Materials - Medical

March 30, 2010

Duann V. Thistlethwaite, RPh, BCNP, FAPhA

Director Manufacturing Compliance

Triad Isotopes, INC.

Introduction

- Myself
 - In nuclear pharmacy practice since 1992.
 - Board Certified in Nuclear Pharmacy since 1994.
 - Fellow of the American Pharmacists Association (2003).
- My company: Triad Isotopes, INC.
 - Guiding Principles
 - **Service:** Our service will distinguish us from all of our competitors. We will exceed the expectations of our customers, vendors and industry standards.
 - Safety: Our priority to our customers, partners and fellow employees is to operate in an environment that features the best possible safety regulations and precautions. We will offer the safest products, work environment and delivery method in our industry.
 - Integrity: Our customers, fellow employees and community will be treated and served with the highest possible standards. We will live and work by those standards.

Introduction

- My professional organization Society of Nuclear Medicine (SNM)
 - An international scientific and professional organization founded in 1954 to promote the science, technology and practical application of nuclear medicine.
 - Its 16,000 members are physicians, technologists and scientists specializing in the research and practice of nuclear medicine.
 - Mission: to improve healthcare by advancing molecular imaging and therapy

 There is a unique nature of radiopharmaceuticals, nuclear pharmacies, and nuclear medicine and the NRC must differentiate these operational and/or practice settings from others in which nuclear materials are used.

- There is a paradigm difference between us and other licensees.
- We come from a variety of industries in all shapes and sizes.
 - From one person to organizations with hundreds or thousands of employees.
 - Hospitals, pharmacies, mobile imaging centers, etc. are all included in our group.

- The concept of "Safety" with respect to nuclear materials conjures up images of nuclear weapons, power plants, dirty bombs, etc.
- Most of these scenarios and legitimate concerns thereof are beyond our realm of operations.

- I believe that there is a positive outcome for radiation in helping to optimize patient care.
 - The benefits are commensurate with risk.

 I believe that safety culture must go from bench to bedside.

- I believe in the concept of a safety culture and with the definition that was developed in the February 2010 Workshop.
- I believe with the general categories for traits.
- I believe the NRC should take great care in the implementation of this regulation across the licensees it represents as "One size may not fit all."

 I believe the idea of zero tolerance for violations is an unattainable goal which will lead to under reporting of issues and eventually deteriorate the fabric of a safety conscious work environment.

 I believe the idea of a safety culture cannot be burdensome for those involved.

 I believe that a positive Safety Culture should encompass our patients, our personnel, the public and the environment.

 I believe without a doubt it is every person's responsibility no matter their position to continuously cultivate the culture of safety.

 In the medical community, security is inherent in our safety culture.

 Security and Safety go hand-in-hand to ensure our products are handled properly from bench to bedside.

Thanks

- Thanks for this opportunity to be here today.
- Also special thanks to my company for allowing me the time to be here and to my family & my nuclear pharmacist friends.