



# Challenges and Communication Issues for Emerging Technology Licensees

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# Untangling Investigation Requirements:

## Challenges and Communication Issues for Medical Events

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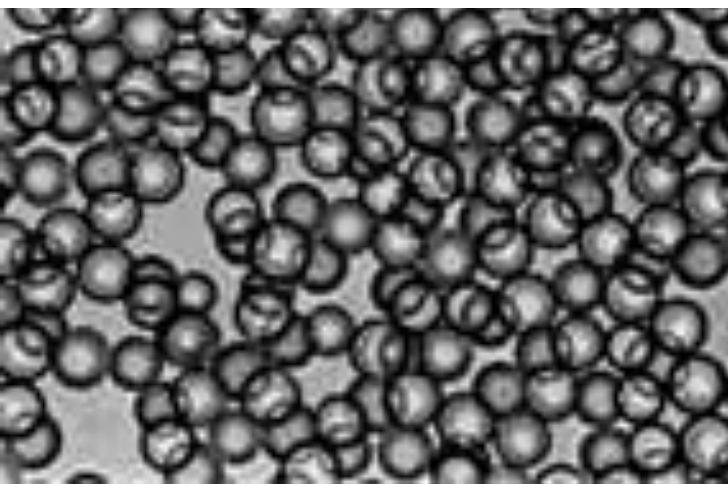
# Y-90 Micro Spheres

## A New Investigation Was Prompted:

- One licensee with four incidents
- Poor documentation
- Unclear results
- **Need to investigate the investigation**

## Results of the New Investigation

- 1 of 4 was a “real” reportable event
- Other, technical, issues discovered
- **Several Communication problems**



Is this a good choice for an Auditor?



# This Was Oregon's Investigator



# The New (Old) Approach

- Team-work
- Use Written Procedure
- Focus on the Requirements
- **Improvement Actions for All**



# Communication Barriers

## Written Communication

- **Unclear, Contradictory Regs**
- Overly complex procedures
- **Interdisciplinary over-lap**
- Documentation for investigation



## Interpersonal Communication

- **Failure to read/understand regs**
- Uncooperative vendors
- **Translation errors among “Nerd” dialects**
- Loose, non-formal audit process





**We're Looking for a Few Good  
Mind-Readers...**

...Until we find them, you're all we got



# Questions?



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Not feel well · Get drunk.  
体調の優れない方 · 酒気帯の方