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 (Obsoleter)
- 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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a) Monthly
b) semi-annually
c) Annually
d) Daily
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/Cosmetics/Labeling/ExpirationDating/default.htm