

Physicist's Responsibility On End-Of-Life for Brachytherapy Devices and Software

Wayne M. Butler, PhD.
Schiffler Cancer Center and
Wheeling Jesuit University
Wheeling, WV



Customers who choose to continue
clinical use of transfer tubes,
applicators and accessories beyond the
expected life assume responsibility and
liability for all use.

Nucletron User Notice
IUN 799701-00
11 Nov 2013

Who is responsible?



**Who, Me?
Yes, You!**

Patient safety is important to manufacturers and users

- Other motives may be present but so what?
 - Manufacturer would like to sell more widgets or services
 - User wants to minimize capital and service expenditures

Scenarios

- Manufacturer publishes guidance for end-of-life
 - Limited time of service — expected life
 - Limited number of uses — useful life
- Manufacturer declares end-of-life
 - Will no longer service the device

Oversimplification of the choice to replace or not



Are older devices more hazardous?

Survey on 2,031 pieces of equipment in Norway

- Average age of 7.4 years
- Mean life span of 15 years
- Failure rate higher for newer equipment
- Operator errors higher for newer devices
 - Older equipment less complex and easier to use

If you choose not to replace ...

- You will need an inspection log
 - Hardware intact and undamaged
- You will need a testing log
 - Software functioning correctly
- How often have you seen device failure shortly after a Preventive Maintenance Inspection?

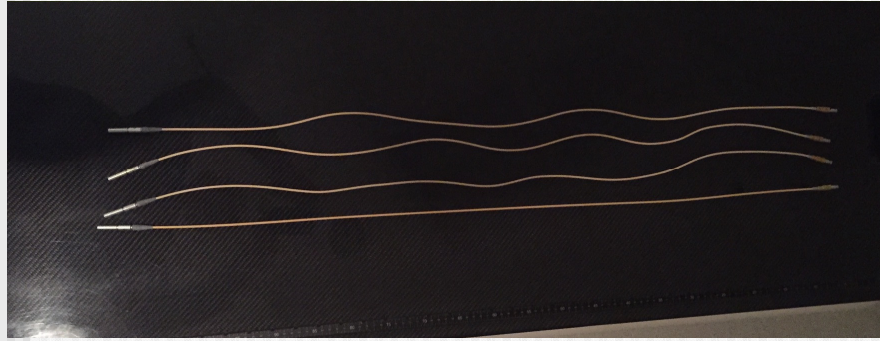
What constitutes sufficient data and analysis to avert liability?



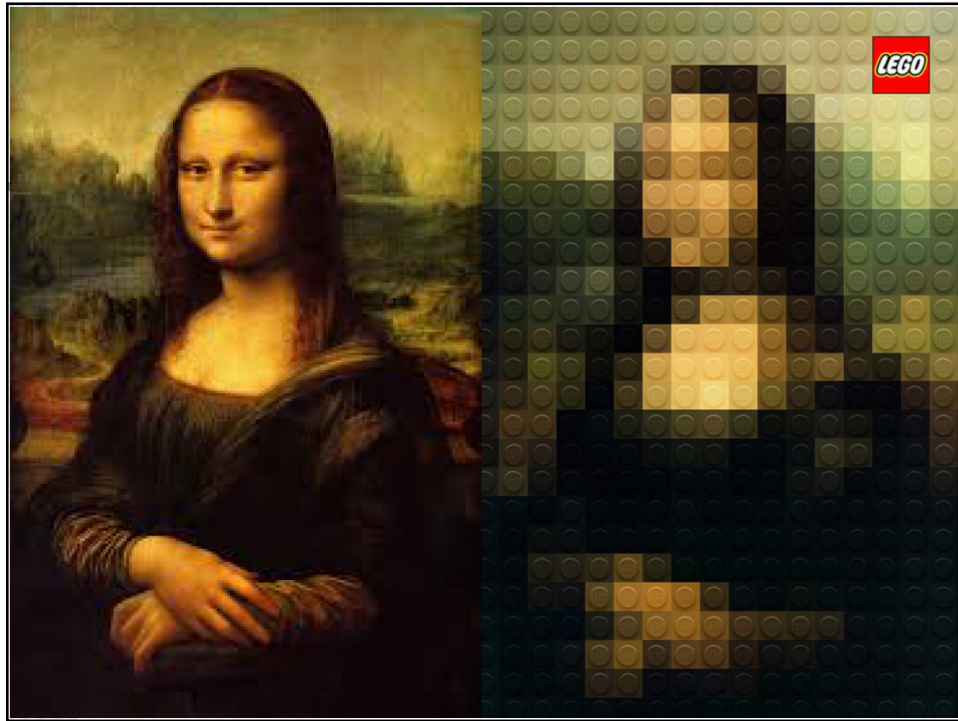
Predictors of failure

- Radiation damage not often visible
- Testing for aging effects may cause harm
 - Elasticity, tensile strength, burst strength
- Adverse storage conditions
 - Temperature, humidity, light exposure
 - Different from manufacturer's life cycle tests
- Sterilization procedures take a toll

One transfer tube was not
sterilized



Is your data sufficiently granular
to allow a faithful representation
of the clinical reality?



Track applicator use

- Date when first placed in service
- Log sterilization cycles (or cleaning & disinfection)
 - Add field to patient database to record applicator used
- Log number of uses for transfer tubes

Consider replacement informed by risk analysis

Risk assessment: 1. Determine the likelihood of harm

Likelihood Group	Example of Probability of Harm
4	Occurs every time
3	High likelihood or considerable certainty, reasonable probability to occur
2	Expected to occur from time to time, infrequent or small likelihood
1	Not expected to occur
0	Inconceivable, not possible

Risk assessment: 2. Determine the severity of harm

Severity Level	Examples of Harm
4	Directly results in death
3	Serious or life-threatening injury, permanent impairment
2	Results in moderate injury, temporary impairment, or self-limiting illness
1	Results in minor or no injury

Risk assessment: 3. Determine acceptability

Likelihood	Severity			
	1 Minor	2 Moderate	3 Serious	4 Death
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further analysis needed	Unacceptable	Unacceptable
1	Acceptable	Acceptable	Further analysis needed	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

A risk decision

An HDR brachytherapy component failed during treatment. Alerts to staff prevented any harm to the patient. National tracking data show the mean time to failure of this component to be 1,000,000 uses. There are 4,000 devices in the field used once daily.

Is this risk acceptable?

Navigation aids for prioritized replacement



Public health perspective

- Return on investment for medical device safety should be proportional to other social investments in safety
- Global replacement vs. selective replacement
 - Global replacement ensures all failed components are removed
 - Selective replacement minimizes disruption

Life cycle cost analysis

- Prospective system values derived from anticipated operations and maintenance costs
 - Projected revenue
 - Availability of new technology
- Medical equipment insurance programs
 - Flexibility of on-demand service
 - Safety of a capped budget

Cooperation between Physics and Bio-Med Engineering useful



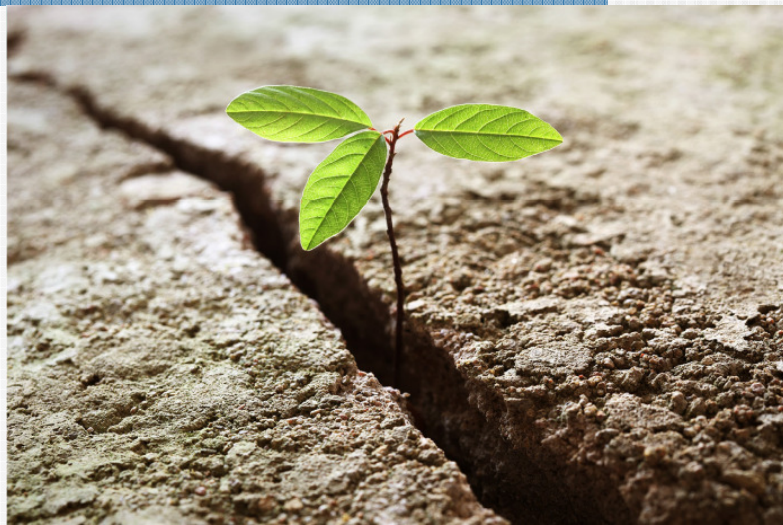
Prioritizing equipment for replacement

- Track service history
 - Records kept by Physics or Bio-Med Engineering
- Ranking should include:
 - Function, utilization and risk
 - Equipment age and vendor support
 - Maintenance cost
 - Efficacy of newer technology

Institutional policy on replacing obsolete or expired equipment

- Should be based on historic use data
- Cost/benefit analysis
 - Whole systems will be capital purchases
 - Components may be billed as repair
- Availability of competent treatment nearby

Your environment is unique



Statistical criteria are not individually predictive

- Statistics from large samples are useful for comparisons
- Mean or median life expectancy is useful for planning
 - The uncertainty or deviation may be large, small, or unknown
- Every device will fail, and the time to failure may be surprisingly short or unusually durable or as expected

Good luck & thank you
