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Quality and safety concepts have remained important to Radiation Oncology. Historically, adherence to strict and prescriptive quality assurance paradigms was prioritized, but attention has recently shifted towards prospective risk mitigation—including holistic review of processes and workflows; it is individualized to a center's treatments, equipment, workforce, and community standards.

One relevant criticism is that departments without such ample resources are unlikely to be able to commit to such a time and personnel intensive review.

Emergent radiotherapy treatment is a high-stakes environment combined with a challenging scenario. Unsatisfied with vendor-provided solutions, we had sufficient in-house expertise to craft our own software solution, called the Sim-Free Wizard (SFW). We utilized the principles of Safe-By-Design (SbD) to vet its development, testing, and implementation.

INNOVATION/IMPACT

We consider this work highly important and timely because we perceive an unfortunate undercurrent of an “all or nothing” approach towards prospective safety paradigms. Although AAPM as an entity, along with many individual physicists, have worked hard to simplify the FMEA process, and share how they were able to implement it within their own challenging clinical environments, we have anecdotally noted a continued perception that it is a long, arduous, resource-intensive process. There doesn't seem to be doubts that it is worthwhile when completed, just that it remains out of reach for many.

TAKE HOME

Using SbD principles, an in-house software was created to reduce the risk associated with emergent radiotherapy treatments.

Medical physics-facing examples of practical options for those clinics who cannot commit to the FMEA paradigm have been very limited. As we are a team with significant FMEA experience, we explored other lesser-known safety paradigms as viable alternatives to FMEA, which therefore could be attractive to safety-minded groups who would be unable to pursue a full FMEA. Among our substitute choices, one stood out among the rest as a serviceable answer: Safe-by-Design (SbD). Based on our experience using that paradigm during the evaluation of an in-house software program, we found SbD to be a robust, effective, and relatively simple pathway that gave comparable insights into potential pitfalls and avoidable failure modes. Our team was happy to see that the SbD option gave us actionable opportunities to increase safety and reliability for a process that we were developing essentially from scratch. We believe this represents an augmentation to the quality and safety activities that clinics may choose to engage with, as they navigate their own challenges.

We referenced the 2021 work of van Gelder P et al [Safe-by-Design in Engineering: An Overview and Comparative Analysis of Engineering Disciplines](#) Int J Environ Res Public Health. doi: 10.3390/ijerph18126329 to structure our analysis of our software development process in accordance with the principles of SbD.

Namely, we had the following expectations for our software: it must be “safe” meaning that it rarely crashes and when it does the user is informed of what happened and can safely begin the process from a known point; it generates the anticipated outcome in the anticipated timeframe; the UI is easy to understand and follow after minimal training or with sufficient training but use under adverse conditions; it is not vulnerable to unintentional or intentional misconduct because of a series of checks and balances which are applied throughout the process.

To ensure our in-house software met those expectations we used the techniques from the above-mentioned work: dynamic analysis and testing, static analysis and formal verification, and design patterns and coding convention review. In doing so we were able to eliminate multiple hazards from the software in a reasonable timeframe and predictable fashion. We intend to use those techniques in future development efforts as well.



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