

Brachytherapy Devices: Definition of "End of Life"

¿ Why do we have such a thing?

Christopher S. Melhus, Ph.D.

Tufts Medical
Center

Disclosures

- None



2 July 14, 2015

Definition: End of Life

Tufts Medical
Center

Goals

- Introduce *End of Life*
- Implications of *End of Life*
- Manufacturers perspective
- Clinicians perspective
 - To be revisited later this session...
- Regulatory perspective
 - To also be revisited later this session...



3 July 14, 2015

Definition: End of Life

Tufts Medical
Center

End of Life

A simple phrase – extreme connotations...



4 July 14, 2015

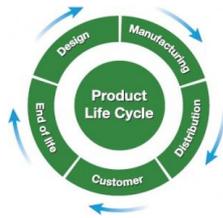
Definition: End of Life

Tufts Medical Center

Product Life Cycle

• Devices follow a general "life cycle"

- Conception
 - Inspiration & idea
- Design
 - Development & validation
- Realization
 - Manufacturing & sales
- Use & service
 - Operation & maintenance



5 July 14, 2015

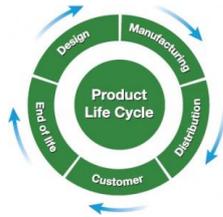
Definition: End of Life

Tufts Medical Center

Focus on Clinical Use & Service

• While the product is in the field, vendor must...

- Support training
 - Clinical users
 - Field service engineers
- Supply parts
 - Hardware
 - Software
- Support product utilization
 - Appropriate use
 - Instructions for Use (IFU)
 - Preventative maintenance



6 July 14, 2015

Definition: End of Life

Tufts Medical Center

Focus on Clinical Use & Service

- Need to set expected use and expectations for use
 - Devices are not indestructible
 - Wear and tear can limit device lifespan
 - Expanded use can identify new / unforeseen failure pathways
- Need to allow for new product development
 - Product improvement
 - *New materials / product modifications / new design*
- Competing technologies can lead to obsolescence
 - Manufacturers need ability to discontinue products



Tufts Medical Center

Definition

- End of Life (EOL)
 - US Food and Drug Administration (21 CFR 803.3)
 - **Expected life** of a device means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "**end of life**" (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.

8 July 14, 2015

Definition: End of Life

Tufts Medical Center

Implications of EOL

- Time / instance at which the manufacturer will
 - No longer guarantee safe & regular operation of a device
 - Implicit full transfer of liability to the institution
 - May be based on time and/or number of use or cleaning cycles
- Differentiate EOL from "shelf life"
 - Shelf life is the length of time that a commodity may be stored without becoming unfit for use, consumption, or sale
 - *Medication, food, and perishable items*
 - *Also, could be applied to packaging sterility*
 - Note: could play a very important role in brachytherapy, too!

9 July 14, 2015

Definition: End of Life

Tufts Medical Center

Factors of Applicator Function and Longevity

- Cleaning agents
 - Exposure to gasses, chemicals, UV radiation
- Mechanical “wear and tear”
- Radiation damage
- Time / aging of materials
- Unknown product defect
- Storage conditions

10 July 14, 2015

Definition: End of Life



End of Product Sales / Support

- No longer provide remote- or field-service on product
- No longer provide training / clinical education for product
- No longer maintain parts inventory
- No longer guarantee appropriate clinical function
 - *Device may not be at EOL, but may not be supported!*

11 July 14, 2015

Definition: End of Life



How is EOL Determined?

- Testing of products
 - Performed under conditions that simulate use
 - Estimate number of use cycles
 - *Including impact of sterilization*
- But, product use can vary widely...
- Solution: base EOL on time period
 - Using appropriate assumptions



12 July 14, 2015

Definition: End of Life



Different Product Perspectives

Manufacturer's Point-of-View



Acknowledgement: David Harrington, ABS 2015

13 July 14, 2015

Definition: End of Life

Customer's Point-of-View



The only shared value...

Manufacturer's Point-of-View



14 July 14, 2015

Definition: End of Life

Customer's Point-of-View



Vendors and medical practitioners are both impacted by adverse events...

Hospital / Users Compliance Obligations

- Follow manufacturers guidance
 - Instructions for Use, Reference Guide, Product Manuals
 - Note EOL expectations
 - Multi-disciplinary approach to program management
 - Note appropriate clinical use parameters
 - Promote and distribute appropriate sterilization conditions
 - Off-label use applies to **indications** for use
 - Does not apply to parameters for use

Life Expectancy
 The life expectancy of the [redacted] is [redacted] to 3 years.

Warning
 The [redacted] [redacted] should only be used by physicians trained in general surgery techniques. The physician is responsible for the proper clinical use and the prescribed radiation dose. Prescribing and administering an unstable radiation dose may lead to clinical complications.

15 July 14, 2015

Definition: End of Life



Hospital / Users Compliance Obligations

- Receive, interpret, and comply with vendor notices
 - Different notice types
 - Urgent Medical Device Notice
 - Field Change Order (FCO)
 - Field Corrective Action (FCA)
 - 21 CFR 820.100(a) Specifies manufacturers quality requirements
 - Vendor may require acknowledgement of receipt and/or response
 - Regulatory bodies may also check for compliance
 - By vendor
 - By user / clinician
 - Compliance offices often want copies of notices & correspondence
 - May be a multi-disciplinary approach to program management

Example User Notice

Important User Notice

Check Applicators and Transfer Tubes aging, integrity and suitability

Product:
Date: 15-11-2013
FCO#: 8J89 799501-00

17 July 14, 2015

FCO Action Notification Report

Please complete details on this report and sign the appropriate sub-management section

- Existing regulatory requirements for the customer
- User education: User education: Confirmation to the installing
- Informational: User education: Confirmation to the installing
- Informational: User education: Confirmation to the installing

Check with the report for your kind

FCO Summary

Classification: Urgent User Notice **FCO No:** 8J89 799501-00-00

FCO#: 8J89 799501-00-00

Subject: Check Applicators and Transfer Tubes aging, integrity, cleanliness and suitability

Scope: All general

Product:

Device Serial No. (s): **Location of Use:**

Administrative to customer:
The manufacturer or agent has advised that management that have read and understood this FCO and accept implementation of any given recommendations

Notes: **Date:**

Key operational considerations:
The installation is in line with the existing or harmonized conditions

Notes: **Date:**

FCO (8J89 799501-00-00) Page 1 of 1

Copyright © 2011 All rights reserved ghl0001

Are There Benefits to End of Life?

- Patient Safety
- For manufacturers:
 - Products to sell
 - Ability to manage liability
- For institutions and medical centers:
 - Assure applicators are consistent with current standard of care
 - Limit exposure to adverse events due to applicator failure
 - Ability to manage liability
- For the field of brachytherapy:
 - Improved image through error reduction

Thanks for your attention

- Acknowledgements
 - Zoubir Ouhib, MS
 - Mark Rivard, PhD & Dorin Todor, PhD
 - Wayne Butler, PhD
