

# Technical Electronic Product Radiation Safety Standards Committee (*TEPRSSC*): Radiation Therapy

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# Radiation Therapy Overview

External beam radiation therapy

- Linear accelerator (LINAC)

- Particle beam therapy

- Surface electronic brachytherapy: x-ray source applicators

Internal radiation therapy

- Electronic brachytherapy: x-ray source



Figure 1. Linear accelerator for external beam radiation therapy (from [www.cancer.gov](http://www.cancer.gov))



Figure 2. Radiation therapy head mask used during external beam radiation Therapy (from [www.cancer.gov](http://www.cancer.gov))

# Advancement of Radiation Therapy

## Linear accelerator (LINAC)

- Intensity Modulated Radiation Therapy (IMRT)
- Volumetric Modulated Arc Therapy (VMAT)
- Image-Guided Radiation Therapy (IGRT)
- Stereotactic Radiosurgery (SRS)
- Stereotactic Body Radiotherapy (SBRT)

## Particle beam therapy system

- Proton beam therapy
- Neutron beam therapy

## Electronic brachytherapy

- Surface/interstitial/intracavitary

# Safety Concerns

## Dose delivery accuracy

- Ability to deliver the prescribed dose to the correct locations
- Radiation exposure to healthy tissue – increased risk of secondary cancer as a result

Integration of design and multiple components (often third-party) have introduced new complexity in treatment delivery. Examples:

- Treatment planning software
- Treatment accessories, e.g., collimators, patient support system, motion management system



# Voluntary Consensus Standards

Currently, FDA has no specific performance standards for radiation therapy devices, and relies on existing international voluntary consensus standards for LINAC:

- IEC 60601-2-1: Linear accelerator safety
- IEC 60976 and 60977: Linear accelerator performance
- IEC 60601-2-68: IGRT safety
- IEC 61217: Coordinates, movements and scales



# Voluntary Consensus Standards

## Particle therapy

- IEC 60601-2-64: Light ion safety
- IEC 62667: Light ion performance

## Treatment planning

- IEC 62083: Treatment planning systems
- IEC 62274: Safety of radiotherapy record and verify systems
- IEC-61852: DICOM-Radiotherapy objects

## Radiotherapy simulators

- IEC 60601-2-29: Radiotherapy simulator safety
- IEC 61168: Radiation therapy simulators performance

## Electronic brachytherapy

- IEC 60601-2-8: kV X-ray therapy system safety



# What Would FDA Like to Do?

- We are considering developing specific performance standards applicable to electronic products used for radiation therapy
- We are considering developing additional guidance to facilitate and encourage the use of the relevant consensus standards
- We encourage manufacturers to adopt features that promote patient safety and to conform to existing voluntary consensus standards

# Questions

- What is the committee's opinion on the desirability of establishing performance standards for electronic products used for radiation therapy, such as linear accelerators and particle accelerators systems used to deliver external photon or particle radiation?



# Questions

- Are mandatory performance standards necessary for electronic products used for radiation therapy, or is it sufficient to develop and encourage the use of voluntary consensus radiation safety standards?

# Questions

- If FDA develops performance standards for electronic products used for radiation therapy, what functions, systems, products, etc. should we focus on to achieve the largest public health benefit?

# Questions

- What is the committee's opinion on the desirability of establishing performance standards for accessories to radiation therapy systems (e.g., treatment planning software, quality assurance equipment and software, patient positioning systems, patient motion tracking systems) that can control the quality, quantity, or direction of the radiation beam?

# Questions

- Are mandatory performance standards necessary for accessories to radiation therapy systems, or is it sufficient to develop and encourage the use of voluntary consensus radiation safety standards?
- If FDA develops performance standards for accessories to radiation therapy systems, what functions, systems, products, etc. should we focus on to achieve the largest public health benefit?

