Medical Device Management: A new paradigm for QA

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What is a medical device?

A device that is used to evaluate, manage, or affect a person’s health.

<table>
<thead>
<tr>
<th>Type</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging</td>
<td>CT, MR, PET scanner</td>
</tr>
<tr>
<td>Modeling</td>
<td>Treatment planning system</td>
</tr>
<tr>
<td>Delivery</td>
<td>Linac, HDR afterloader</td>
</tr>
<tr>
<td>Data</td>
<td>Patient data system (R and V)</td>
</tr>
</tbody>
</table>

The life of a medical device

- Initial planning
- Purchase
- Installation
- Acceptance testing
- Commissioning
- Decommissioning
- Uninstallation

Wholistic view of a medical device

There is more to it than making sure the device works.

All activities related to the use and function of the device should be considered.

The identification of involved people and activities, as well as device performance, constitutes device management.

Categories of things that can go wrong

- Configuration error
- Operator (pilot) error
- Spontaneous malfunction or failure
- Performance drift
- Unintended functionality
New York Times articles

• Series on injury and errors in the use of medical radiation
• Profiled two horrific cases in the New York area
• Followed by:
  – Congressional hearings
  – Activities and statements by professional organizations
  – A lot of attention to the profession
• Brought to light that not all facilities are not cutting corners

IAEA protection web site

IAEA case studies

2.10 Accident update, some newer events - UK, USA & France

• Catalogs about six events
• Discusses and highlights what was done and what led to unintended radiation delivery
• Includes IMRT case cited by New Times articles

Root cause analysis points to both the quantity and quality of staffing.

What is QA?

A collection of activities designed to ensure that we deliver on what we intend.

These activities can include:
  – Creation and enforcement of policies and procedures
  – Training
  – Auditing and assessment
  – Measurement and testing
  – Documentation and reporting

Joint AAPM / ASTRO meeting on QA

In Dallas in 2008:

• Discussed many topics and drew from other industries such as airlines and process engineering.
• Essentially tried to redefine what we mean by “QA.”

My take home message:

New approaches and systems for management will have to be understood by end-user (physicist), but will not be created by them.

The problem

Advances in treatment involve increases in:

• Complexity
• Change

Players create their own structure and processes that:

• Are often incomplete
• Vary from day to day or month to month, etc.
Change

- New technologies land more frequently.
- Early versions lack features and have bugs.
- Everything has a computer either attached to it or embedded within.
- If it has a computer, the software can and will be subject to updates.

Change is something that has to be managed.

Multiple players

- Facility
  - Users
  - Custodians
  - Owner
- Non-Facility
  - Installers
  - Maintainers (service)
  - Changers

TG report driven approach

- Well, we do things to satisfy the recommendations in TG-40, and now TG-142.

- Activities focused on specific performance metrics to be met at some frequency.

- Device users and service people are relegated to indirect roles.

A homegrown MDMS

Roles and responsibilities

- An important component of device management is the creation and assignment of roles and responsibilities.
- Once these are clear, then a framework of activities can be created.

Result: (1) People know what they are to do and when.
       (2) Creates a framework of accountability.

Clinical physicists as managers

- Independence and self-direction are very appealing to physicists. Management is not.
- To effectively guide quality in processes and tools used in patient care, there has to be some management.
- There is little, if any of this emphasized in a medical physicist’s training.
What is the point?

• Medical physicists are well-positioned for many of the roles in MDM.
• Education and training do emphasize understanding complex systems.
• Physicists need to be integrated in the management of staff, devices, and processes.

Well, this isn’t what I signed up for!

Obstacles to change

• Institutional
  – Facilities have own culture
  – Hierarchy with physicians at top
  – May not want to pay for additional staff
• Vendors
  – Have own interests
• Physicists’ roles
  – Vague definition
  – In-house versus consultant

The autonomy trade-off

An “invariant” is that as complexity of devices and systems increases, individuals lose some things:

• Overall control of design
• Independence to vary implementation
• Ability to specify design or make change
• The opportunity to do things as you darn well please

Proposal (or pie in the sky wish…)

• More defined roles in clinic that are formalized.
• Clinical physicists manage more.
• Tools are created to assist in managing.
• Agreement and joint standards put forth by ACR, AAPM, and ASTRO.
• Physicians and administration buy into the idea of physicists functioning in these new ways.

Summary

• Nationally there is a spectrum of radiation therapy facilities, from the very small to very large.
• There is a large degree of independence and autonomy amongst these facilities.
• Each facility is responsible for developing and implementing their own programs, processes and procedures.
• As more complex equipment and methodologies appear, this model of management will have to change.
• One means to address increasing complexity and change is to frame it in terms of medical device management.