

# Medical Device Management: A new paradigm for QA

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This is where I work...



## What is a medical device?

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

Type	Example
Imaging	CT, MR, PET scanner
Modeling	Treatment planning system
Delivery	Linac, HDR afterloader
Data	Patient data system (R and V)

## The life of a medical device

Initial planning  
Purchase  
Installation  
Acceptance testing  
Commissioning  
Decommissioning  
Uninstallation

Use  
Repair  
Adjust  
Upgrade  
Validate



## 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



## 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.**

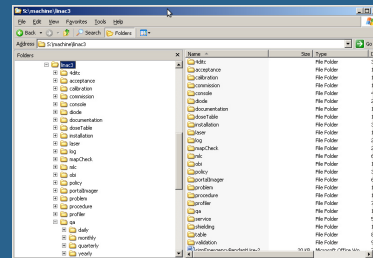
## Multiple players

- 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



Folder	Name	Role
401	401	Facility
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## 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.