
- Patient #4 (Un-named) – **Correctly planned** by Planner E on 1/12/06
- Patient #5 – 2/1/06 – While planning a new CNS patient, Planner D discovers **procedural error**; reviews Norris's chart, halts treatment!

■ Staff Job Titles & Un-named Key Personnel

- **Clinical oncologist** – Prescribed dose
- **Planner B** –Primary Planner for Norris; Made crucial error!
- **Principal Planner A** –Partially planned spinal fields; passed unfinished plan to Planner B; Erroneously reviewed Norris's Plan by Planner B; considered mainly responsible for the error!
- **Senior Planner C** –Erroneously reviewed Norris Brain Plan
- **Senior Planner E** – Correctly planned another CNS patient during course of Norris's treatments
- **Senior Planner D** - Correctly reviewed another CNS patient's plan during course of Norris's treatments
- **Therapeutic Radiographer** - Calculated final MU for linac; Treated patient Norris; **never realized** that MUs were high for brain field!

■ Timeline of Key Dates (Part 1)

- 8/11/98 – Written procedures prepared for Medulla Planning, Calculations, etc. as part of ISO 9000 documents for Quality Systems
- 5/05 – *VARIS* software upgrade to *VARIS 7.0*
- 6/28/05 Planner B training reviewed by Principal Planner A
- 9/13/05 - Consultant clinical oncologist refers patient Norris to BOC for Rx Tx for “rare brain tumor; and prescribes a dose of 35 Gy to whole CNS, 20 fxs, 1.75 Gy each; followed by a boost to tumor 19.8 Gy in 11 fxs, of 1.8 Gy each. (Tumor in head, NOS)
- 11/05 – Planner B performs CNS plan for another patient (#2) requiring 100 MU for 100 cGy, ie, no normalization needed as with patient Norris; Plan is “Inadvertently Correct”

■ Timeline of Key Dates (Part 2)

- 12/15/05 – 12/19/05 Norris Treatment Planning carried out by Planners A & B; unexplained fraction change from 20 to 21
- 1/5/06 – 1/12/06 – Norris treatments erroneously given for one week 1/13/06 – 1/31/06 – Additional 12 daily treatments days before discovery of error on 2/1/06
- 1/12/06 – Senior Planner E, reviewed by Principal Planner A, correctly plans another CNS patient, but Principal Planner A fails to notice the differences with respect to prior Norris plan that he reviewed.

■ Timeline of Key Dates (Part 3)

- 2/1/06 – Planning procedural **error discovered** by Planner D in reviewing plan prepared for another CNS patient (#5).
- 2/2/06 -**Verbal report** to Scottish Executive Health Board
- 2/3/06 – **Initial report** by BOC staff to Scottish Executive Health Board
- 2/10/06 – **Internal review** by Administrative Staff (Earlier Slide); **preliminary report** by Dr. Martin –Head of Health Physics Section of Greater Glasgow Health Board
- 2/23/06 –3/8/06 – **Interviews** with staff by Administrative Staff
- 2/17/06 – **Formal** incident report by Dr. Martin to the Scottish Ministers
- 10/06 – **Final** Scottish Ministers Report by Dr. Johnston – Scientific Advisor

Relevant **Regulatory** Documents

- **Health & Safety Work Act** 1974 (Sec. 28 (7) – Disclosure Restrictions
- **Data Protection Act** –1998 – Use titles!
- **Statutory Instrument** 2000 No. 1059, *The Ionising Radiation (Medical Exposures) Regulation 2000* [CKA: IR(EM) Regs]
- (Dosimetrists: Note structure similar to state/federal structures in USA!)

Controlling Documents

- IR (ME) Sec. 4(5) –When employer...believe an incident may have occurred...make an immediate **preliminary investigation**... notify appropriate authorities.
- IR(ME) 11(1) - “No practitioner...shall carry out a medical exposure or any practical aspect without having been **adequately trained.**”
- IR(ME) 11(4) “The employer shall keep...up-to-date record...showing dates...**training**...and nature of training.
- BOC Quality Systems Doc. QS14.13 –Checking/Issuing Plans – “Prior to issuing a plan, calculations...will be **independently checked** ...by suitably qualified member of Physics planning staff.”

Royal College of Radiologists...**Guidelines** for external beam radiotherapy

- Recommendation 30 – “**One individual, the planning oncologist, 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.”
- Recommendation. 48 - “Monitor unit calculations must be rigorously and **independently checked.**”
- Regarding equipment replacement...“fully test all the data...to establish confidence in clinical safety...before ...enters clinical service”
- Recommends “Transfer...data...by local area network”

Surprising Statements!

- Regarding **Clinical Oncologist responsibilities** (...is responsible...whole plan..., final plan, ...dated acceptance of plan...) per Royal College Radiologists Guidelines, on P 26, Paragraph 6.33 we find "...general agreement among the staff interviewed that it would be *illogical* (NB: Emphasis mine! – GPG) 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."
- Regarding the **Medical Director's responsibilities** for implements IR(ME) Regs, "... had received no written statements he was responsible for implementing IR(ME) Regs!
- Regarding the **Medical Director's responsibilities** for quality systems... "...considered that he had no written, formal responsibility... no personal involvement in quality audits"

Did **inadequate staffing** contribute to the incident? Yes!

- During last quarter of '05, staff levels were adequate, but...
- During prior years **staff levels** were **inadequate**
- Prior years special **one-time projects** (Commissioning a new radiotherapy facility, purchasing & commissioning *Varis 7*, etc.) contributed to **deficient maintenance** of Quality Systems (lack of annual reviews & updates to written procedures & forms)

■ Observations Applicable to USA Centers: Part 1)

- All Scottish Regulations, Guidelines, Quality Systems, etc., are similar to those in USA; there are no statements in the Report unfamiliar to USA participants
- While our organizational structures may differ, the *omissions* – **lack** of training, **inadequate** written procedures, **inexperienced** personnel tasked beyond their competency, etc. – are common in many organizations. They contribute to organizational failures directly effecting patients.

■ Observations Applicable to USA Centers: Part 2

- Our “Rewards” system focuses on the “New”, not the “Current”.
- “Supervision” means *direct* guidance. However, ***indirect supervision*** is far more common (and dangerous!); workers learn informally from the most experienced worker in the group. This often leads to inadequate/incomplete training, poorly documented!

■ Specific Recommendations

- **Reference check lists** with expected ranges of MU per treatment field and fraction for commonly treated sites must be understood for all! (See *Statistical Consistency Reviews as a Chart Checking Tool* -
- **"In Vivo" dosimetry**, for first fractions, *may* have prevented this error! While its "yield" of errors is minuscule in a well functioning clinic, the effort is justified when a significant error is discovered.
- IAEA 2006 "...Safety Standards in Radiotherapy" notes: "...an effective QA programme...demands **strong managerial commitment** and support in training, time, personnel and equipment resources"

■ Typical Organizational Cycle: Part 1

- At some early time, there is organizational “balance” between resources and responsibilities, ie, there are enough (100%) competent workers to cover 100% of responsibilities (**Health Steady State Condition**) in a small system.
- External/internal forces (competition, funding cuts, perceived need to grow, etc.) demand more (>100%) responsibility with same or less resources (<100%) for new responsibilities.
- Over time, more and more responsibilities (>>100%) (new programs, new linacs, new computers, etc., all of which require ongoing attention, upkeep, maintenance, employee training, etc.) are added without addition of staff (<<100%) to support efforts. Upper management focuses on revenues or “programs”; not “people”. Large organization now “unbalanced” (**Unhealthy Non-State State Condition**)

■ Typical Organizational Cycle: Part 2

- Excellent staff, now stressed, take “**shortcuts**” to maintain all components.
- **Major medical event occurs**, ie, organization breaks down (**Un-controlled State**); either regulators, lawyers, or “new” management team brings organization back into balance. Cycle starts over!

■ What Can “You”, **The Worker**” Do? (Part 1)

- **Simplify** - For every routine tasks, ask: What can I (we) do to make this task easier, faster, and **safer** the next time!
- **Write Procedures!** The purpose is multiple. Writing identifies the flaws in processes. If you cannot describe a process easily, it may be too complex and needs simplification. Identify **Who** is to do **What When and How!**
- **Become Component** – Repeat tasks so often you rarely have to refer to the written procedure!
- **Be Wary** - Think how processes break down and subsequent consequences of failure. Imagine what can go wrong!
- **Train Using Written Procedures** – Showing a fellow worker how to do a task is common, but critical details or variations in processes often are omitted. Use written procedures and examples (standard plans!) to document training.

■ What Can “You”, **The Worker**” Do? (Part 2)

- **Be responsible for Others** – Recognize what others know; intervene (supervise, offer to help, advise others of problem); prevent simple tasks from being medical events!
- **Omit your ignorance!** Regardless of your rank, and status, in any group, the knowledge base is large and distributed unevenly; no one knows everything! Always be willing to learn from those who know more than you do about a specific task or topic. Radiation therapists (techs), fellow dosimetrists, physicists, etc., have practical process task knowledge! Don't be afraid to ask and learn! **If you don't know how to do a procedure, defer it others who do know how to do it!**
- **Don't Cheat** – Understand timelines, due-dates, and do required required tasks timely. Don't “dry-lab” reports, back-date data, or falsify records in any manner! You'll be tempted! **Don't do it!**

■ What Can "You", **The Worker**" Do? (Part 3)

- **Study and Cross-Train** – Dosimetry & Medical Physics are increasingly complex; **learn all you can about all you can!**
- **Know Your Administrators** – Don't be *face/less!* Know your administrative structure and administrators. You'll have more credibility when you ...
- **Complain** – Recognize when an organization is becoming "**unbalanced**"! Let supervisors, administrators, etc., know your concerns. Usually administrators do not know the details of the daily work place; they want to believe that all is well! They will not know about omissions, shortcuts, regulatory non-compliance, and break downs that can cause a medical event. Your ultimate responsible is to help prevent medical events! Protect your organization!
- **Comply** – Know regulations, guidelines, quality system requirements, and comply with them. There are **good reasons** they exist!