

**Best**<sup>®</sup>  
Theratronics

**Best<sup>®</sup> Theratronics  
meeting with the  
U.S. Nuclear Regulatory  
Commission**

**Sept 24, 2009**

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healthcare for everyone

## Where we are and how we got here

- 16 months as Best Theratronics
- QA Program transferred as-is from MDS Nordion
- Received NRC NOVs Sept 18, 2009

## Inspection Findings

- Procedure not clear (3)
- Procedure incomplete (5)
- Procedure inappropriate (3)
- Procedure out-of-date (1)
- No procedure (3)
- Training (1)

## Actions Taken

- 8 of 16 findings corrected
- Target completion dates
  - Sept 30, 2009: 11 of 16 completed
  - Oct 30, 2009: All completed
- External consultant booked for Oct 28-30, 2009

## Actions to be Taken

- Outside consultant will be used to assess compliance to 10 CFR 71
- Training
- Review Best Theratronics procedures
- Work closely with MDS Nordion

## Ron Pope (consultant)

- 1999 – 2004: Head, Transport Safety Unit, IAEA, Vienna, Austria, responsible for the initiation of development of what has now been published as THE MANAGEMENT SYSTEM FOR THE TRANSPORT OF RADIOACTIVE MATERIAL, Safety Guide TS-G-1.4.
- Trained and certified as an NQA-1 Quality Assurance Lead Auditor (June 2008).
- Lectured on regulatory aspects of packaging at the DOE Packaging Certification Program (EM-63) Training Course on Quality Assurance for Radioactive Material Packaging (March 2009).
- Assigned lead by Argonne National Laboratory to develop a US DOE EM-14 PCP GUIDE ON QUALITY ASSURANCE FOR PACKAGES FOR THE TRANSPORT AND STORAGE OF RADIOACTIVE MATERIAL (which will address application of requirements from 10 CFR 71, subpart H and 10 CFR 72, Subpart G).
- Editor-in-Chief of the Packaging, Transport, Storage & Security international journal

# Training Needs Assessment

## Internal

- Quality System including Part 71

## External

- Quality Assurance of Radioactive Materials Packaging
- Welding Criteria for Shipping Containers

## Publications

- *“Packaging, Transport, Storage & Security of Radioactive Material”* Journal

## Standard Operating Procedures

- Identify all standard operating procedures for current products, i.e. manufacturing & inspection
- Review and update as appropriate
- Work with MDS Nordion

## Best<sup>®</sup> Theratronics Commitment

- Be a leader in regulatory compliance
- Open and honest communication
- Excellent working relationship with USNRC

413 March Road, Ottawa, ON K2K OE4 Canada  
phone 613 591 2100 | 866 792 8598 [www.theratronics.ca](http://www.theratronics.ca)

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