

Source Supplier's Perspective on Proposed Part 37

19 April 2011

Kate Roughan

***Director, Regulatory Affairs/Quality
Assurance***

ISSPA and QSA Global

ISSPA Mission

To ensure that the beneficial use of radioactive sources continues to be regarded by the public, the media, legislators, and regulators as a safe, secure, viable technology for medical, industrial, and research applications.

Orders vs. Regulation

ISSPA strongly supports moving the security requirements associated with Category 1 and 2 quantities of Radioactive Material from NRC Order space and into Regulation space.

- ***Provides an opportunity for Stakeholders to engage in the rule making process.***
- ***Achieves desired level of transparency***

In addition; ISSPA appreciates the development of implementation guidance in parallel with the rule.

- ***Ease implementation***

Current Controls

- ***The current controls in place have been demonstrated to be robust and effective***
- ***Increased controls along with other NRC initiatives (NSTS) provide a multi layered comprehensive approach to security***
- ***There are no indications that current controls are not adequate to prevent a malevolent act***

Economic Burden vs. Benefit

- ***Additional economic burden on licensees is significantly underestimated and rule will have a substantial financial impact on both large and small businesses***
- ***There is not sufficient justification to impose additional and more stringent security measures, when the perceived benefits are only described as qualitative and there are no identified quantitative benefits***

One Size Fits All

- ***The security Orders were developed and issued to licensees using a graded approach – they considered the nature of the business and quantity of material authorized to possess***
- ***Proposed rule attempts to envelop the byproduct community and other communities as a whole and this is not effective***

Graded Approach

- ***Recommend using the graded approach so requirements are appropriate to the license type***
- ***Use NUREG 1556 series approach and add the security requirements to specific regulations (Part 34, 35, 39) based on type of license***

Prescriptive Requirements

- ***Proposed changes are very prescriptive and not easily implemented – deviates from NRC's normal policy of risk informed and performance based regulation***

Background Checks

- Trustworthiness and Reliability determinations are a critical security aspect yet the current Orders and proposed rule fail to provide definitive criteria that would qualify or disqualify an individual from obtaining unescorted access to materials.***
- Lack of criteria makes the T&R assessment arbitrary and an inspection against the requirements will be subjective and inconsistent.***

Transportation

- ***Concerned with the unrealistic expectations regarding planning and coordination of shipments***

- ***Potential for Agreement State additions to the NRC Proposed Rules – unreasonable permitting fees – port of entry restrictions – additional package tracking***

Specific Issues

- ***Credit history***
- ***Notification of local LLEA at temporary job sites***
- ***Weekly verifications of sources***
- ***Pre-planning and follow-up***
- ***LVS***
- ***T&R on reviewing official***
- ***Documentation and audits***

Conclusions

- ***Re-assess the needs vs. real risks vs. costs vs. benefits***
- ***Need to assure can actually implement the rules otherwise they are ineffective***
- ***Identify the roles and authorities of other Agencies such as the DOT***
- ***Continue to maintain an open dialogue with Stakeholders during the rule making process***