

Finding your Role in the Regulatory World: Tourist or Participant?

Gerald A. White, M.S., FAAPM
Chair, AAPM Professional
Council



Regulatory Science 101

- Legislative action – creates the need for implementation



Regulatory Science 101

- Legislative action – creates the need for implementation
- Executive Order – creates the need for implementation



Regulatory Science 101

- Legislative action – creates the need for implementation
- Executive Order – creates the need for implementation
- Citizen Initiative – creates the need for implementation



Regulatory Science 101

- Legislative action – creates the need for implementation
- Executive Order – creates the need for implementation
- Citizen Initiative – creates the need for implementation



Regulatory Science 101

- Regulatory action is based on the enabling legislation.
- Those creating the regulations do not have the option to stray from the enabling legislation.
- Those who wish to influence the regulatory process must have at least a cursory understanding of the underlying legislative imperatives.



Regulatory Science 101-D

- The Legislative and Regulatory priorities are driven by:
 - Science and Risk Analysis
 - Considerations of Cost and Practicality
 - Influence in the Political Sector
 - Public Perceptions of Risk and Benefit
 - Inspection and Enforcement practicalities



Regulatory Science 101-D-P

- The Legislative and Regulatory priorities are driven by:
 - Science and Risk Analysis
 - Considerations of Cost and Practicality
 - Influence in the Political Sector
 - Public Perceptions of Risk and Benefit.
 - Inspection and Enforcement Uniformity
- Professional Guidelines are driven by:
 - Science and Risk Analysis
 - Dependence on Professional Judgment, Knowledge and Skill adapted to particular situations
 - Considerations of Cost and Practicality
 - Peer Review and Feedback



Potential Areas of Hybridization

- Nuclear Regulatory Commission:
 - Part 35 revisions:
 - Risk Informed
 - Performance Based



Mutual Interest in Professional Standards

- RH 20.6 Radiation Therapy Physicist Support.
 - 20.6.1 The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines. The Radiation Therapy Physicist shall be responsible for:
 - 20.6.1.1 Full calibration(s) required by RH 20.7.16 and 20.8.19 and protection surveys required by RH 20.4.1; 20-11
 - 20.6.1.1.1 Supervision and review of dosimetry;
 - 20.6.1.1.2 Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
 - 20.6.1.1.3 Quality assurance, including quality assurance check review required by RH 20.7.17 and 20.8.20.
 - 20.6.1.1.4 Consultation with the authorized user in treatment planning, as needed; and
 - 20.6.1.1.5 Perform calculations/assessments regarding misadministrations.



Recognition of the Necessity of Professional Expertise

- 20.8.19.2 Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group (TG) 45



Recognition of the Necessity of Professional Expertise

- 20.8.19.2 Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group (TG) 45", unless the radiation therapy physicist determines that a particular recommendation of the TG 45 Report is not warranted for the clinical tasks for which the equipment will be used.



Subpart J (Board Pathway)

- Copy of ABR Certification from the Web



Current

- Contact Physician, inquire as to T&E, and discuss advantages and disadvantages of the options that are available. Decide on pursuing the "on a license prior to 25 October 2005" option.
- Contact Medical Physicist at current institution. (Phone call and e-mail
- Referred to RSO. E-mail and phone RSO. Discuss the required documentation., Request copy of the license and verification of AU status of the Physician.
- Phone call and e-mails to RSO further discuss documentation requirements
- Phone call and e-mails to site AMP to further discuss documentation requirements and request interaction with site RSO
- Receive license and associated documentation from RSO with supporting documentation from site AMP.
- Submit license amendment request to state.
- State requests revised documentation.
- Phone call and e-mails to RSO further discuss documentation requirements
- Phone call and e-mails to site AMP to further discuss documentation requirements and request interaction with site RSO
- Receive revised documentation from RSO.
- Submit revised documentation to State
- Action still pending.



Release of the patient must be approved by an individual listed as an authorized user on the license from the Department who is approved for the type of radioactive material use in the patient being released.



Regulatory Science 500 (Pre-req- RegSci 101)

- Understand the legislative and regulatory climate
- Know and maintain cordial and respectful relationships with the regulatory staff
- Understand the history of the existing regulations.
- Be familiar with regulatory solutions in other venues
- Know how NRC and CRCPD regulations will be implemented in your jurisdiction.



Regulatory Science 500 (Pre-req- RegSci 101)

- Speak softly and carry the big knowledge.
- Engage the Regulatory Community
- Engage the Regulatory Community
- Engage the Regulatory Community

