OPERATING A PROTON THERAPY SYSTEM AT INDIANA UNIVERSITY*

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Abstract

The Indiana University Cyclotron Facility 208 MeV cyclotron has been converted from an accelerator-based basic and applied research laboratory to a medical clinic with the addition of the Midwest Proton Radiotherapy Institute (MPRI) [1,2,3]. IUCF delivers protons from the refurbished cyclotron to MPRI's three treatment rooms for patient treatments, quality assurance and development efforts. In addition, IUCF was responsible for the design and construction of the Proton Therapy System and as such is required to follow FDA Quality System Regulations for medical device manufacturers. This commitment required a dramatic change in the culture of the laboratory. The emphasis now is truly on maintaining reliability within a constrained operating budget, but at the same time meeting stringent FDA quality system requirements in an academic setting. This paper will describe the progress we have made toward meeting these goals and at the same time keeping our users satisfied.

IUCF BEFORE 2000

Before construction of the Proton Therapy System (PTS) began, IUCF had many missions. The separated-sector cyclotron, completed in 1974, was used for a medium energy nuclear physics research program using light ions and polarized beams. In the 1990's funding for the science with the cyclotron was phased out and the cyclotrons were primarily used for the study of protons for medical uses and radiation effects testing. Basic research continued on the electron-cooled proton and deuteron storage ring accelerator complex. All these facilities were designed and engineered by the IUCF physicists whose focus was completing their own research program. The concept of a quality system was considered as something too expensive to implement. There was little formal engineering process control nor was there much effort to standardize procedures or perform any statistical analysis of operational events.

Work was performed by dedicated individuals whose mission was to get the machine working as soon as possible so that time would not be lost to experimenters or users. Clever design changes were made on-the-fly in order to keep the machine running. There was often no follow-up. In 26 years of operation, machine reliability fluctuated from 80% to 94% in any given year.

OPERATION OF THE PTS

Design of the PTS began as in the old days. Physicists were primarily responsible for the design and engineering of the medical device. It soon became apparent that in order to meet FDA requirements, IUCF needed to follow appropriate design and document control. It needed engineers and a Quality System Plan (QSP)! The Quality System Plan has gone through several iterations as the organization has matured.

Features of the IUCF Quality System Plan

Varying degrees of quality control are ascribed to devices based on their impact to safety and efficacy of the PTS. Safety is defined as serious injury or death to the patient and efficacy is defined as delivering the prescribed dose within a certain tolerance. Safety and efficacy limits were defined and devices that impacted these limits were then separated into two classes:

- Tier I devices – Can directly affect the safety and efficacy of the PTS.
- Tier II devices – Have no effect or their effect is mitigated by a Tier I device.

The responsibility of the Operations group is to see that the Medical Device is operated and maintained under strict quality control and documentation standards (Figure 1.). If a patient is injured due to a mistake following these processes the responsibility belongs to operations.

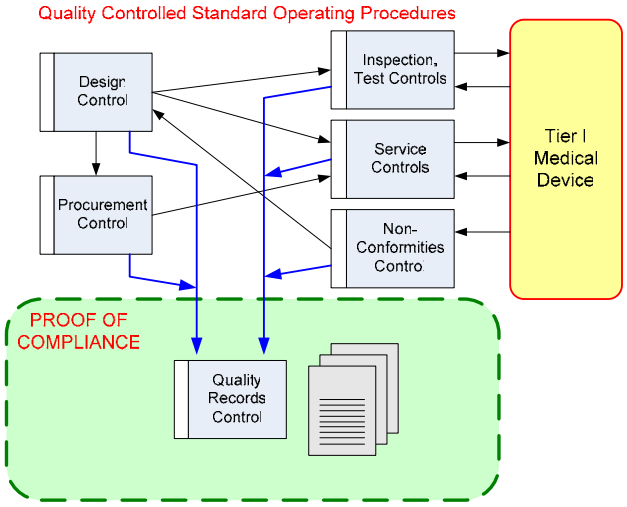

Figure 1: Quality Procedures Related to Operations.

Tier I devices undergo rigorous quality system procedures and documentation control. In addition, a Corrective and Preventive Action (CAPA) process, and Non-Conformance process with root cause analysis must be completed and documented.

Tier II devices might be devices installed in research labs under almost no quality control, yet there must be

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proof that they do not negatively impact any Tier I devices. This responsibility lies within the Operations Group.

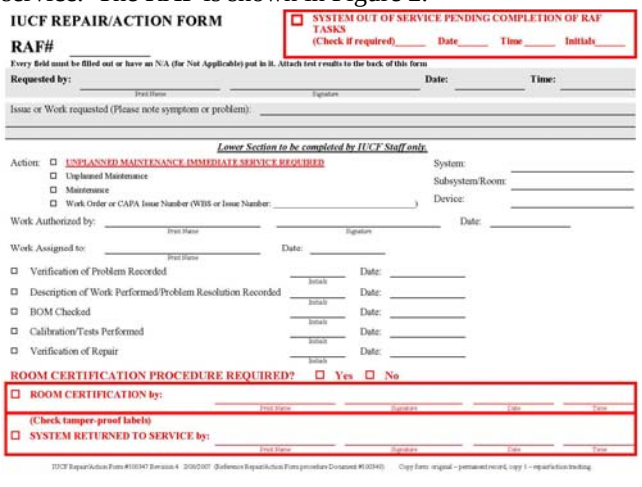
Table 1: Examples of Tier I and Tier II devices

Category	Device	Comments
Tier I	Dose monitor	Safety and Efficacy. Overdose and Underdose
Tier I	Robot dead man switch but not robot	Safety from robot collisions.
Tier II	Gantry magnets	Mitigated by Dose monitor
Tier II	New copy machine	Does it put excessive noise on AC line?

How Work is Completed Today

Today, different processes are used to perform work on the Proton Therapy System. Maintenance procedures and repairs are controlled to bring the system back into operation. Only repairs that return the system or part to its original configuration are allowed. Any changes to a Tier I device on the PTS must be reviewed and approved by engineering. Clever changes to the design to more rapidly facilitate a repair must be reviewed before bringing the system back into service. In addition, testing procedures that verify that the maintained or repaired system meets the device requirements must be completed and documented before being returned to service.

From the operations side, any maintenance, repair, or installation of approved changes must be tracked using the IUCF Repair Action Form (RAF). This form is a traveler that is used to document all of the steps necessary to complete the work and bring the system back into service. The RAF is shown in Figure 2.


IUCF REPAIR/ACTION FORM

SYSTEM OUT OF SERVICE PENDING COMPLETION OF RAF TASKS (Check if required)_____ Date_____ Time_____ Initials_____

RAF# _____

Every field must be filled out or have an N/A (for Not Applicable) put in it. Attach test results to the back of this form

Requested by: _____ Date: _____ Time: _____

Issue or Work requested (Please note symptom or problem): _____

Lower Section to be completed by IUCF Staff only.

Action: ☐ UNPLANNED MAINTENANCE IMMEDIATE SERVICE REQUIRED ☐ Unplanned Maintenance ☐ Maintenance ☐ Work Order or CAPA Issue Number (WBS or Issue Number: _____)

System: _____ Subsystem/Room: _____ Device: _____

Work Authorized by: _____ Date: _____

Work Assigned to: _____ Date: _____

☐ Verification of Problem Recorded _____ Date: _____

☐ Description of Work Performed/Problem Resolution Recorded _____ Date: _____

☐ BOM Checked _____ Date: _____

☐ Calibration/Tests Performed _____ Date: _____

☐ Verification of Repair _____ Date: _____

ROOM CERTIFICATION PROCEDURE REQUIRED? ☐ Yes ☐ No

☐ ROOM CERTIFICATION by: _____

(Check tamper-proof labels)

☐ SYSTEM RETURNED TO SERVICE by: _____

Figure 2. Front side of the IUCF Repair/Action Form. This form is placed in document control once completed.

If the RAF is generated due to a failure, a Non-Conformance report is generated and an initial root cause assessment is completed by the operations group before handing it off to the engineering group. Engineering could initiate a CAPA after evaluating the failure.

RAF's are also generated for preventive maintenance actions which are triggered by a home built maintenance database. Additions or changes to the PTS pass through an engineering process before a RAF is generated for installation. In all cases, appropriate tests are identified, executed and documented before returning the system to the clinic for treatments. Figure 3 shows a flow chart for any repair or action to the PTS.

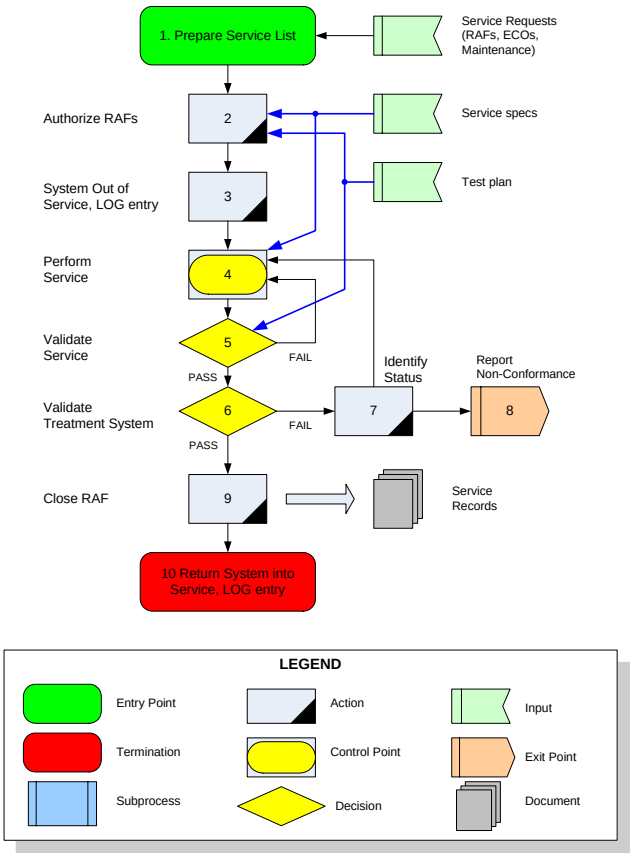


Figure 3. Work flow for completing a Repair/Action on the Proton Therapy System.

FAILURE AND ANALYSIS

The PTS at IUCF is a medical device and is used for medical treatments on a strict schedule from 8 AM to 8 PM five days each week. As such, a disruption of more than one to two hours in one day will cause the loss of patient treatments. MPRI is now treating pediatric cases for which potentially dangerous anesthesia is required for each treatment fraction. The cost of losing more than three days of beam time is that the patients have to be moved to other machines or clinics for treatment often at cost to the clinic. Rebuilding the patient base takes many weeks.

The Quality System Plan puts into place many tools that should maintain the availability of new equipment and improve the availability of old equipment with time. As described above, IUCF is putting into place a rigorous method for tracking failures, maintenance activities and changes. The full rigor of the QSP must be applied to any

Tier I device, complete with reporting requirements that have not been described. On the other hand, all PTS-related Tier II components will also use the most useful aspects of the QSP but without the requirement to prepare a document trail that may be audited by the FDA. This gives us the opportunity to use salient aspects of the QSP to steadily improve performance.

Reducing the Likelihood of Failure

The IUCF cyclotrons are now in their 34th year of operation but the trunkline and treatment rooms have been in operation for only a few years. Our main focus is therefore on maintaining and improving old equipment that may cause us long down times as well as keeping the new equipment operating at high reliability and performance.

At IUCF we are on a 4 year program to replace aging major equipment that has been identified as being very time consuming to repair. We have analyzed the probability of failure and combined with the time to repair have prioritized major upgrades that are required. A repair plan and preparations for repair are being developed to further reduce long downtimes on the cyclotrons.

The relatively new Treatment System equipment and trunklines have been robustly designed, even so, there are operational problems and infancy failures that we try to anticipate and correct before we lose treatment time. A spare parts inventory is maintained for the treatment systems and also for the cyclotrons.

The maintenance and repair events are well documented by following Quality System procedures but also by diligent recording in the operator's log book. Both sets of records and the maintenance data base can be searched to look for recurring problems. In addition, operator's complaints and clinic complaints often are reliable precursors to failures.

Operating data based on the operator's log book is very useful in identifying systems that require more serious attention. A graph showing failure events per system for a year of operation (Figure 4) is very useful.

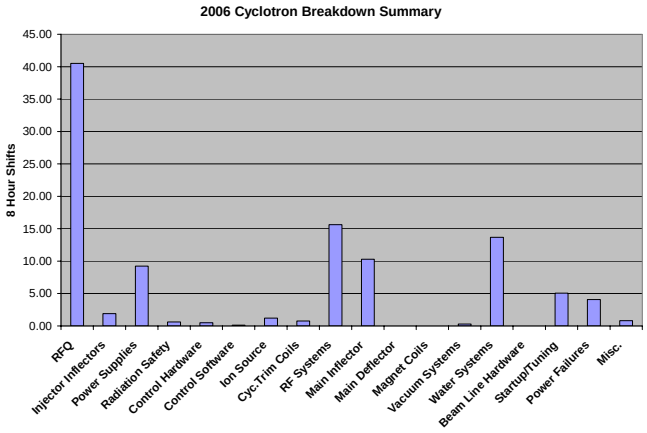


Figure 4. Cyclotron System breakdown summary for 2006. Improving RFQ reliability is a high priority.

Reaction to Failures

IUCF operators staff the facility 24 hours per day, 7 days per week. The operators are very skilled at determining in which device or system the problem lays. They then call in the appropriate expert to repair the failure at any time of day. Technical staff in essential skill areas remain on site at all times during patient treatment hours. The Treatment Systems have trained personnel familiar with all aspects of their operation and maintenance and are also on 24/7 call.

Budgeting for Reliability

The IUCF has an operations and maintenance contract with the MPRI clinic. The budget for this contract is separated into four sections. These are 1) Cyclotron System bare bones operations, 2) Treatment System maintenance, 3) Reliability Retention, and 4) Quality Assurance. Cyclotron bare bones budget is for very basic operation of the machine with little technical help for maintenance and repair. Reliability Retention was developed from a 4 year program to replace major failing equipment in the cyclotrons and to replace obsolete parts as required. It also includes regular cyclotron maintenance. The final contract is still under negotiation but we predict the cost to exceed 1.2 M US$ in each of the 4 categories, electricity not included.

The new IUCF/MPRI contract will stipulate a minimum availability of 92% calculated based on equipment availability during scheduled treatment times compared with the original contract which had 98% availability. During the last three years we have achieved close to 94%. Time will ultimately be the final judge of the effectiveness of the IUCF Quality System.

ACKNOWLEDGMENTS

The information in this paper represents a huge effort by many very hard working staff members at IUCF. I do not in any way propose that I am responsible for the successes of the IUCF and MPRI operation but I do take responsibility for any misinformation presented herein or forgotten credits.

Thanks to Mark Luxnat, Tom Meaden, Vladimir Anferov and all of the operations staff. Also special thanks to Mike Parker, our Quality Manager, who is patiently herding us to reach the QSP nadir.

REFERENCES

[1] More about the IUCF and MPRI facilities can be found by browsing to: www.iucf.indiana.edu and www.mpri.org.

[2] D.L. Friesel, et al, Proc of EPAC 2002, Paris, France, p. 2736.

[3] V. Anferov, et al, Proc of the International Particle Accelerator Conference 2003, Portland, OR p. 699.