WORKING TOWARDS CONSISTENT RADIATION THERAPY REGULATIONS IN THE UNITED STATES

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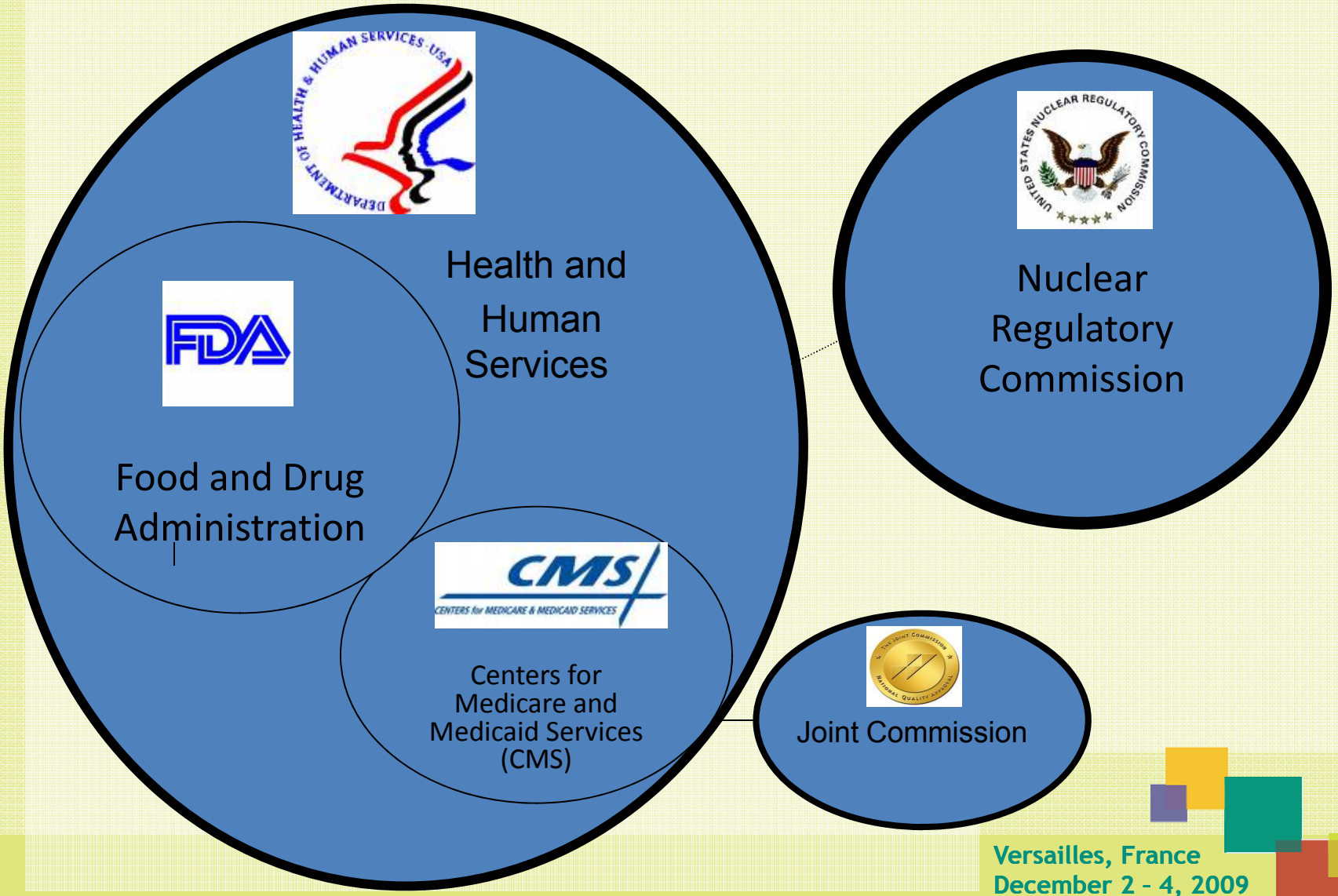
Objectives

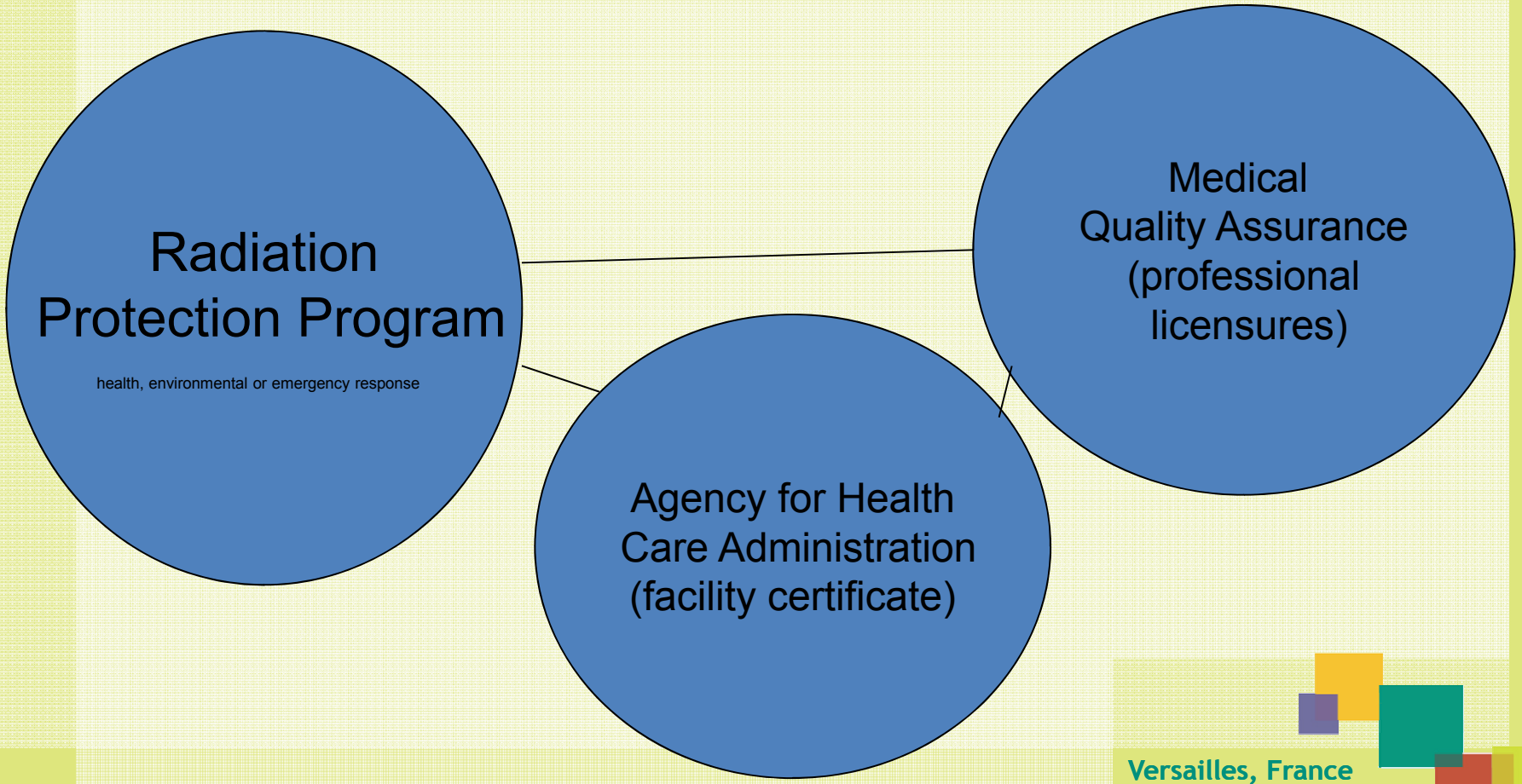
- Provide the participant with a general overview of the radiation therapy regulatory authority within the federal and state government.
- Provide the participant with an understanding of the efforts to coordinate consistency in radiation therapy regulations, inspections and enforcement actions.
- Provide the participant with information on current challenges to achieve a consistent regulatory framework in radiation therapy.

Federal Regulatory Programs



State Regulatory Programs

There are 50 variations to this model



Advocacy Groups

- Informed Public
- Professional Associations
  - American College of Radiology
  - Society of Nuclear Medicine
  - American Society of Radiation Oncology
  - American Association of Physicists in Medicine

Influencing through lobbying, nomination of individuals to advisory boards, commenting on regulatory products and public outreach

Federal and State Advisory Committees

- FDA Technical Electronic Radiation Safety Standards Committee
- CMS Reimbursement Committee
- Joint Commission Advisory Committee for standards and evaluation of sentinel events
- NRC Advisory Committee on Medical Uses of Isotopes
- State Radiation Protection Advisory Council
- State Medical Boards

How do we go about getting consistency in radiation therapy regulatory oversight?

- Conference of Radiation Control Program Directors
- Organization of Agreement States

Coordinated Efforts

- Development of Regulations
  - Concerted effort for federal and state regulatory organizations to work together. NRC working groups for rule development and CRCPD suggested state regulations committees
- Inspection Procedures
  - Concerted effort to share information within states on the most effective methodology to gain compliance. NRC working groups and CRCPD healing arts committees
- Training
  - NRC supported training for radioactive materials
  - Self study and focused training on radiation therapy devices with support from professional organizations. CRCPD G-61 Training
- Notification and Enforcement
  - Development of regulations requiring notification of medical errors/events
  - Development of enforcement guidance to assure similarities between electronic device and radioactive materials
  - Supporting NRC NMED for materials events
  - Supporting FDA MAUDE for device failures
  - Discussing the potential feasibility of a national events data base for electronic device events that are not device failures
  - Discussing the potential feasibility to work with Joint Commission in capturing sentinel events for the purposes of regulation revisions

Regulations

- CRCPD suggested state regulations are comprehensive
- CRCPD suggested state regulations are undergoing revisions as technology changes
- CRCPD suggested state regulations reflect NRC-agreement state minimum compatibility
- CRCPD suggested state regulations gain consensus with stakeholders in the developmental stages

Inspection Procedures

- NRC provides guidelines for the development of state inspection procedures
- NRC evaluates compliance with agreement state authorization through an audit program IMPEP (Integrated Materials Performance Evaluation Program)
- CRCPD creates task force to develop inspection protocols for members

Training

- NRC supports Agreement States with “cost free” training for radioactive materials
- FDA provides limited training for device specific activities (mammography)
- CRCPD offers training in conjunction with their annual meeting (Linear Accelerators)
- CRCPD G-61 Committee on Training collates state training programs into one easy to find location and develops general training programs that states may adopt

Notification and Enforcement

- For radioactive materials, notification requirements are codified through federal and state regulations
- For radioactive materials in non agreement states enforcement procedures are developed by NRC and include penalties commensurate to the severity of violation
- State radiation control programs have varying degrees of enforcement capabilities that may include punitive actions based on severity of the violation
- There is no current national database to record accelerator medical events that are not the results of device failures

Future Activities

States have identified a need to strengthen regulatory oversight for radiation therapy devices and are working with the NRC and stakeholders, through the CRCPD to develop regulations, inspection procedures, notification and enforcement actions using existing federal models as a template

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