

A Medical Device Manufacturer's Perspective of an Accelerator Laboratory

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Designing, building and operating a Proton Therapy Clinic requires a different mindset than the usual project at a university or DOE laboratory. Naturally some similarities exist but the Code of Federal Regulations Title 21 drives medical device manufacturers such as ProNova Solutions, LLC and my former employer Indiana University to maintain strict control of design, verification and validation, manufacturing and operation. The drive for reliability is present in all phases of the medical device including Design with adequate Verification and Validation, Manufacturing with controlled and well defined processes, and Operation by tracking device configuration, servicing, non-conformances and customer complaints.

Examples of how ProNova Solutions is complying with the regulations will be described and how it impacts the goal to make the system reliable both from a patient safety and treatment efficacy point of view.

