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Possible solutions to End of Life

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Facts with EOL issue

- Limited solutions
- Costly to the users
- Unplanned and very little warning to users
- Not convincing policy to some
- Stressful (Administration)
- Very little guidance available
- Is here to stay and resolutions are needed

Options available

- The simple and logical road: follow manufacturer recommendations and act on it.
- The possible risky one: simply do nothing
- Use current devices/software and prepare justification/negotiation for full or partial replacement

Disclaimer: the following statements are only suggestions and everyone is responsible for his/her decisions!

Remember: "I know nothing and see nothing!"

Follow manufacturer recommendations

Follow manufacturer recommendations

- Ask manufacturer to provide you a list of all devices and dates acquired by your institution
- Verify against items being currently used by the institution
- Get an estimate of the replacement cost and negotiate.
- Request upfront future EOL dates to plan ahead
- Look into an agreement to have the next replacement cost be embedded in your service contract (assuming you want to keep the same equipment).

Follow manufacturer recommendations (Cont'd)

- Remember technology is evolving and new devices might provide better outcome
- Consider changing vs. replacing. Some items might no longer be available (Obsolete)
- Consider a plan for your institution based on the usage (#) and not time (length)

How am I going to convince my institution with this?

- Present facts about what ***could*** happen if you do not comply or act on it
- Look into websites (NRC or others) for reported events to use for documentation
- Your lifeline for negotiation: "patient safety is your concern"
- Include risk management, administration, legal, medical director in the discussion

How am I going to convince my institution with this? (Cont'd)

- Let administration make the final decision. Liability can be costly
- Protect yourself: explain the limitations on evaluating equipment subjected to radiation, cleaning, sterilization etc…Not a simple task

Option 2: do nothing

- Risky road. Must have ***unconditional*** support and full agreement from your institution
- Perform your tests and document everything using published recommendations for Q.A. (Daily, ***quarterly***, yearly etc..)
- Educate the staff about being twice as diligent before and after device usage, cleaning and sterilization
- Any malfunction or sign of abnormality, even if resolved, should be reported to you immediately

Option 2 (Cont'd)

- Perform more frequent visual and radiographic inspection
- Stay abreast with reportable events, recall related to equipment malfunction

Reference for Q.A.

"Code of practice for Quality Assurance of Applicators and Transfer Tubes for Ir-192 Afterloaders"
http://radiationdosimetry.org/qa-of-afterloaders-for-brachytherapy
Pre-publication of the Netherlands Commission on Radiation Dosimetry
9 July 2015
NCS, Netherlands Commission on Radiation Dosimetry, http://www.radiationdosimetry.org)
J.B. van de Kamer, Chairman

Continue “status quo” and prepare

- Too costly to institution for replacement
- Consider replacing obvious devices based on usage, conditions, their material (plastic vs. tungsten), age etc.
- Provide recommendations or suggestions (but not a decision) (Similar to option 1)

How about the manufacturer’s responsibility

- Better communication (notification, details)
- Make products that will last longer
- Have flexible plans for each institution to manage this costly replacement
- Provide supporting information (Test cycle, runs etc.) to AMP for discussion with administration

Question 1

Once a device has reached its end of life cycle, the responsibility and liability falls on:

a) Both manufacturer and user
b) Manufacturer
c) On the manufacturer for the responsibility
d) On the user for the liability
e) The user

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Answer: e) the user
Nucletron: FCO IUN 799701-00 (19-11-2013)

EOL is
End Of Life
End Of Liability!

Question 2

The recommended frequency of HDR QA for device related equipment is:

a) Monthly
b) semi-annually
c) Annually
d) Daily
e) Only after repair
f) Quarterly

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e) Only after repair
f) quarterly

Answer: every quarter
Reference: AAPM TG-56

Possible scenario: never happened!

- Assume Mrs. Jones was treated with a GYN applicator at institution X
- During the second application the applicator broke (Hard to believe) while inside the patient
- Difficulties in retrieving the jammed source and applicator, but successful after 10 minutes beyond Tx time
- Delivered dose evaluated and results indicated a medical event has occurred
- As a result there was a … lawsuit

So what happened!

- Patient's attorney did his homework and discovered something called "EOL"
- Physicist was asked to testify on this case
- Physicist was shown EOL document from the manufacturer
- Based on documentation, device was 10 years beyond EOL (Do not be surprised, check your HDR inventory!)
- Attorney's conclusion: the device should not have been used. Too old and unsafe
- Outcome: patient overdose, financial burden to institution, and Percocet (or something stronger) for all staff

Purpose of this case

- One case on EOL issue can make the headline
- Bad outcome for the patient (most important)
- Financial loss for the institution
- Financial consequences vs. applicator (s) replacement (Use your imagination!)
- Bad reputation for the modality (NY Times might be on the lookout)
- Bad reputation for the practice

Conclusions

- EOL policy has been around
- Perhaps people need to read all documentations
- It is here to stay
- Institutions need to be creative and proactive to look into practical solutions
- Manufacturers need to look into lasting products (longer than current lives)
- Manufacturers need to work with users for reasonable plans towards HDR equipment replacement
- Further discussion (Physicists and manufacturers) on this will be valuable (OncoPeer or other engines)

Discussion within the AAPM to have a group to draft some guidelines on this issue. Stay tune

References for the topic
(Special thanks to Tom Heaton)

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm150083.htm
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/QualitySystemRegulationLabelingRequirements/default.htm
- http://www.fda.gov/downloads/MedicalDevices/.../UCM081366.pdf
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=Members-Only%20Updates
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- http://www.alticoadvisors.com/Portals/0/Device%20Packaging%20-%20Top%2010%20Mistakes%20-%20Copy.pdf
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- http://www.btlaw.com/alert-fda-amends-proposed-rule-on-unique-medical-device-identification-november-2012/