Brachytherapy Devices: Definition of "End of Life"

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Goals

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

Disclosures

- None
**End of Life**

A simple phrase – extreme connotations…

**Product Life Cycle**

- Devices follow a general “life cycle”
  - Conception
    - Inspiration & idea
  - Design
    - Development & validation
  - Realization
    - Manufacturing & sales
  - Use & service
    - Operation & maintenance

**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
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

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.

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!
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

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!

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
Different Product Perspectives

**Manufacturer's Point-of-View**

- Well Defined Use Limits
- Patient Safety
- Revenue

**Customer's Point-of-View**

- Compliance with IFU
- Cost of Use
- Patient Safety

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The only shared value...

**Manufacturer's Point-of-View**

- Patient Safety

**Customer's Point-of-View**

- Patient Safety

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

**Warning:** Life Expectancy

- The life expectancy of the product is up to 5 years.

- Not for use after the date of manufacture or expiration date.

- Use with appropriate sterilization conditions as specified by the manufacturer.

- For use within the parameters specified by the manufacturer.

- Use with appropriate clinical use parameters.

- Use within the indicated indications.

- Not for use outside the intended use parameters.

- Use according to the manufacturer's recommendations.

- Use with appropriate storage conditions.

**Note:** The content of the slide is for educational purposes only and should not be considered as medical advice. Always consult with a qualified healthcare professional for medical advice.
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

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
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