

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

Safety Culture

March 30, 2010

Office of Enforcement

**Office of Federal and State
Materials and Environmental
Management Programs**

Agenda

- **Opening Remarks**
 - **Bruce Mallett, DEDR**
- **Overview**
 - **Roy Zimmerman, Director, OE**
- **Internal Safety Culture**
 - **Laura Gerke, OE**
- **External Safety Culture**
 - **Dave Solorio, OE**
 - **James Firth, FSME**

Internal Safety Culture

March 30, 2010

**Laura Gerke, Acting Senior
Safety Culture Program
Manager, OE**

Internal Safety Culture

- **Update on actions to implement the Internal Safety Culture Task Force Recommendations**
- **Analysis and actions based on OIG's Safety Culture and Climate Survey**

Update on Task Force Recommendations

- 1. Incorporate safety culture into strategic plan**
- 2. Train on internal safety culture expectations and behaviors**
- 3. Assess and improve issue - resolution processes**

Update on Task Force Recommendations, Cont'd

- 4. Establish expectations and accountability for maintaining internal policies and procedures**
- 5. Create the Safety Culture Program Manager position**

Safety Culture and Climate Survey: Analysis

- **Analysis of survey results**
- **Review of Task Force results relative to survey responses**
- **Agency-wide focus groups**
- **Office-specific facilitated discussions**

Safety Culture and Climate Survey: Actions

- **Agency-wide actions**
 - **Communication, staying connected, knowledge management**
 - **Open, Collaborative Work Environment**
- **Office-specific action plans**

Next Steps

- **Align with Safety Culture Policy Statement**
- **Facilitate agency-wide and inter-agency Safety Culture contacts**
- **Continue to:**
 - **Implement Task Force recommendations**
 - **Address survey results**

External Safety Culture

March 30, 2010

**Dave Solorio, Chief,
Concerns Resolution Branch, OE**

External Safety Culture

- **New Issues on Draft Policy Statement**
- **Efforts on Common Definition and Traits**
- **Increase attention in material area**

Commission Direction

February 2008 SRM

- Increase SC attention in the materials area**
- Reach out to all types of licensees and certificate holders**
- Consider any unique aspects of security**

Commission Direction, Cont'd

October 2009 SRM

- Publish draft policy**
- Consider including vendors and suppliers**
- Engage stakeholders**
- Comport NRC terminology, if possible**

Stakeholder Engagement

- **Draft SC Policy Statement and FRN notices**
- **February workshop and other public meetings**
- **External SC website**
- **Material users – specific outreach**

Draft Policy Statement

- **Issued FRN November 2009**
- **Extended 90 day comment period**
- **Received public comments:**
 - **Policy Statement vs. Regulation**
 - **Policy Statement at high level**
 - **Implementation concerns**

Draft Policy Statement

- **Public Comments – cont'd**
 - **Prefer single definition for all licensees; differences in traits**
 - **Support for NRC draft definition**
 - **Support for workshop definition**
 - **Few wanted “security” in definition**

February Workshop

- **Workshop structured to promote interaction**
- **External stakeholder involvement**
 - **Workshop planning committee**
 - **Representatives from various forums (i.e., Tribal, reactor, medical, public, industrial, vendors, fuel cycle)**
- **Panel members aligned on SC definition and high level traits**

Workshop Definition

Nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

High Level Trait Categories

- **Problem Resolution and Metrics**
- **Personal Responsibilities and Attitudes**
- **Processes and Procedures**
- **Continuous Learning**

High Level Trait Categories, Cont'd

- **Leadership Safety Behaviors**
- **Effective Safety Communication**
- **Encouraging Report of Problems -
SCWE**
- **Respectful Work Environment**

External Safety Culture

March 30, 2010

**James Firth, Project Manager,
Rulemaking Branch B, FSME**

Response to Commission Tracking

- **Strategy and Efforts to Increase Attention to Safety Culture (Materials)**
- **Feedback from Agreement State Licensees**

Engaging Materials Users

- **Past Efforts**
 - **Policy Statement**
 - **Public Workshop**
- **Continuing Efforts**

Engaging Agreement States

- **Shared Draft Policy Statement with States**
 - **Comments from 11 Agreement States**
- **Requested that Agreement States Share with their Licensees**
 - **At least 33 Agreement States Shared Information with their Licensees**

Next Steps

- **Workshop information and public comments on draft policy**
- **NRC SC Steering Committee review**
- **Outreach public meetings**
- **Final draft policy due March 2011**
- **Phased implementation**

Table of Acronyms

EDO	Executive Director for Operations
FRN	<i>Federal Register</i> Notice
FSME	Office of Federal and State Materials and Environmental Management Programs
OE	Office of Enforcement
OIG	Office of the Inspector General
SC	Safety Culture
SRM	Staff Requirements Memoranda

Safety & Security Culture Commission Briefing

Shawn W. Seeley, Chair
Organization of Agreement States
March 30, 2010



Organization of Agreement States



Organization of Agreement States

- In favor of policy statement
- Regulation too formal
- Agreement States: co-regulator in process



Organization of Agreement States

- Workshop
 - Overall a success

 - Amazing process

 - 3 groups almost consensus



Organization of Agreement States

- Specific Comments
 - Safety Culture – starts at the top
 - Management attitude/commitment
 - Physical Supervision
 - Practice what you preach



Organization of Agreement States

- SC definition: must include ALL disciplines
- Should be clear & concise
- Need to continue early and often stakeholder input



Organization of Agreement States

- Need easy to follow guidance for all
 - Make it “un-burdensome”
- Included in training all programs
- Must be performance based



Organization of Agreement States

- Challenges by States
 - Unfunded mandates?
 - Limited resources?

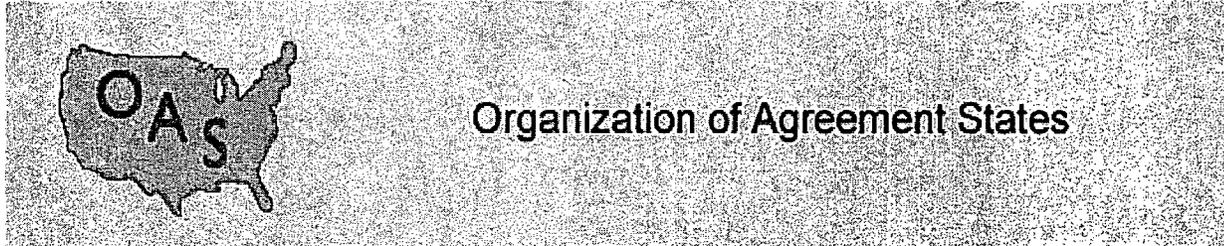
- Safety & Security are interconnected
 - Currently being done in most States
 - Is it really different?



Organization of Agreement States

- States are On-Board
 - Will spread the word

- Have same mission
 - Comprehensive radiation protection programs



- Thank you
 - for the opportunity to participate & comment

- We look forward to working alongside NRC
 - In this and any other project(s)



Organization of Agreement States

Questions



Nuclear Regulatory Commission
Commissioner Briefing
March 30, 2010

Safety Culture in the Power Reactor Industry

William E. Webster Jr.
Senior Vice President, Industry Evaluations
Institute of Nuclear Power Operations

INPO's Mission

- To promote the highest levels of safety and reliability – to promote excellence – in the operation of commercial nuclear power plants.



Current INPO Nuclear Safety Culture Principles

An organization's values and behaviors—modeled by its leaders and internalized by its members—that serve to make nuclear safety the overriding priority.

- Everyone is personally responsible
- Leaders demonstrate commitment
- Trust permeates the organization
- Decision-making reflects safety first
- Nuclear technology treated as special/unique
- Questioning attitude is cultivated
- Organizational learning is embraced
- Undergoes constant examination



Use of INPO Safety Culture Principles

INPO

- Evaluations
- Training
- Event Analysis
- Assistance

Industry:

- Reinforcement of standards/expectations
- Event investigations
- Periodic self assessments
- Performance reviews



Draft Safety Culture Policy Statement Comments

What should be strengthened:

- Focus on Nuclear Safety Culture needs to be preeminent
- Recognition that the primary responsibility for healthy safety culture resides with line leadership
- Common language within the power reactor industry is critical



Considerations Going Forward

- Develop a common language for underlying descriptive attributes
- Focus on nuclear safety - recognize similar values/behaviors apply to security, radiological safety and industrial safety
- Develop a standard methodology for assessing health of safety culture.
- Reinforce the responsibility for the licensee to foster and assess its safety culture



Final Thoughts

- Nuclear operating company leadership is responsible
- Constant reinforcement of nuclear safety culture leadership and individual behaviors is necessary
- Safety culture requires frequent evaluation
- Safety culture is a continuum – even the best plants work at it every day



Safety Culture: 2010

Making Safety the Overriding Priority

March 30, 2010

**Billie Pirner Garde,
Attorney
Clifford & Garde, LLP**

Safety Culture Workshop

- **Congratulations and Recognition!**
- **Extraordinary success as a facilitated workshop involving all stakeholders**
 - **Meaningful participation by all**
 - **Wide range of views at the policy level**
 - **Significant interaction between impacted groups**
 - **Transparency and collaboration**

Draft Safety Culture Policy Statement

- **Definition of Draft Safety Culture Policy Statement a good exercise**
 - **Compromises all had sound basis**
 - **Removal of special reference to “security culture” appropriate in draft statement**
 - **Agree with draft statement, with following exception:**
 - **“Safety as the overriding priority.....”**

Fostering A Strong Safety Culture

- **Next steps critical to ensure that the policy statement is comprehensive:**
 - **Personal concerns about the attention to Safety Conscious Work Environment (SCWE) issues;**
 - **Personal concerns about ensuring that policy expectations drive improvements in anti-retaliation behaviors and respectful work environment accountabilities**

Assessing Safety Culture

- **Believe that regulation is necessary and prudent in this area**
 - **Adopt and restate my position from March, 2002 that regulation will provide consistent, reliable, and repeatable expectations;**
 - **Urge reconsideration of the position of the Commission that we can get there without regulation.**
 - **Recommendation based on philosophical view that we understand and work to what is measured, and for which we are held accountable.**

Implementation of Safety Culture Policy Across Industries

- **More workshops appropriate to address a comprehensive implementation plan;**
- **Critical that this issue be finalized before new construction begins**
 - **New construction should all have training, infrastructure, and employee concerns programs that reflect NRC's Safety Culture policy.**
 - **New construction and international corporations must be accountable to demonstrate proactively that each meets and incorporates new Safety Culture policy expectations.**

Internal NRC Safety Culture Work

- **Substantial progress from the days when intimidation was a significant factor in how the Agency was managed;**
- **Strong recognition that the freedom to raise concerns and express differing professional opinions is the foundation for good decision-making process;**
- **Generally, a healthy respect for diversity of opinions and collaboration.**

Internal NRC Safety Culture Work (cont'd)

- **However, Commission should be vigilant in this area and seek to ensure Staff understands:**
- **No tolerance for intimidating behaviors by managerial staff;**
- **Commitment to respectful dialogue on differences of opinion for all staff;**
- **Develop a better internal alternative avenue for NRC employees to obtain timely and effective intervention on their concerns.**

Internal NRC Safety Culture Work (cont'd)

- **Support placement of the Safety Culture Program Manager position;**
- **Support issuance of behavioral expectations and Agency training and accountabilities;**
- **Support Office-Specific Action plans in those areas in which problematic behaviors have been identified by employees;**
- **Transparency with respect to those plans and actions;**
- **Important that these programs reach all NRC employees – in the Regions and at the facilities, where much of the day to day pressures impact staff.**

**Thank you for opportunity to
participate in this important
topic.**

**Billie Pirner Garde
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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

Materials/Medical

- 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.

Materials/Medical

- 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.

Materials/Medical

- 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.

Materials/Medical

- 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.

Materials/Medical

- 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.”

Materials/Medical

- 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.

Materials/Medical

- 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.

Materials/Medical

- 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.