

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

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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

“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)

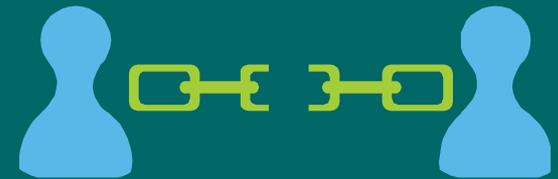
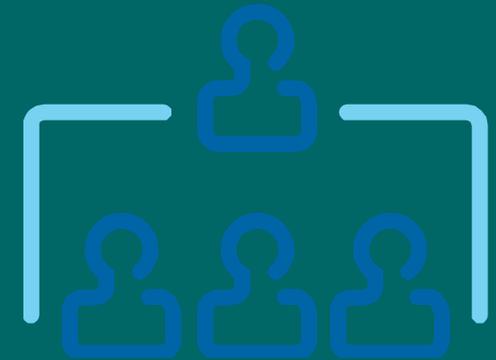
- ~~Identification and Control of Materials, Parts and Components~~
- ~~Control of Special Processes~~
- ~~Inspection~~
- Test Control
- Control of Measurement and Test Equipment
- ~~Handling, Storage and Shipping~~
- ~~Inspection, Test and Operating Status~~

18 Articles (Continued)

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

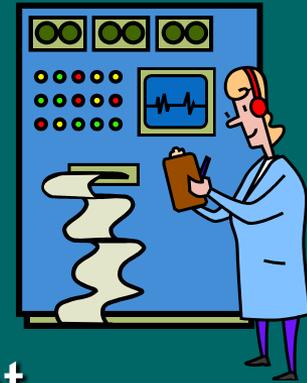
Organization

- 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 requires 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.

Instructions, Procedures & Drawings

- 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

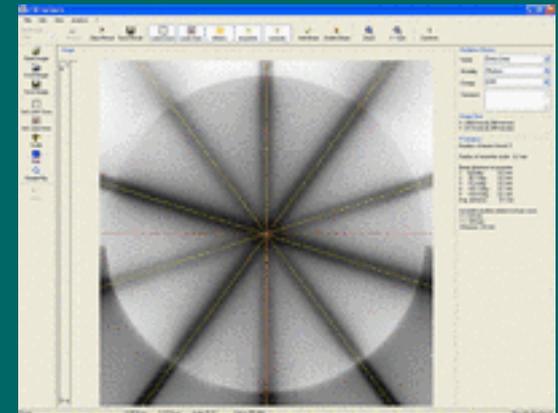
- Test program shall be established to ensure all structures, systems and components perform as intended
- Must be similar operational & environmental conditions and fully documented
- Preoperational and trial tests



Male ART and Female ART

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



Root Cause Analysis

Wrong Body Part Irradiated October 2005

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 delivered.

Although there was no damage to the patient's health, this incident impacted the facility's patient safety goal, because of the potential for injury to a patient's skin radiation is delivered unnecessarily. Additionally, it impeded 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. Lastly, there are impact to the materials and labor goals due to the additional treatments that were required to deliver radiation to the upper spine.

Step 2. Cause Map Goal Level



Step 2 to avoid radiation therapy errors: verify the WHERE - which body part requires the radiation therapy.

Step 1. Problem Outline Define the problem

What	Problem(s)	Wrong part of patient's body irradiated
When	Date	October, 2005
	Different, correct, unique	Patient had previously received radiation to esophagus
Where	Facility, site	?
	Unit, area, equipment	?
	Task being performed	Radiation therapy to upper spine
Impact to the Goals	Patient Safety	Potential for harm to patient
	Compliance	?
	Organization	Reportable error
	Materials	Radiation misdirected to wrong part of body
	Personnel	?
	Property, Equip, Mnt	?
	Labor, Time	Additional radiation treatments required
		This incident ?
		Annualized Cost ?
Frequency		?
Annualized Cost		?

Step 3. Action Items Solutions to Implications

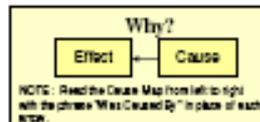
No.	Action Item	Cause
1	Use a double tattoo for second round of therapy	Esophagus tattooed for radiation therapy
2	Repair software issues	Software problems
3	Add previous therapies to set-up notes	Not mentioned in computer set-up notes
4	Give chart to therapist	Therapist did not have access to patient's chart ?

The situation was complicated by the software error that brought up an old picture, indicating that the therapy should treat the esophagus. To add to the confusion, there was a tattoo on the esophagus designating it as the site of the therapy. There was nothing in the set-up notes to indicate that the patient had had a previous round of radiation therapy. It is unclear whether the therapist had access to the patient's chart, which would have designated the area to be irradiated and would mention the previous therapy.

The facility involved introduced measures to solve the software problems which resulted in the old photograph being downloaded. Second therapy sites are now marked with double tattoos. Information such as the therapy location and any previous radiation therapy sites are now included in the set-up notes. Additionally, ensuring that the therapist has access to a patient's medical chart will help allow the therapist to ensure a patient's therapy is delivered properly.



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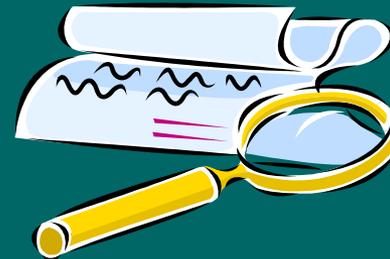
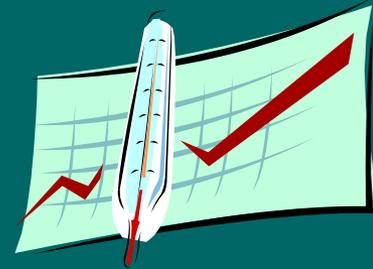


Therapy Root Causes

- 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 of 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



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

- 10CFRPart 50, Appendix B, “Quality Assurance Criteria of Nuclear Power Plants and Fuel Reprocessing Plants, 3/26/2010
- <http://www.facebook.com/pages/Cause-Mapping-Root-Cause-Analysis/114421256981>
- Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, Center for Devices and Radiological Health, USFDA, February 2010.