Overall Quality Assurance and Review – Auditor Perspective

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Aims

Given: “Assuring accurate and safe delivery of radiotherapy to cancer patients through setting up a quality assurance/review system”

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All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality

How to implement within dosimetry?
Quality Assurance (QA)

Defined as:

All those planned and systematic actions necessary to provide adequate confidence that a product or service will meet the given requirements for quality.

ISO 9000:1994
Internal QA/QC programs

Quality Control

Quality Assurance

Attr: Alan L McKenzie, Bristol, UK.
QC is one part of overall quality assurance and is defined as:

A regulatory process through which the actual quality performance is:

- Measured
- Compared with existing standards
Quality Framework

QUALITY IMPROVEMENT
Such as incident monitoring

STANDARDS
Development of (or refinement) of Standards or Guidelines

QUALITY ASSURANCE
Such as regular dosimetric auditing

ASSESSMENT
Conformity assessment against standards

NEW: Australian Clinical Dosimetry Service
A few points

• The plural of anecdote is not data
• A measurement without uncertainty is not a measurement
• Testing an existing system is not replicating previous measurements
• An audit which does not test to failure has limited utility
• If it is not recorded, it didn’t happen
• The normal distribution *rules.*
The normal distribution

Is not your enemy

Is not your enemy
Example: OSLD readings

Data from individual batches

All audit data

Out of tolerance

Action Level

Optimal Level

Deviation between ACDS measured dose an facility stated dose (%)
• “Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death”

Sir Liam Donaldson
Chair, World Alliance for Patient Safety
Executive Summary

4 Misinformation or errors in data transfer constituted the greatest bulk of incidents in modern radiotherapy services. Of all incidents without any known adverse events to patients, 9% (N=420) were related to the ‘planning’ stage, 38% (N=1732) were related to transfer of information and 18% (N=844) to the ‘treatment delivery’ stage. The remaining 35% of the incidents occurred in a combination of multiple stages.

5 More system or equipment-related errors documented by medical physicists were reported, as compared to errors that occur during initial choice of treatment, dose prescription and other random errors not related to equipment or system faults.

Radiotherapy Risk Profile
WHO/IER/PSP/2008.12
Data

The measurements, the data, you possess from your own facility’s measurements are your most important property.

Analysis of this data enables you to present evidence which can inform your own practices and decisions.

Think about the conversations you have in the clinic
Preventing treatment errors in radiotherapy by identifying and evaluating near misses and actual incidents

O. Holmberg, BMcClean: J Radiotherapy in Practice Vol 3 no 1 2002

• Are variations meaningful?
  – New checkers?
  – New Techniques?
  – New Technology?
  – Indication of complacency?
Replication is not testing

8 February 2006

EXCLUSIVE: 17 DEADLY DOSES OF RADIATION

EXCLUSIVE: LISA FACES TERRIFYING FUTURE AFTER HOSPITAL BLUNDER
Agony of brain cancer teenager

Lisa was not the first patient to be treated on the system.
Attr: Alan L McKenzie, Bristol, UK.
For most treatments, MU for 1.67 Gy is transferred electronically to Varis

For CNS treatments only

For CNS, calculate MU for 1 Gy and transfer to paper record

Radiographers/Technologists multiply MU for 1 Gy by 1.67 and enter into Varis

Attr: Alan L McKenzie, Bristol, UK.
For most treatments, MU for 1.67 Gy is transferred electronically to Varis.

Physicist forgot to normalise MU for 1 Gy.

Radiographers/Technologists multiply MU for 1 Gy by 1.67 and enter into Varis.

For CNS treatments only.

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### Table

<table>
<thead>
<tr>
<th>MU per 100 cGy</th>
<th>50 MU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed Dose</td>
<td>1.67 Gy</td>
</tr>
<tr>
<td>Calculated MUs</td>
<td>$1.67 \times 50 = 83$ MU</td>
</tr>
</tbody>
</table>

Attr: Alan L McKenzie, Bristol, UK.
Audit design

A useful audit measurement must be able to determine if the process being audited has a flaw, ideally:
Different measurements in the same audit will cover different risks of the process
The magnitude of any difference from the ideal will indicate the type of flaw.
Analysis of individual measurements will isolate any major contributing factors.
For example:
Example: ACDS Level III

Audit is an end-to-end test for the beam model

Plans based on international standards (IAEA TECDOC 1583) + selection of meaningful additional measurement points

First measurement under near reference conditions, (sanity check).
Audit design: Sensitivity

Ant beam: Points 1 & 10 give basic dose and beam quality.
Lat beam: Point 4 very position sensitive
The Forth Railway Bridge completed in 1890 by engineer Benjamin Baker, who said “the successful engineer is the one who makes the least errors”.

Attr: Alan L McKenzie, Bristol, UK.
There is evidence in Benjamin Baker’s log book that he checked his work.

Attr: Alan L McKenzie, Bristol, UK.
Epinal

• Consequences:
  – 24 patients over irradiated, 20-30%, prostate cancer
  – 4 deaths
  – For the rest: important complications (intense pains, blood transfusions, being unable to stay seated, nervous depression
  – No one is unharmed
Epinal 1989 - 2006

1 error calculation - Breast
2 error calculation - wedge
3 heart overdosage
4 portal imaging overdosage
5 error calculation - wedge - prostate

In vivo dosimetry
Testing is not replication
Why Audit?

“Firstly and most directly, in every dosimetry audit programme, measured doses have been observed and reported which have been outside the required tolerances, in some cases significantly so.”

Thwaites DI, SSDL 58, June 2010
Izewska J, et al., SSDL 58, June 2011
Ibbot, G.S., Followill, D.S., SSDL 58, June 2011.
“… I have always found that plans are useless, but planning is indispensable.”

- Gen D Eisenhower