Morgan Lewis

# *FAST BREAK*: NRC AND AGREEMENT STATE REGULATION OF MEDICAL USES OF BYPRODUCT MATERIAL

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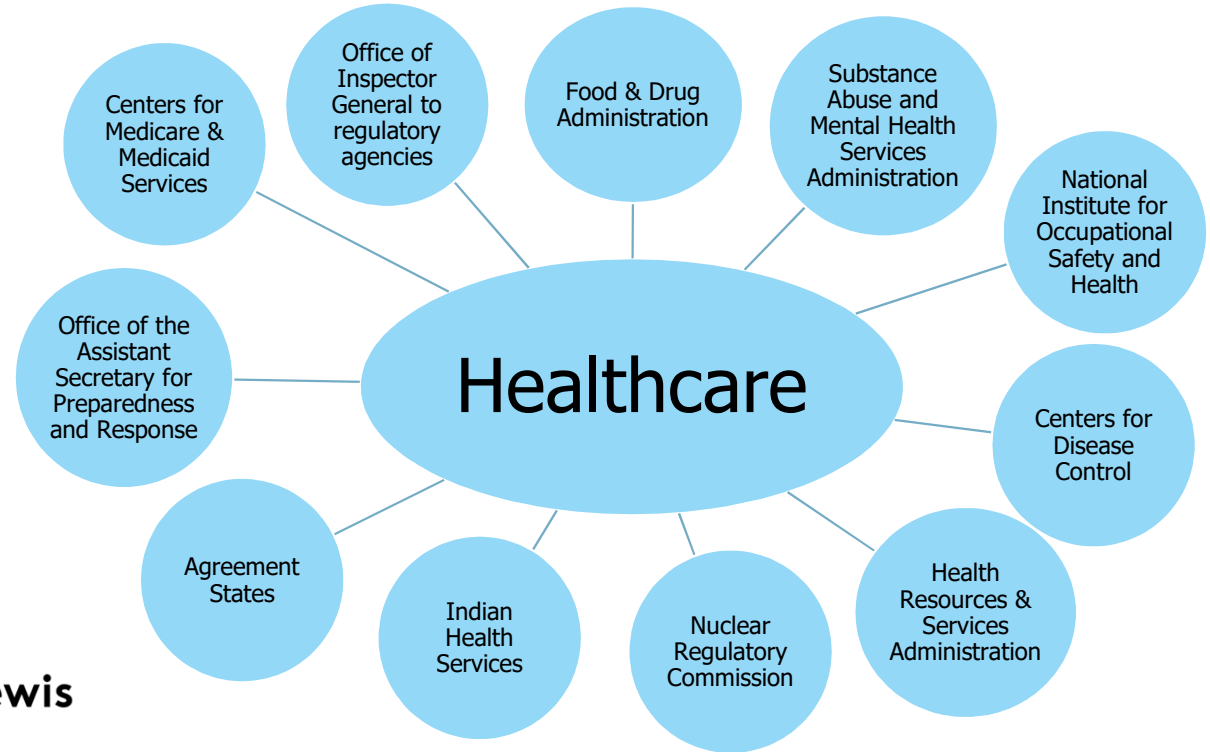
March 21, 2019

# Healthcare: A Regulated Industry

Health systems, hospitals, and post-acute care providers are subject to regulation and oversight by many departments and agencies, among others:



# NRC and Agreement State Regulation of Healthcare Providers

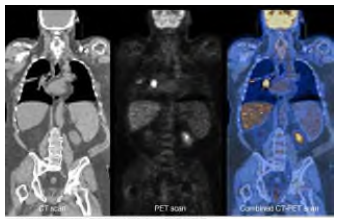
- Atomic Energy Act of 1954, 42 U.S.C. §§ 2011-2021 (AEA) et seq.
  - Created the Atomic Energy Commission (AEC)
  - Authorized the AEC to regulate the use, storage, transfer, etc. of radioactive material
- Energy Reorganization Act 1974, 42 U.S.C. § 5801 et seq.
  - Created the Nuclear Regulatory Commission (NRC)
  - Protects employees and contractors who raise nuclear safety concerns
  - Protects workers at power reactors and materials licensees
- 10 C.F.R. Parts 30, 31, 32, and 35, among others
- State laws and regulations

# NRC Regulation of Byproduct Material

- NRC regulates radioactive material, including byproduct material.
- Byproduct material is, among other things:
    - Any radioactive material produced by a nuclear reactor (except enriched uranium or plutonium);
    - Any discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; and
    - Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity.

# Nuclear Medicine

- Byproduct material is used in the field of nuclear medicine both in diagnosis and therapy.
  - Diagnosis – Nuclear Medicine Imaging Procedures
    - Help physicians diagnose and evaluate medical conditions
    - Imaging uses radioactive materials called radiopharmaceuticals or radiotracers.
    - Positron Emission Tomography (PET) scan
  - Therapy
    - Brachytherapy
    - Teletherapy
    - Gamma Stereotactic Surgery



# The Agreement State Framework

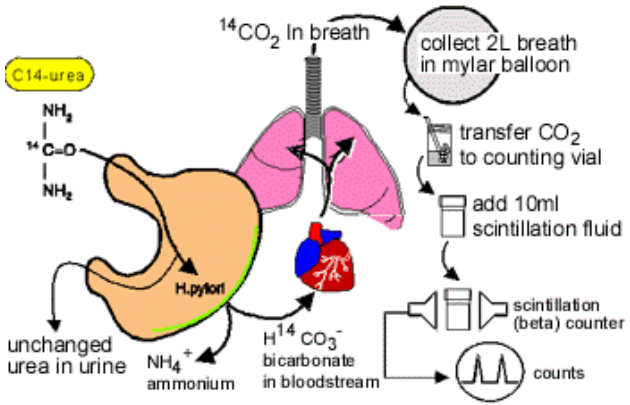
- Delegation of Regulatory Authority
  - The AEA gives the NRC the authority to enter into agreements with state regulators
  - These agreements delegate certain – but not all – regulatory authority from the NRC to the state
  - States that enter into such agreements are referred to as "Agreement States"
- Agreement State Regulation
  - States develop and issue regulations in consultation with the NRC
  - State regulations are implemented pursuant to states' environmental statutes, and managed by states' departments of health and environment
  - Regulations are derivative of the NRC's regulations in 10 C.F.R.


# Licensing Framework – General and Specific Licenses

- General License
  - License is issued by operation of regulation
  - No application is required
  - Notice may be required
  - Knowledgeable Person
  - No safety (i.e., radiation protection) program
- Specific License
  - Application to the regulator (NRC or Agreement State) is required
  - Regulator will review the application and supporting documents
  - Issue the license, requests for additional information, or a denial
  - Radiation Safety Officer
  - Radiation Protection Program

# Use of General and Specific Licenses in Healthcare

- Specific Licenses – Almost exclusive use of specific licenses
- General Licenses – NRC regulations issue only one general license related to medical uses of byproduct material (certain in vitro clinical or laboratory testing) (10 C.F.R § 31.11)
- Exemption – Applies to persons who possess certain capsules of Carbon 14 urea for "in vivo" diagnostic use in humans (10 C.F.R. § 30.21)




# NRC Regulation of the Medical Uses of Byproduct Material

- 10 C.F.R. Part 30: Rules of General Applicability to Domestic Licensing of Byproduct Material
- 10 C.F.R. Part 31: General Domestic Licenses for Byproduct Material
- 10 C.F.R. Part 32: Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material
- 10 C.F.R. Part 35: Regulates the Medical Use of Byproduct Material
- 10 C.F.R. Parts 20 and 71: Labelling and Transportation

# 10 C.F.R. Part 30

- Governs domestic licensing of byproduct material regardless of the use (i.e., including, but not limited to medical uses)
- Provides for Employee Protection (§ 30.7)
- Completeness and Accuracy of Information (§ 30.9)
- Deliberate Misconduct (§ 30.10)
- Application for Specific Licenses (§ 30.32)
- License transfers (§ 30.34)
- Decommissioning funding plans for certain unsealed and sealed byproduct material (§ 30.35)

# 10 C.F.R. Part 31

- Establishes general licenses for the possession and use of byproduct material (including, but not limited to, medical uses)
- As noted, NRC regulations issue only one general license related to medical uses of byproduct material (Use of Byproduct Material for Certain In Vitro Clinical or Laboratory Testing) (10 C.F.R § 31.11)

# 10 C.F.R. Part 32

- Governs the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to recipients that are:
  - Exempted from the licensing requirements of Part 30; and
  - Generally licensed under Parts 31 or 35
- Applies primarily to entities that manufacture, prepare, or transfer capsules containing carbon-14 urea for "in vivo" diagnostic use, as noted

# 10 C.F.R. Part 35

- Governs the medical use of byproduct material and the issuance of specific licenses authorizing the medical use of that material
- Provides that a person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the NRC or an Agreement State (10 C.F.R. § 35.11)
- Specific licensees are required to maintain a functioning radiation protection program and a Radiation Safety Officer who supervises, manages, and administers that program
- Provides for license application, amendment, and renewal (10 C.F.R. §§ 35.12 & 35.13)

# 10 C.F.R. Part 35 (continued)

- Notifications to the NRC or Agreement State (10 C.F.R. §§ 35.14)
- The use of sources for manual brachytherapy (10 C.F.R. Subpart F)
- The use of sealed sources for diagnosis (10 C.F.R. Subpart G)
- The use of remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units (10 C.F.R. Subpart H)
- Recordkeeping (10 C.F.R. Subpart L)
- Reports to the NRC or Agreement State (10 C.F.R. Subpart M)

# 10 C.F.R. Part 30: Employee Protection

- Employee Protection (§ 30.7)
  - Prohibits retaliation by licensees, applicants, and contractors / subcontractors to licensees & applicants against individuals for engaging in protected activity
  - Protected activity includes raising concerns internally or externally and/or refusing to work under unsafe conditions
  - NRC does not provide personal remedies but can take enforcement action for violations of employee protection provisions

- Safety Conscious Work Environment (SCWE)
  - NRC expects all licensees to establish and maintain a work environment in which individuals feel free to raise safety concerns without fear of retaliation
  - NRC issues Requests for Information (RFIs) and conducts inspections that include evaluating the work environment

# 10 C.F.R. Part 30: Completeness and Accuracy

- Completeness and Accuracy (§ 30.9)
  - Information provided to the NRC / Agreement States "shall be complete and accurate in all material respects"
  - Covered information includes information provided to the NRC (orally or in writing) and information maintained pursuant to NRC requirements
  - "Material" information is information that has the ability to influence the agency in the conduct of its regulatory responsibilities"

- Compliance with Completeness and Accuracy requirements is critical to the NRC
  - NRC relies on information provided and maintained by licensees
  - Protects public health and safety
  - Reflects the integrity and trustworthiness of licensees and their representatives
  - Violations occur regardless of intent or whether NRC relies on information

# 10 C.F.R. Part 30: Deliberate Misconduct

- Deliberate Misconduct (§ 30.10)
  - Deliberately submitting incomplete or inaccurate information
  - Deliberately causing a violation of any other NRC requirement

- NRC defines "deliberate" as:
  - Knowing a requirement exists
  - Understanding the requirement
  - Knowing the requirement applies
  - Acting contrary to the requirement—voluntarily
  - Knowing the action is contrary to the requirement

- High standard, but "careless disregard" also is actionable

# 10 C.F.R. Part 30: Enforcement

- Sanctions
  - Notices of violation
  - Civil penalties
  - Orders modifying, suspending, or revoking licenses
  - Letters of reprimand
  - Orders prohibiting involvement in licensed activities
  - Criminal prosecution

- Considerations
  - Level of responsibility of those involved
  - Opportunity to correct
  - Issue identified by NRC or licensee
  - Corrective actions taken
  - Safety consequences
  - Mistake or willful

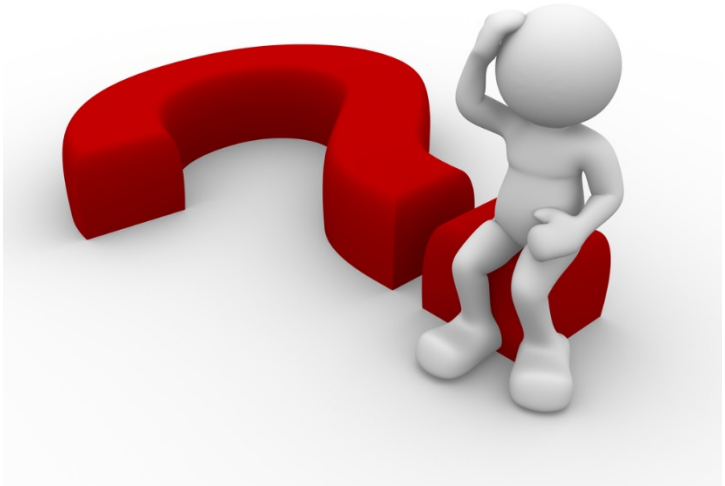
# Recent NRC Enforcement Actions

- Christiana Care Health Services, Inc. (2018)
  - Failure to control and maintain surveillance of iodine-125 seeds. Violation of 10 C.F.R. § 20.1802. Self-identified and reported, but licensed material "lost," so civil penalty issued.
- Missouri Baptist Medical Center (2018)
  - Failure to develop a procedure to provide high confidence that an administration of iridium-192 was in accordance with written directive. Violation of 10 C.F.R. § 35.41. Self-identified and comprehensive corrective actions resulted in no civil penalty.
- Providence Alaska Medical Center (2018)
  - Failure to follow license requirements or have written directives for therapeutic doses of yttrium-90 microspheres, resulting in a medical event. Violation of 10 C.F.R. § 35.41 et al. Missed opportunities and failure to perform extent of condition resulted in civil penalty.
- Avera McKennan (2017)
  - Failure to properly package, secure, and monitor shipment of technetium-99m. Violation of 10 C.F.R. § 71.5(a). Comprehensive corrective actions taken (including personnel actions), but violations deemed willful. Escalated enforcement action taken without civil penalty. Enforcement action taken against individual.

# Best Practices

- Refamiliarize yourself with applicable licensing and regulatory requirements
- Establish internal controls to ensure compliance
- Know your (individual) obligations and (supervisory) responsibilities
- Take prompt and appropriate corrective actions
  - Address adverse condition
  - Evaluate causes and extent of condition
  - Implement corrective actions to prevent recurrence
  - Corrective actions can include technical, programmatic, and personnel-related actions
  - Remember SCWE

# Questions?



# Thanks!

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Lewis M. Csedrik represents clients before the US Nuclear Regulatory Commission (NRC), Department of Energy (DOE), and Department of Labor in whistleblower litigation and government investigations, including investigations into alleged retaliation and regulatory violations. Lewis also performs independent investigations into various types of alleged wrongdoing. He assists clients with assessing and enhancing their work environments and provides training in the area of investigations, complete and accurate reporting, and maintaining and enhancing the Safety Conscious Work Environment and Safety Culture.

# Thanks!

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Roland Backhaus' practice focuses on transactional and dispute resolution matters primarily related to the international nuclear industry. Roland regularly represents nuclear materials licensees in commercial, transactional, regulatory, and dispute resolution matters and before both state and federal regulators. As a nuclear-trained submariner, Roland has extensive experience working with engineers and technical experts to provide guidance regarding a variety of legal and technical issues.

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*Fast Break*: HealthTech Startups

Featuring Jeff Bodle and Andy Ray

- April 25, 2019 3:00 PM (EST)