



Establishing a Comprehensive Radiation Oncology Facility in India: Compliance, Safety and Efficiency

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ABSTRACT

The establishment of a comprehensive radiation oncology facility in India is a critical endeavor to address the rising cancer burden and improve patient outcomes. This paper provides a step-by-step guide for setting up a state-of-the-art radiation oncology department, emphasizing compliance with Atomic Energy Regulatory Board (AERB) regulations, optimal facility design, and seamless integration of advanced technologies. Key steps include site layout planning, AERB approvals, construction, equipment procurement, installation, commissioning, and operational licensing. The guide underscores the importance of early involvement of medical physicists and radiation safety officers to ensure regulatory adherence, safety, and efficiency. By incorporating best practices in radiation safety, quality assurance, and staff training, this paper aims to facilitate the creation of world-class radiation oncology centers that prioritize patient safety, operational excellence, and long-term sustainability.

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Introduction

The establishment of advanced radiation oncology departments in India is a critical step in addressing the growing burden of cancer and improving patient outcomes. Given the complex regulatory landscape and the need for state-of-the-art infrastructure, hospitals must adopt a strategic approach to ensure compliance with Atomic Energy Regulatory Board (AERB) regulations while delivering high-quality, safe, and effective radiation therapy.

This paper serves as a guide for hospital managements, consulting medical physicists, and radiation safety officers, outlining the key steps involved in setting up a radiation oncology department. It highlights the importance of early collaboration among stakeholders to facilitate seamless planning, regulatory adherence, and optimal resource utilization. From facility design and equipment procurement to regulatory approvals and quality assurance, this guide provides best practices to create a world-class radiation oncology center that prioritizes patient safety, operational efficiency, and long-term sustainability.

Recruiting medical physicists and radiation safety officers early in the process is crucial for setting up a radiation oncology department in India. Their expertise ensures compliance with AERB regulations, preventing costly delays and legal issues. They provide vital input on facility design, shielding, and infrastructure, optimizing safety and efficiency from the outset.

Their guidance in equipment selection, procurement, and infrastructure planning helps avoid costly mistakes while ensuring regulatory compliance. Establishing safety protocols

early minimizes risks, enhances patient and staff safety, and streamlines commissioning. While radiation oncologists lead clinically, medical physicists and safety officers serve as technical and safety guardians, making their early involvement a strategic investment for a safe, compliant, and efficient department.

A visit to a well-established radiation oncology department with consulting medical physicists, hospital management, and the architect is an extremely valuable step in planning a new facility. Observing patient flow, staff workflow, and equipment utilization provides valuable insights to optimize design, efficiency, and safety. The architect gains a better understanding of integrating radiation therapy equipment, while medical physicists assess shielding effectiveness and safety measures. The team can evaluate technologies like linear accelerators and brachytherapy units, as well as essential infrastructure systems such as HVAC and electrical integration.

Beyond technical aspects, the visit offers lessons in operational efficiency, including patient scheduling, treatment planning, and quality assurance. Learning from experienced professionals fosters knowledge sharing and helps avoid costly mistakes. Hospital management benefits from a clearer vision of the final department layout and functionality. To maximize the visit, structured planning, a prepared list of key questions, and thorough documentation are essential. This firsthand experience enhances decision-making, ensuring the successful design and implementation of a new radiation oncology department.

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Discussion

Site Layout and Planning

The initial phase of planning a radiation oncology department involves the development of a comprehensive site layout that adheres to the safety standards set by the Atomic Energy Regulatory Board (AERB). This process necessitates close collaboration among a multidisciplinary team, including architects, radiation oncologists, medical physicists, biomedical engineers, and hospital management, to finalize a design that is both efficient and functional. The facility must incorporate designated spaces for various critical functions, such as treatment rooms, simulation areas, control rooms, dosimetry labs, patient recovery zones, and waiting areas, all of which are essential for ensuring a seamless workflow and high-quality patient care. Radiation shielding measures must be carefully integrated into the design to minimize

exposure risks for both staff and patients, ensuring compliance with safety regulations.

Before construction can commence, the finalized site layout must be submitted to the AERB through the eLORA (figure 1) (electronic Licensing of Radiation Applications) platform for approval. Any subsequent modifications to the approved plan require additional clearance from the regulatory body to ensure continued compliance with safety standards. To enhance the overall design and operational efficiency of the facility, practical insights and best practices should be gathered from visits to well-functioning radiation oncology departments. These insights can inform the design process, helping to create a facility that not only meets regulatory requirements but also optimizes patient care and operational workflows.

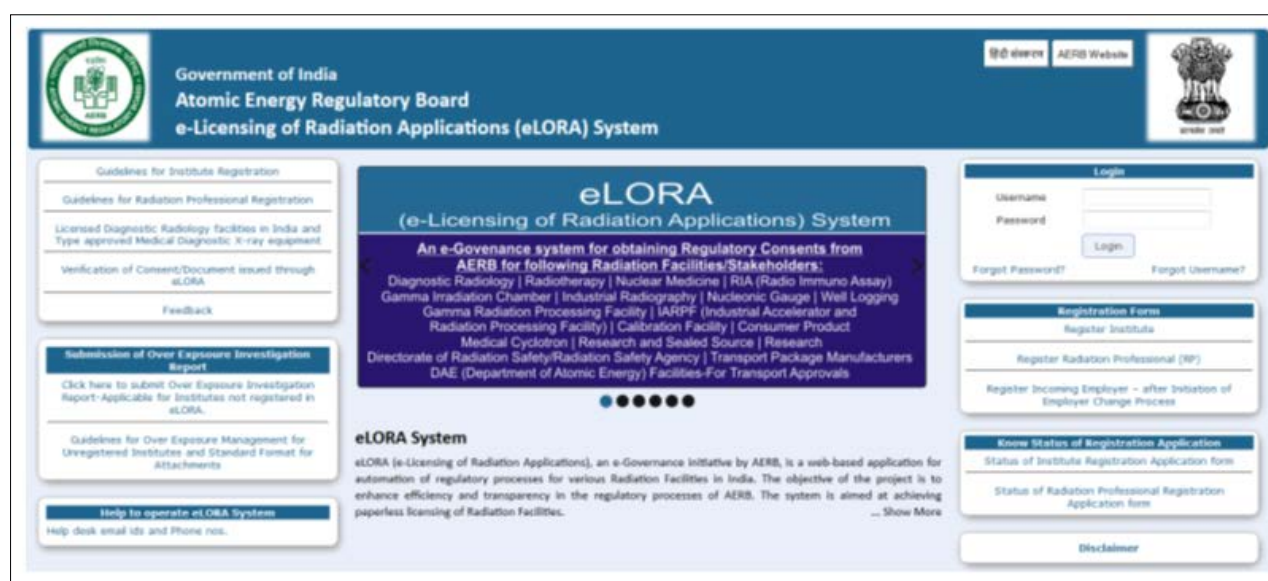


Figure 1: AERB eLORA Website

The planning process must also consider the integration of advanced technologies and future advancements in radiotherapy. The facility should be designed with flexibility in mind, allowing for the incorporation of new equipment or treatment modalities without compromising safety or efficiency. Additionally, designated areas for equipment calibration and quality assurance testing are crucial to maintaining the accuracy and reliability of radiotherapy systems. Emergency preparedness is another critical aspect of site planning, with clearly marked and easily accessible emergency exits and pathways incorporated to ensure swift and safe evacuation if necessary.

Furthermore, the facility's infrastructure must support the complex demands of radiotherapy operations, including the integration of electrical conduits, ventilation systems, and data networks essential for the smooth functioning of equipment and related systems. A well-planned radiotherapy facility not only enhances treatment efficiency but also upholds the highest safety standards, ensuring that the facility remains adaptable, functional, and aligned with the evolving needs of both patients and medical professionals. By incorporating these considerations into the initial planning stages, the facility can achieve a balance between regulatory compliance, operational efficiency, and patient-centered care.

AERB Approval Process for Site Plan

Navigating the AERB approval process for a radiotherapy facility's site plan requires a comprehensive understanding of regulatory requirements and meticulous attention to detail. The application for "Site and Layout Approval" must be submitted through AERB's eLORA system, an online platform designed to streamline regulatory compliance and facilitate the approval process.

The first step involves digital submission, requiring all layout drawings to be converted into PDF format while adhering to AERB's specific naming and formatting conventions. These drawings must be meticulously prepared to ensure compliance with regulatory

guidelines, including proper labeling, scaling, and dimensions. Any deviation from these standards may result in delays or outright rejection. Once submitted, the application undergoes a rigorous review process conducted by AERB to assess adherence to radiation safety standards. This evaluation often necessitates multiple iterations, where additional details or clarifications may be requested before final approval is granted.

Formal approval from AERB is a prerequisite for commencing construction. Any modifications to the approved plan must also be submitted in advance for approval to prevent regulatory penalties. One of the most common pitfalls in this process includes submitting plans in an incorrect format, providing insufficient information in the drawings, or presenting a layout that fails to meet radiation safety standards. To avoid such issues, hospitals must ensure that the selected radiotherapy unit is either type-approved by AERB or has obtained a No Objection Certificate (NOC) for import.

Before construction begins, the finalized site layout plan must be submitted for a thorough review to verify compliance with safety and regulatory standards. AERB will conduct an in-depth assessment, focusing on factors such as radiation shielding, workflow efficiency, and adherence to established safety protocols. If modifications are deemed necessary, the hospital will receive feedback and must revise and resubmit the plan for further evaluation. Construction can only commence once formal approval is granted, ensuring that the facility meets all necessary safety and operational requirements while maintaining compliance with AERB regulations.

Construction Phase

Following the receipt of AERB approval, the construction phase begins, requiring strict adherence to the approved site layout plan. This phase is critical in ensuring the development of a safe and compliant facility, with a primary focus on the proper implementation of radiation shielding. The selection and installation of shielding materials such as concrete, lead, or steel must be carefully executed to construct the treatment vault and other radiation-shielded areas. The thickness and composition of these materials are determined based on the type and energy of the radiation source, making precision an essential aspect of the construction process.

Infrastructure integration must be seamlessly incorporated, with careful planning for the installation of electrical conduits, ventilation systems, and other necessary components that support the operation of radiotherapy equipment. Throughout construction, regular quality control checks must be performed to ensure strict adherence to the approved plan and compliance with both material and workmanship standards. Any deviations from the specified guidelines can lead to safety risks and regulatory complications, making routine inspections a necessary part of the process.

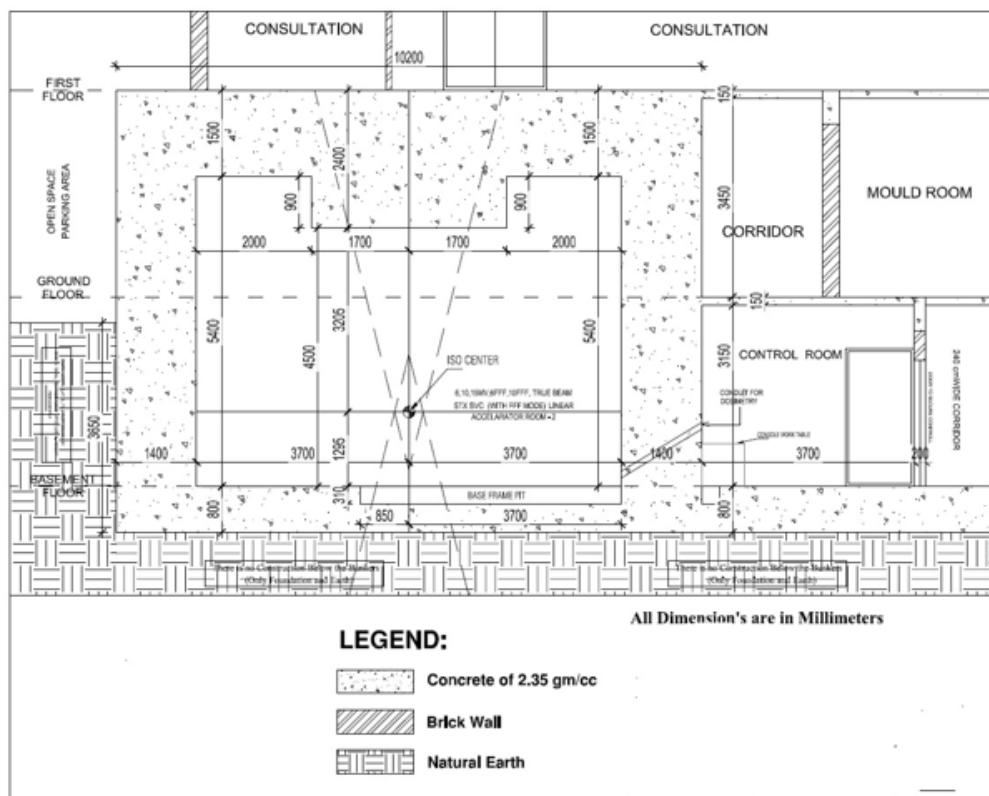


Figure 2: Cross Sectional Plan of Radiotherapy Facility

Meticulous record-keeping is essential, documenting every construction activity, including material specifications, installation procedures, and quality control assessments. These records serve as critical references for AERB inspections and regulatory compliance, ensuring transparency in the construction process. The involvement of experienced contractors with a background in building radiation-shielded facilities is vital, as their expertise minimizes construction errors and enhances overall efficiency.

The construction phase must strictly follow the AERB-approved site layout plan (figure 2), ensuring that all radiation shielding measures are correctly implemented. Regular inspections should be conducted to verify compliance with safety standards and address any potential issues. If structural modifications become necessary during construction, additional approval from AERB must be obtained before making any changes. Proper documentation of the entire construction process should be maintained for regulatory review and future reference. Throughout this phase, consultation with medical physicists and radiation safety officers is crucial to ensure that shielding measures are implemented correctly, providing maximum safety for both patients and staff.

Equipment Procurement and Importation

The procurement and importation of radiotherapy equipment require meticulous attention to AERB's type approval and No Objection Certificate (NOC) requirements. Before placing any orders, it is essential to verify that all equipment is either type-approved by AERB or has a valid NOC. This verification process involves obtaining copies of the relevant certificates from the supplier to ensure compliance with regulatory standards. Selecting reputable suppliers with extensive experience in providing radiotherapy equipment and comprehensive support services is a crucial step in this phase.

Before procuring radiotherapy equipment such as Linear Accelerators, Telecobalt units, Brachytherapy systems, Simulators, and CT-Simulators, the hospital must secure authorization from AERB through the eLORA system. If the equipment is being imported, additional approvals are required to guarantee adherence to Indian radiation safety standards. To proceed with procurement authorization, a certified Radiation Safety Officer (RSO Level III) must be appointed, as this is a mandatory prerequisite. The procurement request, along with all necessary technical documents, must be submitted via eLORA for review and approval before the equipment can be shipped. Consulting medical physicists throughout this process is essential, as their expertise ensures the selection of radiation therapy equipment that meets both clinical and safety requirements.

If the equipment is imported, all procedures must strictly follow AERB's guidelines, which include obtaining import licenses and permits. Prior authorization for procurement is mandatory for all radiotherapy equipment and radioactive sources to ensure compliance with national regulations. Careful evaluation of equipment specifications, performance characteristics, and compatibility with the existing hospital infrastructure must be conducted before finalizing any purchase. Long-term maintenance and support capabilities of the equipment supplier should also be assessed to guarantee the reliability and functionality of the equipment over its operational lifespan.

Equipment Installation and Staffing

Once the radiotherapy equipment has been procured, attention shifts to the installation process and staffing requirements, both of which are crucial for ensuring safe and effective operations. The installation of the equipment must be closely supervised by qualified engineers and medical physicists to ensure strict adherence to both manufacturer specifications and AERB safety guidelines. Vendor-provided engineers should lead the installation, ensuring that all technical specifications are fully met. This supervision guarantees that the installation complies with the necessary safety standards and regulations, setting a solid foundation for the operational phase.

As the installation progresses, the hospital must recruit and appoint a sufficient number of qualified personnel, including radiation oncologists, medical physicists, and radiation therapy technologists. These professionals must meet the qualification and experience requirements outlined in the AERB Safety Code SC/MED-1 to ensure they are capable of safely operating the equipment. A qualified medical physicist must also be designated as the Radiological Safety Officer (RSO), and this appointment requires AERB's approval before the installation can be considered complete.

Personnel monitoring is a vital aspect of this phase, as all radiation workers are required to wear Thermoluminescent Dosimeter (TLD) badges to monitor their radiation exposure. These badges must be obtained from an AERB-accredited agency, and training on their proper use is mandatory for all staff. In addition to personal monitoring, the hospital must develop and implement comprehensive training programs for all personnel, covering radiation safety, equipment operation, and emergency procedures.

Before the equipment becomes operational, the hospital must notify AERB within 15 days of receiving the equipment. Additionally, the installation must comply with AERB regulations and the equipment must receive commissioning approval from AERB prior to use. Biomedical engineers play an essential role in ensuring that the installation process is executed smoothly, meeting all necessary standards to facilitate the safe operation of the equipment. By ensuring a qualified workforce, proper equipment setup, and comprehensive training, the hospital establishes the necessary framework for safe and effective radiotherapy operations.

Radiation Safety Survey

Before clinical operations can begin, a thorough radiation safety survey is essential to verify the effectiveness of the shielding and ensure compliance with radiation safety standards. This survey must be conducted by a qualified medical physicist who uses calibrated radiation survey meters to measure radiation levels throughout the facility. The survey should cover all areas, including those where radiation exposure is possible, to guarantee that shielding measures are working effectively.

The results of the radiation safety survey must be compared with the original design calculations to evaluate the shielding's performance. If any discrepancies or deficiencies are identified, they must be addressed immediately to ensure the facility meets

the required safety standards. The findings of the survey must be documented in a detailed report, which includes the procedures used, the results of the measurements, and any corrective actions taken. This report must then be submitted to the AERB for approval.

In addition to shielding effectiveness, the survey must also measure leakage radiation from the equipment and scattered radiation in the surrounding environment. These measurements are crucial to assess potential radiation exposure risks that could affect staff and patients. After the survey is completed and all necessary corrective actions are made, the report, along with any required revisions, must be submitted via the eLORA system for AERB's review and approval. Only after receiving formal approval from AERB can the facility proceed with further commissioning tests and clinical operations, ensuring that all radiation safety protocols have been met and the facility is fully compliant with regulations.

Machine Commissioning

Machine commissioning is a critical process that ensures the accuracy, reliability, and safety of radiotherapy equipment. This process involves a series of precise steps aimed at calibrating the equipment and verifying its operational performance. Qualified medical physicists must oversee the commissioning, using standardized procedures and protocols to measure key parameters such as beam characteristics, radiation output, and dosimetric performance. High-precision instruments, including ionization chambers, electrometers, and phantoms, are employed to assess the equipment's performance, ensuring that the radiation delivered matches the prescribed treatment parameters.

In addition to these measurements, quality assurance (QA) tests are conducted throughout the commissioning process to ensure the equipment's long-term reliability and accuracy. These tests are designed to verify that the equipment consistently performs to the required safety standards, providing accurate radiation doses for patient treatment. The data collected during the commissioning process, including detailed reports and calibration results, must be carefully documented and submitted to the AERB via the eLORA system for thorough evaluation.

AERB will review the submitted commissioning data to confirm that the equipment complies with all regulatory standards. The equipment cannot be used for clinical purposes until it receives formal approval from AERB, which guarantees that it is safe and effective for patient care. The commissioning process must also involve the development of treatment planning protocols and quality assurance procedures, ensuring that the facility has established clear guidelines for safe and effective radiotherapy treatments.

Application for Operational License

After successfully completing machine commissioning and conducting a thorough radiation safety survey, the next step is to apply for an operational license from the AERB before beginning patient treatment. This application must be submitted through the eLORA system, which is the online platform for regulatory submissions. The process of applying for an operational license involves submitting a comprehensive set of documents that

demonstrate the facility's compliance with all safety and regulatory requirements. These documents should include the detailed commissioning report, radiation safety survey report, proof of staff qualifications, and any other documentation that verifies the facility's readiness to safely deliver radiotherapy services.

The AERB will carefully review these documents to ensure that the facility meets all the necessary safety standards. In some cases, the AERB may conduct an on-site inspection before granting the operational license. This inspection will verify that the equipment is installed correctly, that safety protocols are in place, and that the staff is adequately trained to handle radiotherapy procedures.

Once the application is reviewed and the inspection is completed, the AERB will issue the operational license, authorizing the facility to commence patient treatments. This license is crucial for the facility's ability to operate legally and safely, as it confirms that the facility meets all necessary safety, technical, and regulatory standards. However, the operational license is not a one-time requirement. To ensure the continued safe operation of the facility, it must be periodically renewed. This renewal process involves regular updates to safety protocols, quality assurance procedures, and equipment calibration to ensure that the facility remains in full compliance with AERB guidelines. Regular reviews of the facility's operational standards, staff qualifications, and safety measures are necessary to maintain the license and ensure ongoing patient and staff safety throughout the life of the facility.

Clinical Operations and Patient Safety

Once the operational license is granted, the focus shifts to the commencement of clinical operations, with patient safety being the highest priority. This stage involves the implementation of stringent protocols and systems to ensure that both patients and staff are protected, and that radiotherapy treatments are delivered accurately and consistently. The foundation of safe clinical operations begins with the development and implementation of standardized treatment planning procedures. These procedures are essential for ensuring that each patient receives precise and personalized treatment, minimizing the risk of errors in dose calculation and treatment delivery. By adhering to these standardized procedures, the facility can maintain high levels of treatment consistency, thereby reducing variability and ensuring optimal outcomes for every patient.

A comprehensive quality assurance (QA)^{5,10} program must be established to regularly monitor both equipment performance and the accuracy of treatment delivery. This program is vital to identify any potential issues with the radiotherapy equipment before they affect patient care. It includes routine checks, maintenance schedules, and calibration procedures to ensure that all machinery operates within the required safety and performance standards. Regular QA activities also include evaluating the efficacy of treatment plans and the precision of radiation delivery, ensuring that treatments align with the prescribed protocols.

Alongside quality assurance, patient monitoring during and after treatment is an essential part of clinical operations. Patients must be closely observed for any adverse effects or complications arising from their treatment. A system for tracking any side effects or issues that arise is crucial for timely intervention and management. This involves maintaining a comprehensive

record of each patient's treatment history, including treatment plans, dose calculations, and any deviations from the initial plan. Detailed documentation ensures that all aspects of the treatment process are accurately recorded, which is vital for ongoing care and future treatments.

In addition to treatment protocols, patient safety is further reinforced through the establishment of clear safety protocols and procedures. These protocols encompass patient identification, treatment verification processes, and emergency response plans to ensure that patients receive the correct treatment in a safe environment. Verification procedures, such as double-checking treatment plans and conducting regular safety audits, play an essential role in minimizing the risk of errors.

Throughout clinical operations, radiation oncologists and medical physicists must collaborate closely to review and verify treatment plans. The oncologists are responsible for ensuring that each patient receives the correct radiation dose and that the treatment plan aligns with the clinical objectives. This collaborative approach helps maintain the highest standards of care while safeguarding patient safety. Additionally, the facility must continuously monitor radiation exposure levels to ensure compliance with safety standards, and regular safety audits must be conducted to assess overall risk management.

Finally, it is important to remember that the operational license must be periodically renewed according to AERB regulations. This ensures that the facility remains in full compliance with regulatory requirements and continues to meet safety standards throughout the life of its operations. Regular reviews of safety protocols, quality assurance procedures, and equipment calibration must be performed to maintain the integrity of the facility's operations, ensuring ongoing patient and staff safety.

Radiation Safety and Protection

Radiation safety and protection are fundamental aspects of any radiotherapy facility, requiring strict protocols and continuous vigilance to protect staff, patients, and the public from potential harm. The successful implementation of these safety measures involves several key processes, all aimed at ensuring radiation exposure remains within permissible limits and any potential incidents are swiftly addressed.

One of the core components of radiation safety is regular monitoring. This involves frequent dosimetry assessments to measure radiation exposure levels throughout the facility. These assessments ensure that the radiation levels in treatment areas, control rooms, and surrounding environments are consistently within safe limits as defined by regulatory authorities. Monitoring also helps to identify any anomalies in radiation emissions, allowing for prompt corrective actions. Staff members are required to wear personal dosimeters to track their individual exposure, providing an additional layer of protection and monitoring.

In addition to routine monitoring, staff training is an essential part of radiation safety. Healthcare professionals, including radiation oncologists, medical physicists, radiation therapy technologists, and all other personnel working in the radiotherapy department, must undergo continuous education on radiation safety protocols. This training should cover the proper handling of radioactive materials, emergency procedures in the event of a radiation

spill or exposure, and guidelines for minimizing exposure during treatment. The facility must also ensure that all staff members are trained in using personal protective equipment (PPE) and are aware of the emergency response plans in place.

The Radiation Safety Officer (RSO) plays a pivotal role in overseeing all radiation safety activities within the facility. The RSO is responsible for ensuring that the safety measures outlined in the radiation protection protocols are consistently followed. This includes the verification of radiation dose calculations to ensure that the prescribed treatment doses are accurately delivered. The RSO also conducts regular audits to assess the compliance of the radiotherapy department with safety regulations and the facility's internal radiation safety protocols. This involves reviewing all safety documentation, such as calibration reports, equipment maintenance logs, and radiation safety monitoring records, to ensure traceability and accountability.

In addition to audits, regular safety audits of the entire facility are required to verify compliance with local and national radiation safety standards, such as those outlined by AERB. These audits evaluate the overall effectiveness of radiation safety measures, ensuring that all equipment is functioning within acceptable limits, safety barriers are properly installed, and shielding measures remain intact. Staff training, audits, and safety compliance verification are ongoing processes that reinforce the importance of radiation safety and protection within the facility.

The RSO, along with other members of the safety team, must also ensure that an effective emergency response plan is in place and understood by all staff members. In the rare event of a radiation incident, the plan must outline specific actions to be taken to contain the situation, prevent further exposure, and manage the medical and operational aspects of the incident. This includes emergency shutdown procedures, evacuation plans, decontamination protocols, and coordination with emergency services.

Accurate and thorough documentation is a critical component of radiation safety. All calibration records, safety audits, quality assurance reports, and monitoring results must be meticulously maintained. These records not only provide a comprehensive history of safety measures and compliance but also serve as a reference during AERB inspections or in the event of any regulatory scrutiny.

Ultimately, continuous monitoring, staff education, regular audits, and RSO oversight form the backbone of a robust radiation safety program. By maintaining these practices, the facility can ensure a safe environment for both patients and staff, minimizing the risks associated with radiation exposure and ensuring the facility operates in full compliance with regulatory requirements.

Ongoing Support and Training

Ongoing support and training are essential for maintaining high standards in radiation oncology. This involves providing continuous education to staff on new technologies, treatment techniques, and updated radiation safety procedures. Keeping the team informed about the latest advancements in radiation oncology ensures that they remain proficient in utilizing cutting-edge equipment and delivering optimal patient care.

In addition to training, expert consultation is offered to assist with complex clinical cases and technical challenges. This support helps ensure accurate treatment planning and decision-making. Troubleshooting equipment issues promptly and providing technical support are also critical components, ensuring minimal disruption in operations and maintaining the effectiveness of radiotherapy treatments. Regular support and training help sustain the competence of staff while ensuring that the facility remains compliant with safety standards and provides the highest level of patient care.

The efficacy of cancer treatment is drastically reduced by radiotherapy machine downtime, and this is compounded when no backup machine is available, therefore a deep dive into root causes, including subsystem malfunctions and environmental factors, is required. To mitigate these disruptions, radiotherapy departments must prioritize proactive measures, including rigorous preventive maintenance schedules, quality assurance protocols tailored to equipment usage, the integration of robust backup systems, and comprehensive staff training. Implementing these strategies will not only minimize downtime but also enhance patient outcomes by ensuring the uninterrupted and consistent delivery of critical cancer therapies.

Conclusion

The establishment of a radiation oncology facility in India is a multifaceted process that demands meticulous planning, adherence to regulatory standards, and collaboration among diverse stakeholders. By following the structured approach outlined here, hospitals can ensure the creation of a safe, efficient, and technologically advanced department capable of delivering high-quality cancer care. Early involvement of medical physicists and radiation safety officers, coupled with rigorous quality assurance and ongoing staff training, is pivotal to achieving regulatory compliance and operational excellence. As India continues to combat the growing cancer burden, the implementation of such comprehensive radiation oncology facilities will play a transformative role in improving patient outcomes, enhancing safety, and setting new benchmarks in cancer treatment. Hope this guide serves as a roadmap for hospitals aspiring to establish world-class radiation oncology centers, ultimately contributing to the advancement of cancer care in the country [1-11].

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