Error Prevention: From Nuclear Industry to Medical Uses of X-Rays

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Acknowledgements

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In addition, the opinions expressed in this presentation are those of the presenter and not necessarily those of the Health Physics Society, Dade Moeller & Associates, or Harvard University.
Agenda and Goals

- Provide information on error prevention and quality assurance programs in the nuclear industry
- What articles would an Appendix B type QA program present to medical facilities?
- Who would be the “regulator”?
- “Outsider” Recommendations
10 CFR Part 50, Appendix B?

- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- Covers the design, fabrication, construction, and testing of the structures, systems and components of a facility.
- Pertains only to components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.
“Quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.
18 Articles

- Organization
- Formal QA Program
- Design Control
- Procurement Document Control
- Instructions, Procedures and Drawings
- Document Control
- Control of Purchased Material, Equipment and Services
18 Articles (Continued)

- Identification and Control of Materials, Parts and Components
- Control of Special Processes
- Inspection
- Test Control
- Control of Measurement and Test Equipment
- Handling, Storage and Shipping
- Inspection, Test and Operating Status
18 Articles (Continued)

- Nonconforming Materials, Parts or Components
- Corrective Actions
- Quality Assurance Records
- Audits
Organization

- Ensuring that appropriate QA program is established
- Sufficient authority and organizational freedom from cost and schedule
- QA must have direct access to the top levels of management (senior VP at least)
- Employees are fully empowered and protected to be whistleblowers
Formal QA Program

- Must have approved written policies, procedures or instructions
- Shall identify all safety-related structures, systems and components
- Must possess suitable test equipment, tools and skills to verify, inspect and test
- Required and documented training program and tests for assuring proficiency
Design Control

- Sufficient drawings, plans and specifications to translate to installation and operation
- Acceptable quality deviations and acceptance criteria (calculation or test)
- Formal design control procedures
- Includes in-service inspection, routine maintenance and repair, and delineation of acceptance criteria for inspection and tests.
Procurement Document Control

- Procurement documents shall require contractors and subcontractors to conduct their own Appendix B program or equivalent.
- Contractors and subcontractors providing parts or repairs shall be audited on-site at the vendors’ worksites and design locations.
- All Appendix B provisions flow down to all vendors providing components or service.
Safety-related activities shall be documented by procedures, instructions and drawings and conducted in accordance with them.

Qualitative and quantitative acceptance criteria shall be established to demonstrate these activities have been performed in compliance.
Document Control

- Version Control must be absolute
  - Software and computer hardware
  - Physical design & dimensions of components
- Changes approved by only by same level organization as the original design
- Changes must be fully documented
- Usually a committee is defined for this purpose (senior management as member)
Control of Purchased Materials

- Formal inspection of delivered materials
- Source selection and evaluation procedures
- Documentary evidence of compliance before installation
- Effectiveness of contractor and subcontractor QA programs shall be assessed at regular intervals consistent with complexity
Test Control

- Test program shall be established to ensure all structures, systems and components perform as intended
- Must be similar operational & environmental conditions and fully documented
- Preoperational and trial tests
Control of Measuring & Test Equipment

Measures shall be established to ensure that tools, gages, instruments and other measuring and testing devices are calibrated, controlled and have QC tests.
Corrective Action

- Measures shall be taken to deal with conditions adverse to quality, failures, malfunctions, and nonconformances.
- Root cause and barrier analysis to preclude repetition.
- Documented corrective actions reviewed and approved by senior management.
Root Cause Analysis

In October of 2005, a therapist was preparing a patient for radiation therapy. The therapist used a tattoo on the patient’s body to guide the radiation therapy. Additionally, the therapist brought up a photo of the area to be irradiated. Unfortunately, in this instance the tattoo and the photographs both indicated the patient’s esophagus, which was the site of previously delivered radiation therapy, instead of his upper spine, where the new radiation treatments were to be administered.

Although there was no damage to the patient’s health, this incident impacted the facility’s patient safety goal, because the potential for injury to a patient when radiation is delivered unnecessarily. Additionally, it impacted the patient service goal because the radiation treatment was misdirected to the wrong body part. The organization and compliance goals were impacted because of this reportable error. Last, there are impacts to the materials and labor goals due to the additional treatments that were required to deliver radiation to the upper spine.

Step 1: Problem Outline
- Define the problem

Step 2: Cause Map
- Potential factors to patient
- Technical error
- Equipment error
- Staff error
- Organization error
- System error

Step 3: Action Items
- Use double tattoos for second round of therapy
- Repair software to allow therapist to see where the tattoos are
- Add previous tattoos to set-up notes
- Ensure therapist has access to patient’s chart

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Therapy Root Causes

- Communication Failures
  - Written and verbal
  - Institutional and personal
  - Patient and professional staff
- Inadequate Training & Qualifications
- Lack of a “Questioning Attitude”
- Software errors and/or lack of V & V
- Lack or Procedures and Instructions
Quality Assurance Records

- Audit Reports
- Nonconformance Reports
- Operational Logs
- Inspection and Test Reports
- Calibration Records
- Qualifications of Personnel
- Record Retention Plan
- Material Analyses
Audits

- Comprehensive system of planned and periodic audits
- Audits performed using formal plan, procedures or checklists
- Performed by independent and qualified personnel
- Documented and reviewed by senior management
- Corrective action & follow up

REPORT CARD

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Grade Average: B

Attendance:
- Present: 48
- Absent: 6
- Tardy: 1

A = Excellent • B = Good • C = Satisfactory • N = Needs Improvement
U = Unsatisfactory • I = Insufficient / Incomplete

Student: ____________  Grade: ____________  Year: ____________

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Who Should be the Regulator?

- Machine-produced radiation has no single agency for regulatory guidance
  - NRC only regulates RAM
  - States are inconsistent and staff are largely unqualified in radiation therapy
- Professional organizations have no force of law or can’t force compliance (AAPM, ABR, etc.)
- The Joint Commission?
  - Financial “hammer” via Medicare/Medicaid
  - Staff audit teams with qualified Therapy Physicists
The Joint Commission

- Ambulatory Care
- Behavioral Health Care
- Critical Access Hospitals
- Home Care
- Hospitals
- Laboratory Services
- Long Term Care
- Office-Based Surgery
“Outsider” Recommendations

- Lower the Reporting Thresholds
- Standardize Radiation Therapy QA Program Requirements and Measures
  - 10CFR50 Appendix B or NQA 1 rigor
- Require and Train to Root Cause Analysis
- Adopt a Stronger Safety Culture
- External Oversight and Audits
References


- Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, Center for Devices and Radiological Health, USFDA, February 2010.