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**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



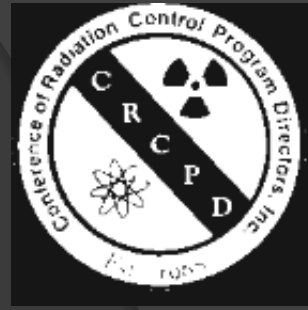
- ⦿ Some used in very limited capacities
- ⦿ Some uses spread very quickly and some do not
- ⦿ Some areas see much more use than others
- ⦿ States are not always aware of the devices in use- found at the time of the inspection
- ⦿ Used in different states/local areas with different requirements
- ⦿ Not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

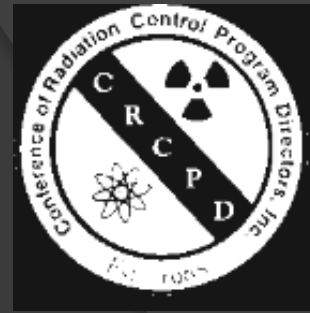
Challenges in the US



● 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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