REGULATING RADIATION SOURCES AND MEDICAL FACILITIES IN THE UNITED STATES INCLUDING CHALLENGES WITH NEW TECHNOLOGIES AND APPLICATIONS
Challenges

- Technologies come on the market very fast
- Large number of regulatory and guidance groups involved
- Length of time required to promulgate new regulations
- Limited budgets and resources to inspect and regulate new technologies
Who is Involved?

- 11 Federal Agencies with some regulation of radiation
- 50 states plus at least three additional local entities
- Various professional organizations, councils and groups
  - CRCPD and OAS
  - AAPM, ACR, ASRT, ASTRO
Who regulates?

- **For Medical Use**

- US Food and Drug Administration - regulates the manufacture of medical devices

- US Nuclear Regulatory Commission - Regulates the use of Radioactive Material in Federal facilities and non-agreement states
Who Regulates?

- States and Local Entities
  - Regulate the use of both x-ray devices and Radioactive Material in their state
  - Regulate/approve licensure for physicians, technologists and physicists in their state
  - Can be multiple state agencies involved
New Devices and Technologies

- New technologies can be in use very quickly; however, the use may change quickly as the technology becomes more prevalent.
- Regulations can take a long time (emergency regulations, public comment)—don’t want to inhibit the use.
- Training for staff can be an issue.
New Devices and Technologies

- Some used in very limited capacities
- Some uses spread very quickly and some do not
- Some areas see much more use than others
- States are not always aware of the devices in use - found at the time of the inspection
- Used in different states/local areas with different requirements
- Not always appropriate regulations in place
Bridging the Gap-Guidance

- The Conference of Radiation Control Program Directors, Inc. and the Organization of Agreement States
  - Develop guidance, inspection procedures and suggested regulations for state and local entities

- The American Association of Physicists in Medicine, the American College of Radiology and many others
  - Produce guidance for facilities on use of technologies
Bridging the Gap-Manufacturer

- Training of facility staff
- Manufacturer recommendations for equipment quality control
- Software upgrades
- Preventative maintenance
- Physicist Involvement
- Regulators-how are they informed?
Challenges in the US

- Hybrid Technologies such as PET/CT, Cobalt/MRI, MR/Linear Accelerators
  - FDA approves the device
  - NRC regulates the Radioactive Material
  - States regulate and inspect both the medical use of the RAM and the x-ray equipment (CT, LinAc) but generally not the MR aspects
  - Usually two sets of regulations at the state level and two separate inspections
  - Separate certification for CT, MRI and nuclear medicine (material use) for technologists
Challenges in the US

- Y-90
  - Although the guidance/regulations are good, the inspection is not always straightforward
  - Use is generally limited to large facilities
  - Cost is still very high which limits use as well
  - Training for users can be an issue with fewer places to get training and fewer procedures
  - “Microspheres” issues with underdosing and traveling to unintended areas of the body
Additional Challenges and Solutions

- States have limited budgets and staff
- Training for new technologies can be difficult to get
  - Some available from manufacturer
  - Guidance available from CRCPD, AAPM and others
  - Many times the inspector “learns” from the facility at the time of the inspection
- Some states have small staffs to handle many issues while some states have larger staff and can devote more time to new issues and share their experiences with other states
- CRCPD and OAS/NRC host monthly conference calls for both x-ray and RAM to discuss issues in states **
- CRCPD and IAEA are working together on guidance for new technologies and new uses of materials **
- **implemented since last meeting in Vienna**
Summary

- Regulating and inspecting new technologies can be complex and difficult
- The safety of the patient and the occupational staff involved must come first
- All parties working together is necessary
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