

Lessons Learned

From Incidents

What is an Incident?

- ❖ Incident - an undesirable and/or abnormal occurrence involving byproduct material.

- ❖ We receive reports through:
 - Regulations - Parts 20, 21, 30, 31, 34, 35, and 36.
 - During Inspections
 - “Oh, by the Way”

Types of Incidents/Causes

- ❖ Mechanical
- ❖ Computer
- ❖ Human
- ❖ Licensing/Regulatory
- ❖ Design
- ❖ Quality Control

Extent of the Incident

- ❖ Concerns a Specific User or Product
- ❖ Concerns a Specific Product Design
- ❖ Concerns a Specific Manufacturer
- ❖ Concerns a Specific Class of Product
- ❖ Truly Generic - Design, Material

General Observations

- ❖ Industrial Gauges
 - Air Quality, Corrosion, Return Springs
 - Mountings (vibration, torque on straps, vibration, incorrectly installed)
 - Loss of Shielding

- ❖ Radiography
 - Lock Failure
 - Connector Failure
 - Corrosion
 - Wrong Lubricant (e.g., WD-40)
 - Worn S-Tube
 - Incompatible Equipment

General Observations (cont.)

❖ Irradiators

- Poor Design and Maintenance of Sources
- Cesium-137
- Transportation Affects
- Source Rack Failures

❖ Brachytherapy

- Computer Errors
- Failed Source Retraction
- Broken Source Wire
- Wrong Treatment Site or Time of Exposure

Communications

- ❖ Generic Communications
- ❖ Newsletters, Workshops, NUREGs, SRPs
- ❖ Recalls

Nuclear Material Events Database

- ❖ NMED: <http://nrc-stp.ornl.gov/>
- ❖ Database of all reported NRC and Agreement State Events
- ❖ Searchable: date, location, event type, isotope, model, manufacturer

Points to Consider

- ❖ People, procedures and equipment with respect to the use environment
- ❖ Apply root cause(s) of past incidents of similar devices to current source/device design evaluation
- ❖ Apply FMEA/hazard analysis to design and user instruction (minimize probability and consequences of failure modes)

Selected Incidents

- ❖ Brachytherapy Source Failure
 - Source Design
 - Device Design
 - Failure to Survey
 - Room Monitor
 - Failure to Respond to Monitor

- ❖ Radiography Cable Connector
 - Design
 - Quality Control

Selected Incidents (cont.)

- ❖ Moisture Density Gauge Source Rods
 - Design
 - Production
 - Quality Control
 - Use Conditions

Selected Incidents

Industrial Gauge Shutter Failure

- ❖ Excessive vibration (070178)
- ❖ Inadequate maintenance (050291)
- ❖ Excessive heat (080149)

Selected Incidents

Irradiators

- ❖ Source rack stuck in exposed position (060588)
- ❖ Intermittent malfunction – need positive position indicator and interlock (060289)

Selected Incidents

Shielding Failures

- ❖ Source cable cut (050569)
- ❖ Source separate from gauge (060404)
- ❖ Melt lead out of gauge (070475)

Varian Varisource HDR SSD CA-0661-D-103-S

- ❖ Overcranking pulls source out of safe
- ❖ Four events from 2004-2007
- ❖ Investigation coordinated between NRC and RHB
- ❖ Varian HQ is in Virginia (NRC regulatory space)
- ❖ M+D done from California (RHB reg space)
- ❖ SSD held under CA

Varisource Overcranking Initial Part 21 determination

- ❖ City of Hope Hospital incident in 2007
- ❖ Two previous similar incidents
- ❖ CA, NRC, Varian agree that a root cause investigation is needed
- ❖ Varian files preliminary report

Varisource Incident impacts

- ❖ 381 mrem total collective dose equivalent
- ❖ 186 units in USA have the potential for the same problem
- ❖ NRC and CA RHB time spent investigating Varian

Varisource Root Cause

- ❖ If you turn the emergency hand crank too far it protrudes from the shielded safe area.
- ❖ More training needed
- ❖ More labeling needed
- ❖ More communication needed

Varisource remedies

- ❖ Issued a Customer technical bulletin
- ❖ Develop and apply a better warning label
- ❖ Revise the user training to include a specific signoff on this issue
- ❖ Revise user manual

Mick Radio-Nuclear Instruments

Mick Applicator

- ❖ Brachytherapy seed source ruptures
- ❖ Occurred when the seed jammed in a Mick Applicator
- ❖ 10 occurrences in 5 years
- ❖ Contamination can be spread to surrounding surfaces

Mick Applicator

Use and Mechanical Description

- ❖ An applicator for manual brachytherapy which is made up of the cartridge of seeds, a plunger and the holder that connects the cartridge to a needle for insertion of the seeds into the patient
- ❖ When the plunger only can go down a small fraction of an inch then the user knows there is a problem

Mick Applicator Investigation Results

- ❖ There is an association of seed jamming and failure to perform the recommended preventive maintenance
- ❖ Seed cartridges just click in place, screwing them in screws them up
- ❖ Disposable seed cartridges should be disposed of, not reused
- ❖ Disposable seed cartridges hold 15 seeds, reusable ones only hold 10 seeds

Mick Applicator Remedial Measures

- ❖ All of these issues are training and labeling issues
- ❖ An NRC Information Notice was issued
- ❖ A State of Wisconsin Information Notice was issued

NDT Repair Service and Supply Part 21 Investigation

- ❖ Two source disconnects were associated with equipment obtained from NDTRSS
- ❖ NDT was notified by TEAM Industrial Service that a source disconnect occurred
- ❖ NDTRSS conducted a root cause investigation
- ❖ NDTRSS determined the root cause and recalled the entire lot
- ❖ NDTRSS filed an equipment failure report with the NRC and had an announced inspection by the NRC to evaluate their response

NDTRSS Part 21 Investigation Description

- ❖ Drive cable was not connected to the source assembly during the connection of the control drive assembly to the exposure device
- ❖ Radioactive source was pushed out of the exposure device with no means to retract it
- ❖ A part of the control drive assembly adaptor did not meet the design specs but was used for distribution

NDTRSS Part 21 Investigation Remedial Actions

- ❖ The entire lot of 25 devices was recalled (only 9 were defective)
- ❖ Customers were notified in writing
- ❖ A quality assurance step was added for after equipment modification within the NDTRSS procedures
- ❖ A defect report was filed with the NRC
- ❖ NRC staff evaluated the investigation