

Enhancing Safety in Healthcare Settings

A Systems Engineering Case Study on Radiation and Procedure Shielding

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Abstract

Radiation shielding is vital for protecting healthcare professionals and patients from scattered radiation during diagnostic and interventional procedures. This case study explores how systems engineering principles can optimize the design and integration of shielding solutions in clinical environments.

The study applies a multidisciplinary systems approach to address safety, effectiveness, and regulatory compliance. By incorporating parameters such as radiation source characteristics, shielding material properties, and clinical system requirements, the methodology supports the development of robust and efficient shielding designs.

Stakeholder collaboration, including clinicians, biomedical engineers, and regulatory experts, plays a critical role in requirements analysis, risk assessment, and compliance with standards such as IEC 60601-1. Their input ensures alignment between technical design, clinical workflows, and operational needs.

The case study also highlights practical integration challenges, such as aligning ceiling-mounted and table-mounted shields with existing imaging systems (e.g., C-arms and accessory rails). It emphasizes maintaining mechanical compatibility, structural integrity, and regulatory adherence within the healthcare system context.

Keywords – System Engineering, Radiation Shield, Radiation Shielding solutions, Requirement traceability matrix.

Introduction

Advancements in medical technology have significantly expanded the use of imaging techniques that rely on ionizing radiation for the diagnosis and treatment of various health conditions. While these tools have become indispensable in modern healthcare, their use brings an increased risk of radiation exposure to both patients and medical personnel, including radiologists, technicians, and interventionalists. Prolonged or repeated exposure can lead to serious health consequences, such as tissue damage and elevated cancer risk.

Radiologists, technicians, and patients are routinely exposed to ionizing radiation during medical imaging, surgical interventions, and other diagnostic procedures. To mitigate these risks, radiation shielding is employed as a protective measure to reduce exposure. Shielding serves a critical role in minimizing

unnecessary radiation without compromising the quality of diagnostic imaging. The primary objective of radiation protection is to ensure that exposure levels remain as low as reasonably achievable (ALARA), balancing clinical necessity with safety.

Despite well-established guidelines, implementing effective radiation safety practices remains a complex challenge. The involvement of multiple stakeholders, including physicians, hospital administrators, equipment manufacturers, and safety officers adds layers of complexity to the enforcement of safety protocols. There are multiple regulatory requirements, and risk assessment is critically important. Therefore, systems engineering becomes essential for effectively managing these complexities, ensuring coordinated decision-making, regulatory compliance, and the integration of safety throughout the system lifecycle.

This paper applies to a systems engineering approach to examine the current challenges and propose improvements in radiation and procedural shielding within healthcare environments. By addressing these issues through a structured, interdisciplinary lens, the study aims to enhance overall safety and effectiveness in radiation use across clinical settings. Top of Form Bottom of Form

Before grounding this systems-based exploration, we will first delve into the fundamentals of radiation shielding, including an overview of radiation hazards in medical environments, commonly used shielding materials, various types of shielding devices, and relevant regulatory standards.

Radiation shielding

Radiation Safety Concerns in the Medical Field

Radiation hazards in medical environments arise primarily from ionizing radiation used in imaging and therapies like X-rays, gamma rays, and radioactive isotopes. While essential for diagnosis and treatment, radiation poses risks to both patients and healthcare workers, including acute effects (e.g., burns, nausea) and long-term risks like cancer.

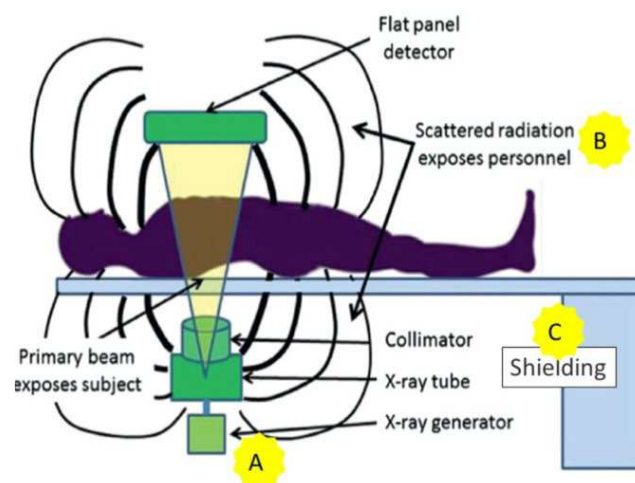


Figure 1. Radiation exposure during Fluoroscopy

Fluoroscopic imaging is a major source of exposure in clinical settings as shown in

Figure 1. Radiation protection relies on three key principles: justification, optimization, and dose limitation. Justification ensures procedures balanced benefits and risks. Detection devices play a critical role in monitoring exposure, ensuring compliance, and promoting safety. As medical technologies evolve, these tools help deliver precise treatments while minimizing harm and advancing safe healthcare practices.

What is Radiation Shielding

Radiation shielding is simply a barrier placed between a source of radiation and the area or person that needs to be protected. The purpose of radiation shielding is to limit, control, or modify the radiation exposure rate at a set point.

Shielding is based on attenuation or the gradual reduction in the intensity of energy through a specific medium. X-ray radiation that passes through certain materials decreases and are absorbed, thereby reducing the exposure to the other side of the barrier.

Radiation Shielding Materials

In medical environments, the most common shielding materials used include lead, lead-free shielding, and lead composites.

Lead is one of the most effective and commonly used materials for radiation shielding due to its high density and atomic number, which allow it to absorb or scatter radiation efficiently. It is cost-effective, easy to process, and can be incorporated into garments or construction materials. Advances in technology have led to the development of lead-free shielding using materials like tungsten, antimony, and tin, which offer similar protection while being non-toxic, recyclable, and lighter—enhancing comfort during prolonged use. Lead composites, made by blending lead with lighter substances such as vinyl or rubber, provide durable protection while reducing weight by up to 25%, improving wearability without compromising safety.

After understanding radiation shielding and its materials, we can now look into the various device types designed for protection.

Types of Radiation Shielding Devices

Table 1 presents a summary of the different radiation shielding devices used to provide protection in a range of medical applications. Figure 2 shows different radiation shielding devices used in Cath lab.

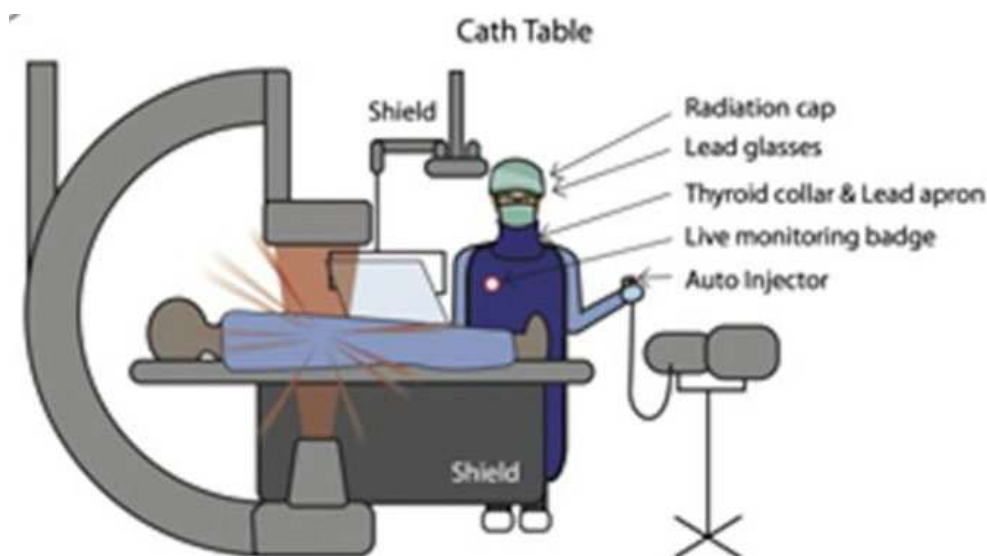


Figure 2. Different Radiation shielding devices in Cath Lab

Category	Shielding device	Description
Personal Protective Equipment (PPE)	Lead Aprons	Worn by staff or patients to protect vital organs during imaging procedures.
	Thyroid Shields/Collars	Protect the thyroid gland from scatter radiation.
	Lead Gloves	Used during fluoroscopic procedures to shield hands.
	Lead Glasses	Shield the eyes, especially for interventional radiologists.
	Lead-Free Garments	Lightweight, non-toxic alternatives made of bismuth, tungsten, or antimony.
Structural Shielding	Lead-Lined Walls & Doors	Fixed barriers in X-ray and CT rooms to shield surrounding areas.
	Radiation Shielded Windows (Lead Glass)	Provide visibility into imaging rooms while blocking radiation.
	Mobile Shielding Screens	Movable barriers placed between staff and radiation sources.
Equipment-Mounted Shielding	Overhead Suspended Shields	Transparent lead-acrylic panels suspended from ceilings in interventional areas.
	Table-Side Lead Curtains (Skirting)	Mounted under fluoroscopy tables to block scatter from below.
	C-Arm Drapes	Attach to imaging equipment to reduce scatter toward operators.
Patient Shielding	Gonadal Shields	Protect reproductive organs, especially in pediatric or abdominal imaging.
	Breast Shields	Used during chest CT scans or X-rays.
	Eye Shields	Shield the eyes from radiation during head or facial imaging.
Room and Equipment Design	Shielded Control Booths	Operator booths built with shielding materials for safe monitoring.
	Radiation-Absorbing Flooring	Installed in high-exposure zones to reduce scatter radiation.

Table 1. Types of radiation shielding devices

To ensure the safe and effective use of these shielding devices, it is essential that they comply with established regulatory and safety standards.

Regulatory and Safety Standards for Radiation Shielding Devices

Table 2 shows the most widely accepted international standards for radiation protection devices:

Standard	Title / Focus	Key Applications	Description
IEC 61331-1	Determination of attenuation properties of materials	Lead aprons, shields, curtains	Specifies how to measure attenuation and equivalent lead thickness
IEC 61331-2	Translucent protective plates	Protective screens in diagnostic imaging	Focuses on shielding that allows visibility while blocking radiation
IEC 61331-3	Protective clothing and eyewear	Lead aprons, thyroid collars, lead glasses	Performance and testing methods for wearable shielding
IEC 60601-1	General safety and performance of medical electrical equipment	All radiation-emitting medical devices	Foundational safety standard for medical devices
IEC 60601-1-3	Radiation protection in diagnostic X-ray equipment	X-ray machines, fluoroscopy units	Collateral standard focusing on built-in shielding and safety features
IEC 62366	Usability engineering for medical devices	All shielding and radiation-related devices	Ensures human centred design to reduce misuse
ISO 14971 / IEC SC 62A	Risk management for medical devices	Risk analysis for shielding systems	Framework for identifying and mitigating radiation-related risks
ISO 13485:2016	Quality management systems for medical devices	Design, production, and servicing of shielding devices	Emphasizes regulatory compliance, risk management, and lifecycle quality.
YY/T 0128-2023 (China)	Protective devices against diagnostic medical X-radiation – Device and Tool	Fixed shielding tools (not wearable) in diagnostic imaging	Issued by NMPA; defines requirements and inspection methods for shielding

Table 2. Standards for radiation protection devices

While these regulatory and safety standards provide a structured framework for radiation protection, implementing them in real-world clinical settings presents several practical and technical challenges.

Key challenges in radiation shielding devices

Radiation shielding devices are important for safety, but they also come with several challenges as shown in Figure 3 that can affect how well they work and how easily they are used in medical settings.



Figure 3. Key challenges in Radiation Shielding Devices

Rapid Technological Evolution

New imaging and procedural technologies may outpace current shielding practices.

Inadequate Shielding Design

Poorly designed shielding can lead to radiation leakage, exposure hotspots, or inefficient use of space.

Fragmented Stakeholder Involvement

Radiation safety involves multiple stakeholders (clinicians, administrators, facility planners, engineers), often leading to miscommunication or misalignment.

Integration Issues Between Shielding and Equipment

Poor coordination between medical device layout and protective shielding (e.g., C-arm machines or fluoroscopy units)

Cost and Resource Constraints

Budget limitations may prevent the adoption of high-quality shielding solutions.

Regulatory Compliance and Documentation

Ensuring compliance with evolving safety standards is time-consuming and error prone. To address these complexities, systems engineering offers a holistic and integrative approach that helps teams collaborate effectively, understand and manage system complexity, and ensure the successful development and realization of complex systems.

Role of Systems Engineering in Managing Radiation Shielding Solutions

Systems engineering plays a crucial role in the development and management of effective radiation shielding solutions by integrating technical, clinical, and regulatory perspectives. Through structured requirement analysis and multidisciplinary collaboration, it ensures that shielding designs are not only technically sound but also compatible with clinical workflows and safety standards.

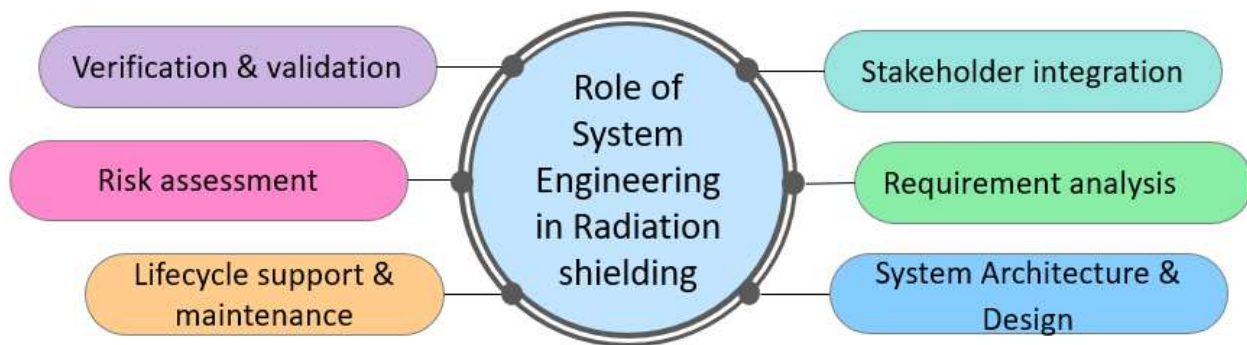


Figure 4. Role of Systems Engineering in managing Radiation shielding solutions

Key Contributions Of Systems Engineering In Radiation Shielding Include:

Stakeholder integration to align diverse needs and expectations

Radiation shielding involves multiple stakeholders—clinicians, Mechanical engineers, facility planners, manufacturers, and safety officers. Systems engineering ensures:

- Effective communication and collaboration across disciplines
- Design decisions that align with both technical specifications and clinical workflows

Requirement analysis to define performance, safety, and compliance criteria

Systems engineering begins with a thorough understanding of user needs, regulatory requirements (e.g. IEC 61331), and clinical constraints. It helps:

- Define shielding needs based on radiation source, procedure type, regulatory standards room layout
- Identify protection goals for both patients and healthcare workers (ALARA principle)

System Architecture & Design

- Integrate shielding into the overall system design
- Select appropriate materials
- Optimize geometry and placement to balance protection, weight, and cost.

Compliance, Verification and validation to ensure performance and regulatory compliance. It ensures that the shielding solution complies with international and national standards, such as:

- IEC 61331, IEC 60601-1 guidelines
- Includes verification and validation steps
- Delivery of solutions within budget and schedule constraints

Risk assessment to proactively identify and mitigate safety concerns. Identify risks such as:

- Shielding degradation over time
- Unexpected radiation leaks
- Material incompatibility

Develop mitigation strategies and contingency plans.

Lifecycle support and maintenance for long-term reliability and efficiency

- Plan for inspection, maintenance, and replacement of shielding components.
- Monitor radiation levels during operation to ensure continued compliance.
- Update shielding models as systems evolve or degrade.

The following case study illustrates how these principles were applied in a real-world scenario involving the integration of radiation shielding with an Image Guided Therapy system.

Case Study: Application of Systems Engineering in Radiation and Procedure Shielding

Background

This case study explores how systems engineering principles were applied to integrate radiation shielding solutions into an Image Guided Therapy (IGT) system. The integration effort required overcoming various mechanical, regulatory, and interface-related challenges to ensure compatibility with the existing imaging infrastructure. A structured systems engineering approach guided the alignment of the shielding design, interfaces, and performance with strict safety standards and system-level requirements, while maintaining clinical efficiency and workflow.

The project involved selecting and validating radiation shields that met regulatory compliance and functionally integrated with the imaging system's physical and operational interfaces. Addressing these requirements demanded resolution of multiple technical and operational challenges throughout the integration process.

Key Challenges

1. User Requirements

Shielding solutions need to support a broad spectrum of procedures—such as interventional cardiology, neuroradiology, and electrophysiology each presenting unique user preferences, access requirements, and radiation exposure conditions. The shields should be easy to position, smooth to maneuver, and stable during use, particularly when ceiling- or table-mounted. Users also expect high shielding performance in terms of attenuation and effective coverage area, along with complete safety—meaning no risk of falling components, sharp edges, or procedural interference.

2. Regulatory Compliance

The radiation shields were required to meet the international standards IEC 60601-1 and IEC 60601-1-3, IEC-61331 -n & NMPA YY/T 0128-2023 standard.

3. Interface Compatibility

The project involved two types of radiation shields: ceiling-mounted and table-mounted as shown in Figure 5. Each had to be mechanically and functionally compatible with the existing interfaces of the imaging system. The ceiling-mounted shield interfaces with the ceiling bracket, while the table-mounted version mounted on the accessory rail of the patient table. Load, torque, and inertia values need to ensure that within acceptable limits defined by the imaging system's interface specifications.

4. Usability Considerations

Usability was a critical aspect in clinical environments. Few usability concerns the radiation shields were required to:

- Avoid obstructing the C-arm movement
- Allow easy mounting and unmounting on designated attachment points (accessory rail or ceiling bracket)
- Maintain an appropriate and safe gap between the table-mounted shield and the patient table

5. Clinical Requirements

Finally, it was essential that the radiation shields did not interfere with the imaging system's functionality or compromise image quality.

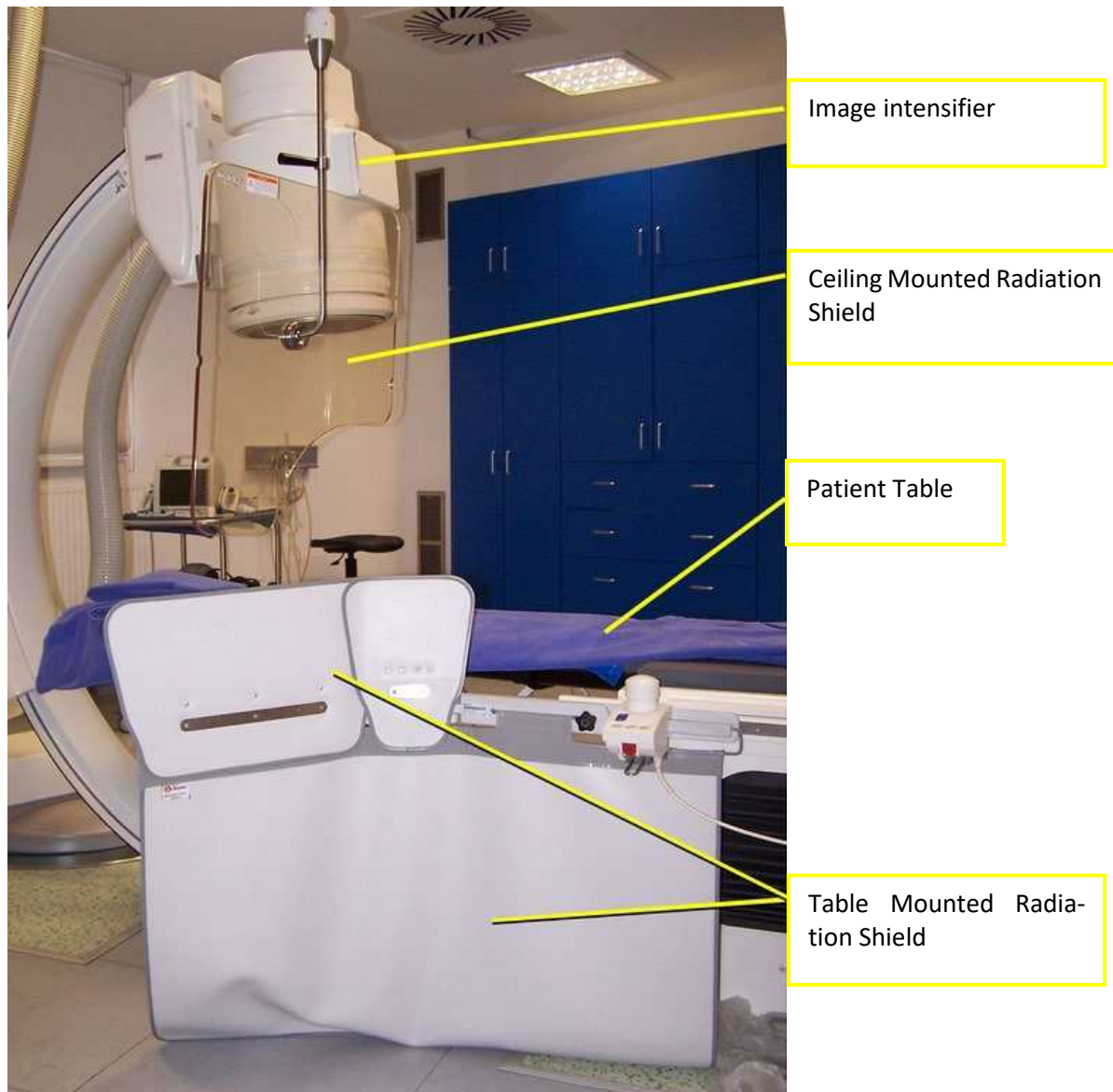


Figure 5. Radiation shield and Image Guided Therapy System

To address the identified challenges and enable successful integration of the radiation shield, a structured systems engineering approach was implemented as outlined below:

- **Identification and specification of suitable radiation shielding solutions** to align with clinical needs and regulatory requirements throughout the system lifecycle.

- **Adoption of the V-Model workflow** to ensure systematic development and traceability across the lifecycle—from requirement definition to final validation.
- **Development of a requirement traceability matrix** to link stakeholder needs with design inputs, regulatory standards, and verification activities.
- **Active stakeholder engagement**, involving cross-functional teams from engineering, clinical operations, and regulatory affairs to ensure all perspectives were incorporated throughout the integration process.
- **Execution of verification and validation (V&V) activities**, including interface testing, usability assessments, and compliance checks against NMPA and IEC standards.

Based on this structured approach, the following section outlines how specific Systems Engineering (SE) steps were applied throughout the integration process to address technical requirements, user expectations, regulatory compliance, and clinical workflow considerations.

Evaluation of Radiation shield Effectiveness

We evaluated the radiation shielding performance across different shielding area sizes and various materials. The testing was conducted assuming conditions at the Designated Significant Zone of Occupancy.

X-ray Tube Voltage (kVp)	75 x 60 cm	70 x 50 cm	60 x 50 cm
70	65	60	55
80	70	65	60
90	75	70	65
100	80	75	70
110	85	80	75
120	95	85	80

Table 3. Attenuation Percentage by Shield Size at Typical Operating Voltages

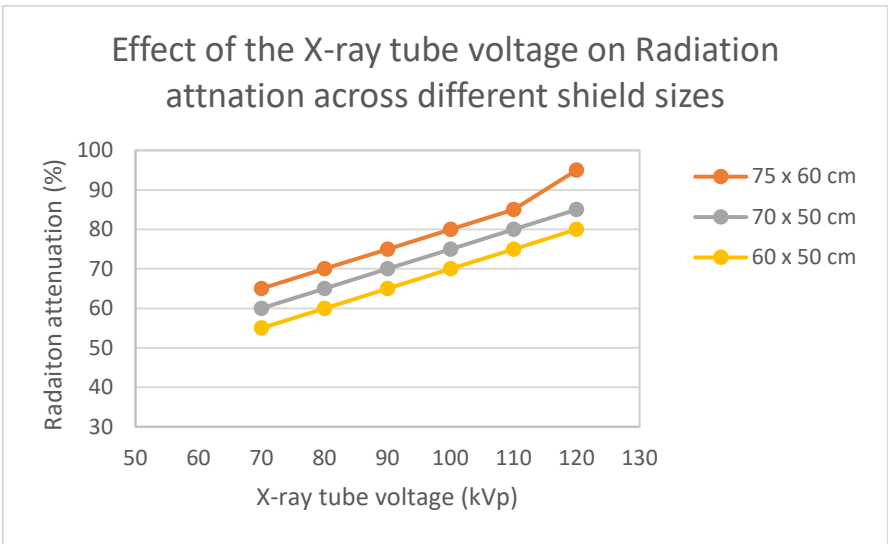


Figure 6. Effect of different shield sizes on radiation attenuation

The graph (Figure 6) & Table 3 illustrates the impact of increasing X-ray tube voltage on radiation attenuation performance across shields of varying sizes. As observed, radiation attenuation consistently improves with rising tube voltage from 70 to 120 kVp across all shield sizes, demonstrating enhanced shielding efficiency at higher energy levels. Notably, smaller shields (e.g., 60x50 cm) exhibit slightly higher attenuation percentages compared to larger ones (75 x 60 cm²), likely due to reduced scatter or geometric positioning.

This data reinforces the importance of optimizing both shield size and material in clinical settings, especially where higher voltage X-ray procedures are involved. It also provides valuable input for selecting or designing radiation protection accessories tailored to specific procedural demands and operator positions.

X-ray Tube Voltage (kVp)	Lead Acrylic (%)	Lead Glass (%)	Lead Composite (%)
70	95	96	94
80	92	93	91
90	88	89	87
100	83	85	82
110	78	81	77
120	72	75	70

Table 4. Attenuation Percentage by Shield material at Typical Operating Voltages

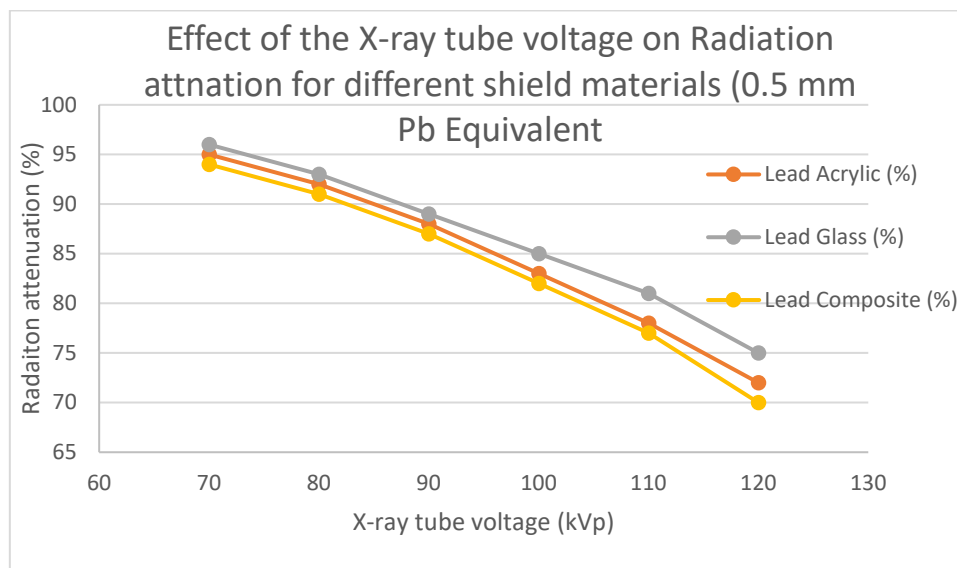


Figure 7. Effect of different shield material on radiation attenuation

This graph (Figure 7) & Table 4 illustrates the relationship between X-ray tube voltage and radiation attenuation performance across three commonly used shielding materials—Lead Acrylic, Lead Glass, and Lead Composite—all at a standard thickness of 0.5 mm Pb equivalence.

As we can see, attenuation generally decreases as X-ray tube voltage increases, which is expected since higher-energy X-rays are more penetrating. Lead Glass shows the highest and most consistent attenua-

tion across the range, followed by Lead Acrylic and Lead Composite, which exhibit a more noticeable decline at higher voltages.

This balance between protection and usability allows us to maintain radiation safety while ensuring smooth operation in high-use environments such as Cath labs and interventional suites

To support material selection, a comparative evaluation of radiation shielding options was performed using a Pugh Matrix approach. The matrix assessed multiple materials against defined criteria such as attenuation, weight, cost, and environmental impact, using lead as the reference baseline. Alternatives were scored as better (+1), equal (0), or worse (−1) compared to lead. The results are summarized in Table 5.

Evaluation Criteria	Lead (Datum)	Lead-Acrylic	Lead-Free Composite	Lead Glass
Radiation Attenuation	0	−1	−1	0
Weight / Ergonomics	0	+1	+1	−1
Durability	0	−1	+1	−1
Transparency	0	+1	0	+1
Cost	0	−1	−1	0
Environmental Impact	0	+1	+1	−1
Regulatory Compliance	0	0	−1	0
Total Score	-	0	0	−2

Table 5. Pugh Matrix for Comparative Evaluation of Radiation Shielding Materials

In the above Pugh matrix Lead is used as the reference (datum). A score of: +1 indicates the alternative is better than Lead. 0 means equal to Lead. −1 means worse than Lead. Lead-Acrylic and Lead-Free Composite perform better in weight and environmental impact, but slightly worse in attenuation and cost. Lead Glass is less favorable overall due to weight, durability, and environmental concerns.

Despite the slight trade-off in attenuation, the Pugh Matrix reveals that Lead-Acrylic offers the most balanced performance across practical criteria without significant drawbacks:

- Superior ergonomics and reduced weight, making it more suitable for ceiling-mounted and mobile shields.
- Transparency, enabling visibility during procedures, which enhances workflow safety and clinical effectiveness.
- Environmental advantages over traditional lead, supporting hospital sustainability goals.
- Although slightly lower in attenuation, this can be compensated through thickness optimization or use in lower-exposure areas.

Critically, Lead-Acrylic scores zero net trade-offs, balancing weaknesses (attenuation, cost) with strengths (ergonomics, visibility, and environmental profile). In contrast, Lead Glass scores −2 and is more fragile and heavier.

The above insights serve as foundational inputs into the System Lifecycle **System Lifecycle Mapping for Radiation Shielding Integration** Mapping for Radiation Shielding Integration ensuring that choices are strategically aligned with each phase of the system lifecycle, from design and procurement to installation, operation, maintenance, and regulatory compliance.

Lifecycle Stage	Shielding Design Activities
Concept & Requirements	- Identification of clinical, safety, and regulatory needs (NMPA, IEC 60601-1/-1-3)- Stakeholder requirement gathering (clinical, engineering, regulatory)- Material, cost constraints assessed
System Design	- Definition of interface requirements for ceiling- and table-mounted shields- Risk analysis (e.g., potential C-arm interference, torque limits)- Development of traceability matrix
Detailed Design & Development	- Finalization of design specs with supplier- Preparation of documents like Interface Design Specifications (IDS), Interface usage Documents, Mechanical load validation
Integration & Verification	- Assembly with MCC brackets and accessory rail- Interface and usability testing (mounting ease, gap with table)- EMC and mechanical verification
Validation	- Clinical simulation to ensure imaging functionality is not affected- Compliance validation with NMPA YY/T 0128-2023 and IEC standards
Deployment & Support	- Documentation update, Clinical training and feedback- post-deployment monitoring for usability issues
Disposal/End-of-Life	- Consideration of material recyclability and safe removal procedures

After mapping how radiation shielding fits into the system lifecycle, we now look at how systems engineering processes were used to guide the integration at each stage

Application of Systems Engineering Processes

The integration of radiation shield with the Image Guided Therapy (IGT) system followed a structured Systems Engineering (SE) process based on the V-model framework as shown in Figure 8. Each phase of the SE lifecycle contributed to ensuring technical compatibility, regulatory compliance, usability, and clinical performance. The key SE processes applied are outlined below:

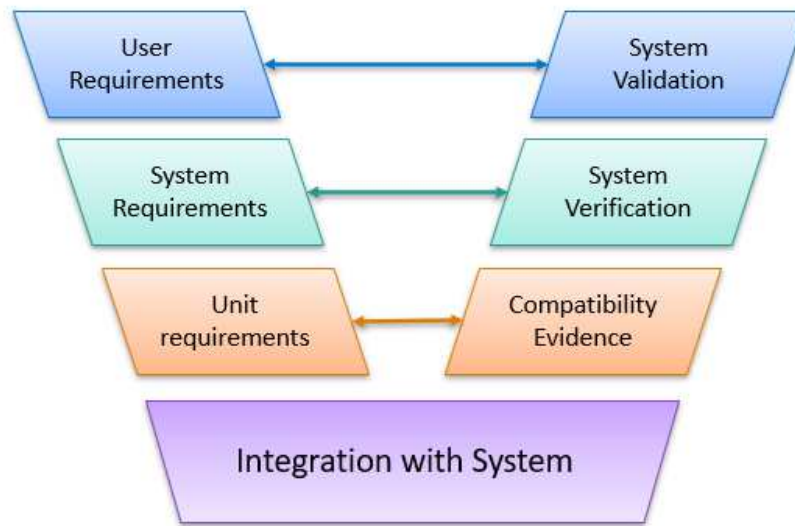


Figure 8. V Model approach

1. Requirements Engineering

- **Stakeholder Requirement Collection:** Inputs were gathered from engineering teams, clinical users, regulatory experts, and suppliers.
- **Requirement Traceability Matrix:** A traceability matrix was developed to link stakeholder needs with design requirements and regulatory clauses (e.g., NMPA YY/T 0128-2023, IEC 60601-1, and IEC 60601-1-3, IEC 61331-1/3 (specify parts and year)) as shown Table 6.

Requirement ID	Requirement Description	Ceiling mounted radiation shield	Table mounted radiation shield	Test case	Evidence	Status
RQ01	Maximum weight & torque on mounting pin	✓	-	TC01	Verify the weight & torque	Passed
RQ02	Maximum weight & torque on the accessory rail	-	✓	TC02	Verify the weight & torque	Passed
RQ03	Comply with IEC 60601-1:2005+A1:2012 (Edition 3.1)	✓	✓	TC03	Inspection of certification	Passed
RQ04	Lead equivalence class	✓	✓	TC04	Verify the certificate	Passed

RQ05	Material	✓	✓	TC05	Verify the test certificate	Passed
RQ06	Appearance	✓	✓	TC06	Verify the appearance	Passed
RQ07	Comply with IEC 61331-1:2014	✓	✓	TC07	Verify the certificate	Passed
RQ08	Comply with EC 60601-1 3: 2008+A1:2013 (Edition 2.1)	✓	✓	TC08	Verify the certificate	Passed
RQ09	Comply with YYT/T 0128 – 2023 standard	✓	✓	TC09	Verify the certificate	Passed

Table 6. Requirements Traceability Matrix

- **Outcome:** Clear definition and traceability of functional, regulatory, and interface requirements for both ceiling-mounted and table-mounted radiation shields.

2. System Architecture and Interface Definition

- **Interface Definition:** Interface assessment is done to ensure compatibility with existing system components such as ceiling brackets and patient table rails.
- **Mechanical Constraints:** Load, torque, and inertia limits were validated against system interface specifications.
- **Outcome:** Prevention of mechanical incompatibility and assurance of safe installation and movement.

3. Risk Management

- **Risk assessment:** Risk assessment is done to identify and mitigate potential risks such as interference with C-arm movement or risk of image quality degradation.
- **Outcome:** Identification and mitigation of risks early in the design phase.

4. Verification and Validation (V&V)

- **Verification:** Component-level tests were performed to ensure the shields met design specifications and regulatory requirements.
- **Validation:** System-level testing, including usability assessments in simulated clinical scenarios, ensured the shields did not interfere with imaging functionality or user workflow.
- **Outcome:** Successful verification of design intent and validation of clinical performance.

5. Configuration and Change Management

- **Document Control:** Changes to design inputs, regulatory references, and interface specs were managed through formal document updates (DoComp, IDS, RMF, etc.).
- **Outcome:** Controlled implementation and traceable change history.

6. Stakeholder Collaboration

- **Cross-functional Reviews:** Regular design reviews with clinical, engineering, and quality teams ensured alignment at every phase.
- **Supplier Engagement:** Continuous coordination with shield suppliers for compliance testing and design optimization.
- **Outcome:** Reduced rework and improved acceptance from clinical and regulatory stakeholders.

The structured application of systems engineering processes anchored in the V-model framework ensured that every phase of radiation shielding integration was aligned with clinical, technical, and regulatory expectations. These efforts culminate in a comprehensive conclusion that reflects the value of a lifecycle-oriented, interdisciplinary approach to enhancing radiation safety in healthcare environments.

Conclusion

This case study demonstrates the critical role of systems engineering in the successful integration of radiation and procedural shielding within complex clinical environments. By applying a structured, lifecycle-based approach, the study addressed key challenges such as regulatory compliance, interface compatibility, usability, and clinical performance. The use of the V-model framework, stakeholder engagement, and rigorous verification and validation processes ensured that the shielding solutions met both technical and clinical requirements.

The comparative analysis of shielding materials and attenuation performance provided data-driven insights for material selection based on X-ray tube voltage, reinforcing the importance of aligning shielding strategies with procedural demands. Furthermore, the System Lifecycle Mapping framework ensured that shielding integration was not treated as an isolated task but as a continuous process embedded across the entire system lifecycle—from concept to disposal.

Ultimately, this study highlights how systems engineering can bridge the gap between safety, performance, and usability in radiation protection, enabling healthcare providers to deliver high-quality care while safeguarding both patients and clinical staff. Future work should focus on adaptive shielding technologies, real-time monitoring, and digital twin simulations to further enhance radiation safety in evolving medical ecosystems. Pilot studies using digital twins for CT suite shielding optimization and adaptive lead curtain systems in hybrid ORs demonstrate the practical feasibility of these innovations.

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Biography



Sharad Rayguru. Sharad is a Lead Systems Designer at Philips Healthcare India, specializing in systems engineering and model-based systems engineering. He has driven R&D initiatives, enhanced best practices, and conducted impactful research showcasing the value of systems engineering in medical devices R&D. Sharad holds a degree in Mechanical Engineering, a master's in Control Systems, is a member of TLI Cohort 9, and an experienced Systems Engineering practitioner.



Anjana Parakhe. Anjana Parakhe is a System Designer at Philips Healthcare India, where she is involved in system requirements engineering, interface analysis, and productivity enhancement for medical devices. She holds a bachelor's degree in mechanical engineering.