**Moira Wedekind**

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**Summary**

Twenty years of Proton Therapy System experience from initial project definition through design, construction, testing and servicing. Twenty years of accelerator-related systems engineering experience. Twelve years in an operations or engineering management position in an FDA-regulated environment. Twenty-five years of experience in a nuclear physics research facility. One year of experience on a DOE project. Specific experience includes:

* + - Systems engineering
		- Engineering management
		- Operations management
		- Project planning & management
		- Medical device design, manufacturing, testing and servicing
		- Hazard Analysis, FMEA, Fault Tree Analysis
		- Quality system development under 21CFR820
		- Technical writing and grant writing
		- Design, fabrication and installation of particle accelerator facility equipment

**Accomplishments**

I am proud to have been part of extraordinary teams who have:

* Performed world-class nuclear physics research at Indiana University Cyclotron Facility
* Designed and built the third Proton Therapy System in the US to treat cancer patients
* Received an Investigational Device Exemption and two 510(k) clearances from the FDA
* Designed and built the first superconducting gantry to deliver proton therapy to cancer patients.

**Employment**

**UT-Battelle, Oak Ridge National Lab**

*Lead Engineer, Accelerator Systems, Second Target Station Project, June 2021-present*

* Responsible for requirements development, risk assessments, interfaces, and system integration for the RTST beam line to the Second Target Station.

**Bechtel National Inc. (UPF project @ Y12 in Oak Ridge, TN) 2020-2021**

*Sr. Systems Engineer, March 2020-May 2021*

* Responsible for completing System Verification Matrices (SVMs) which verify that the engineering design meets the requirements and identify acceptance criteria for Construction and Startup activities
* Plan SVM work and track progress to ensure that we meet the project schedule
* Lead SVM reviews to ensure quality and consistency

**ProNova Solutions, Maryville, Tennessee 2015-2019**

*Manager, Systems Engineering, September 2015 – December, 2019*

* Manage Systems Engineering group
* Responsible for Proton Therapy System verification and validation testing
* Responsible for product risk management
* Review designs from a system perspective

*Systems Engineer III, June 2015-August 2015*

* Assisted with developing user requirements and device functional specifications
* Established product risk management plan
* Revamped product hazard analysis and led development of system-level DFMEAs

**Indiana University Cyclotron Operations (IUCO)**, Bloomington, Indiana **2010-2014**

*Engineering Division Head*

* Managed mechanical, electrical and software engineers
* Responsible for the Proton Therapy System design, with focus on design changes to improve the clinical user experience, improve system availability, address parts obsolescence, and reduce risk

**Indiana University Cyclotron Facility (IUCF)**, Bloomington, Indiana **1985-2009**

*Associate Director of Operations, April 2007-December 2009*

* Managed the engineering, construction, and accelerator operations divisions at IUCF
	+ Staff of 80 people, operating budget of $6.5M
* Responsible for the design, operation, and servicing of the Proton Therapy System
* Provided services to IUCF physics research projects

*Project Manager & Engineering Document Manager, April 2001-April 2007*

* System Engineer responsible for the Treatment Room Control System (design through commissioning)
* Participated in the Proton Therapy System hazard analysis and the system level FMEAs
* Responsible for the development of the Proton Therapy System user manual
* Prepared the 510(k) submission to the FDA

*Project Manager for Proton Therapy Facility & Division Head, Radiation Applications Division*

*November 1997 – May 2000*

* Successfully applied for $15M in federal and state grants
* Developed conceptual design, budget and schedule for the Proton Therapy facility
* Project manager for the construction of a fixed-energy proton radiotherapy treatment room
* Managed the Radiation Applications Division - an umbrella for the non-nuclear physics activities of the laboratory: proton therapy, radiation effects, and radiobiology

*Division Head, Accelerator Division and Group Leader, Mechanical Services Group*

*June 1994 - November 1997*

* Managed a division of 40 people who operated and serviced the accelerators and designed and fabricated accelerator-related equipment
* Developed project plans for experimental and accelerator development projects

*Project Manager and Lead Engineer for the High Intensity Polarized Ion Source, 1990-1994*

* Responsible for a $1.3M budget, project planning, design, procurement, fabrication, installation, and commissioning
* Supervised the design, fabrication, installation and commissioning of magnets, RF, beam production, ionization, and diagnostic systems
* Specific design duties included structural supports, vacuum chambers, pumping systems, and specification of power supplies, control systems, and utilities

*Drafter, Design Engineer, and Project Planner, April 1985-June 1993*

## Education

* Technical Writing Certificate, Northeastern University, 2001
* M.A., American Literature, Indiana University, December 1986
* B.E., Civil Engineering, Vanderbilt University, December 1980

# Continuing Education and Skills Development

* Leadership development (2019)
* The New 60601-1 Amendment: Risk Management and Essential Performance Requirements for Electronic Medical Devices, AAMI (2013)
* Corrective and Preventive Action (CAPA) Controlling Nonconforming Product, AAMI (2012)
* Design History File (DHF): Tips for Creating a Successful DHF, AAMI (2012)
* Document Control and Records Management, AAMI (2011)
* Fault Tree Analysis, AAMI (2011)
* US Particle Accelerator School “Managing Science” (2009)
* Quality Management Certification, American Society for Quality (2001)