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A TG-100–Inspired, Risk-Based FMEA Framework for Enterprise Radiation Oncology Equipment Lifecycle Replacement

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ABSTRACT

Radiation oncology equipment replacement is typically run as isolated capital projects. Failures in portfolio prioritization, enabling work, commissioning, and go-live drive patient-access risk, schedule slip, and cost escalation.

We developed a TG-100 inspired, risk-based framework to standardize and de-risk enterprise lifecycle replacement across three regions and 30+ major assets.

A multidisciplinary team mapped the workflow from enterprise inventory to post-go-live stabilization and performed a domain-level FMEA across 10 risk domains, scoring occurrence, severity, and detectability (1–10) to rank mitigations.

The result is a repeatable, stage-gated playbook with named owners, readiness checklists, redundancy-preserving sequencing, transfer/rollback plans, go/no-go criteria, and a 30/60/90-day stabilization plan.

INTRODUCTION

Equipment replacement is often managed as a series of isolated capital projects, creating risks from poor sequencing, under-scoped enabling work, and delayed IT and cybersecurity readiness.
This work adapts AAPM TG-100 FMEA principles to enterprise equipment lifecycle management, integrating clinical, facilities, IT, vendor, and patient-access considerations into a stage-gated framework.

METHODS AND MATERIALS

A multidisciplinary team mapped the replacement process from enterprise asset prioritization through post-go-live stabilization.

A domain-level FMEA evaluated 10 risk domains using 1–10 scores for occurrence, severity, and detectability. RPN scores (O × S × D) were used to prioritize risks and translate them into stage-gated controls, including defined ownership, readiness checklists, redundancy-preserving sequencing, contingency plans, go/no-go criteria, and 30/60/90-day stabilization.

RESULTS

Figure 1 links the replacement framework to its operational controls. The highest-ranked risks were poor enterprise prioritization, under-scoped construction readiness, and delayed IT, cybersecurity, and system integration.

Projects completed through 2025 achieved more than 30% savings relative to initial capital estimates, with additional observed operational gains. These outcomes were multifactorial and cannot be attributed solely to the FMEA framework.

CONCLUSIONS

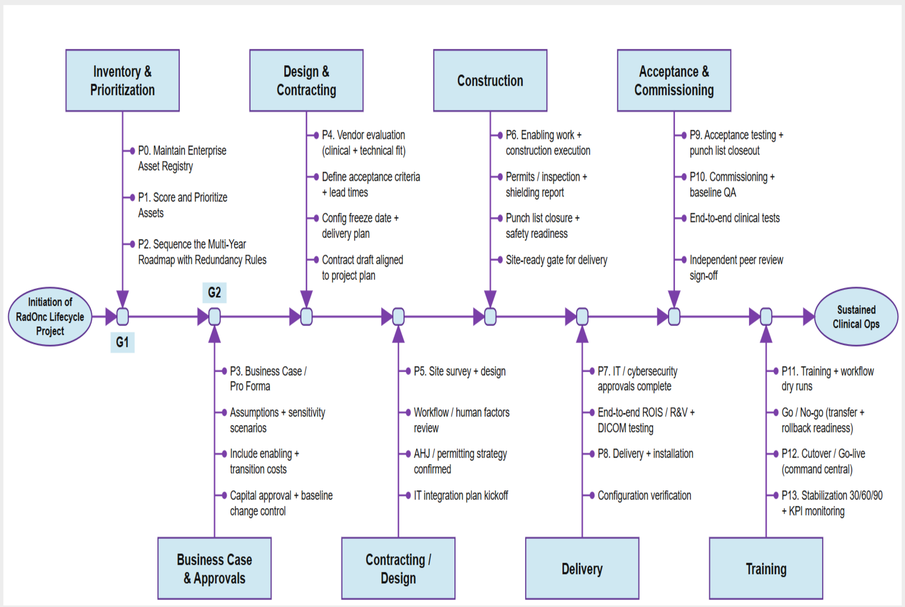
A TG-100 inspired FMEA applied to enterprise equipment replacement provides a repeatable method to prioritize and control risk from pro forma to go-live — improving predictability, protecting patient access, and strengthening lifecycle governance and capital stewardship.

REFERENCES

1. Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management. Med Phys. 2016;43(7):4209–4262.

DISCUSSION

Enterprise inventory and prioritization was the highest-risk domain (RPN 432), reflecting the danger of incomplete asset data and poor replacement sequencing. Major lifecycle risks clustered upstream in prioritization, site readiness, and system integration, where failures can compromise redundancy and patient access. Key controls include a centralized asset registry, standardized scoring, quarterly review, and redundancy-protection rules. Because scoring was consensus-based and outcomes were observational, risk rankings should be reassessed locally.



Risk Domain	Representative Failure Mode	Potential Effects	Potential Causes	Recommended Mitigations	Verification / Evidence	Occurrence (1-10)	Severity (1-10)	Detectability (1-10)	RPN
Enterprise inventory & prioritization	Incomplete inventory and inconsistent scoring cause poor replacement sequencing and loss of redundancy.	High-risk assets remain in service; downtime; lost redundancy; patient transfers; emergency capital requests.	Missing age/EOS/service data; siloed inputs; subjective scoring; inconsistent downtime definitions.	Enterprise asset registry; standardized EOL/EOS, reliability, volume, redundancy, and growth rubric; quarterly updates; steering review; redundancy-protection rules.	Quarterly sample audit; rubric back-testing; steering approval of ranking and sequencing.	6	9	8	432
Construction & site readiness	Enabling work—power, HVAC, shielding, and permits—is under-scoped or identified late.	Schedule delays; cost overruns; prolonged downtime; failed inspections; portfolio-wide delays.	Incomplete surveys/as-builts; late AHJ review; contractor inexperience; inconsistent processes.	Formal readiness assessment; early engineering and AHJ review; construction stage gate; schedule buffers.	Stamped drawings; signed readiness checklist; documented pre-inspection walkthrough.	6	8	6	288
IT / cybersecurity / integration	IT approvals and ROIS/R&V interfaces are not ready when equipment arrives.	Delayed go-live; risky workarounds; data-integrity risk; extended downtime.	Late IT involvement; underestimated reviews; no test environment; unclear ownership.	Integration plan at kickoff; test scripts; cybersecurity milestones; named IT owner; mandatory end-to-end testing.	Signed end-to-end test; cybersecurity approval; completed interface-validation checklist.	5	8	7	280
Patient access & continuity of care	No executable downtime, cutover, or transfer plan; capacity and scheduling rules are undefined.	Treatment interruptions; missed fractions; replans; dissatisfaction; clinical risk.	Lost redundancy; undefined transfers; unrealistic outage assumptions; poor regional coordination.	Transfer playbook; reserved capacity; downtime drills; buffered cutover schedule; predefined triage rules.	Tabletop/live drill results; capacity dashboard; contingency readiness in go/no-go checklist.	5	9	6	270

Figure 1. TG-100–inspired lifecycle replacement framework. Left: stage-gated process from inventory and prioritization through design, construction, commissioning, and go-live. Right: FMEA of key risks, causes, effects, and mitigations across multi-site replacements.

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