2023 SAFETY MANAGEMENT PLAN
FOR
RADIOACTIVE MATERIALS AND RADIATION SOURCES

I. Introduction

The Radiation Safety Management Plan defines the mechanisms for oversight for controlling exposures to radioactive materials and radiation sources in the workplace at Duke University Medical Center and the applicable Duke Primary Care sites. The Joint Commission related policies and Duke University Health System (DUHS) procedures are developed to provide guidance for worker safety, and are based on regulatory requirements and current safety guidelines.

II. Organization of Participants

The administration and oversight of occupational safety management for handling radioactive materials and ionizing radiation sources is primarily the responsibility of the **Radiation Safety Committee** for Duke University Medical Center (**MCRSC**). The Radiation Safety Officer (RSO) for Duke University reports to the Committee (**MCRSC**) and supervises the activities of the Radiation Safety Division of the Occupational and Environmental Safety Office (OESO). OESO provides administrative support for the Radiation Safety Division. The RSO also reports to the **Duke University Safety Committee** (**DUSC**) on any Joint Commission or radiation safety related issues in the Duke University Hospital or Clinics.

The administration and oversight of lasers is primarily the responsibility of the **Clinical Use Laser Safety Committee** (**CULSC**). The CULSC reports to the MCRSC.

The administration and oversight of intentional therapeutic and diagnostic patient exposures to radiation is the responsibility of the Hospital Departments of Radiation Oncology and Radiology, in coordination with the Division of Radiation Safety.

III. Management

The primary policies for managing radiation hazards are found in the *Radiation Safety Manual for Duke University and Duke University Medical Center*, the *Laser Safety Policy Manual* and the *Radiation Safety Division Policies and Procedures*. These policies and procedures will be adapted to the applicable DUAPs in consultation with DUAP staff.

IV. Radiation Safety Management Activities

A. Reporting. Specific reporting responsibilities on Joint Commission related issues include seeking DUSC review and approval of the planning objectives of the Radiation Safety Division, along with a mid-year summary of progress toward accomplishing those objectives. The DUSC also approves Performance Improvement (PI) activity for the Division, along with the reporting of the monitoring results, and routine reporting of safety management activities. The RSO reports to the MCRSC regarding regulatory and licensing issues.

B. Policy Development and Periodic Review. All policies related to the management of radiation and radioactive materials in the workplace are submitted to the MCRSC and the DUSC for consideration and approval.

C. Planning Objectives. The Director of the Radiation Safety Division is responsible for the development of annual Planning Objectives for the Division. These objectives are developed in accordance with the mission of the Institution, any applicable laws or regulations, and all relevant accreditation standards; they define the focus for resource utilization by the Division. Some of these objectives may include measurable outcomes, and thus may be adopted as performance standards for the Division. The Radiation Safety Planning Objectives are submitted to the Duke University Safety Committee (DUSC) for annual approval.

D. Incident Reporting/Emergency Response.

1. **Incident Reporting**. All occupational exposures to or injuries from radiation sources, lasers or radioactive materials are to be reported by employees to the Radiation Safety Division. Exposure definitions and follow-up procedures are included in the DU / DUMC *Radiation Safety Manual* and *Laser Safety Policy Manual*. The Radiation Safety Division evaluates reported exposures and monitors trends. Many of the Planning Objectives and PI Projects of the Division involve routine evaluation and improvement activities aimed at reducing such exposures. Unintentional patient or visitor exposures to radioactive materials are investigated by the Department employing the radiation sources, in collaboration with the Radiation Safety Division. Unintentional patient or visitor exposures to lasers are investigated by the Department employing the radiation sources, in collaboration with the Radiation Safety Division, the Departments of Clinical Equipment and Risk Management. Reporting of radiation or laser incidents to the hospital leadership is accomplished through the MCRSC and the DUSC.

The Radiation Safety Division collaborates with other management entities in the Health System, including Perioperative Services, Radiology, Radiation Oncology and Pharmacy in using the on-line Safety Reporting System to document incidents involving radioactive material, radiation sources and lasers that occur in the clinical setting.

2. **Emergency Response**. Information regarding spills of radioactive materials is provided in the DU / DUMC Radiation Safety Manual, and the department-specific radiation safety policies for the Division of Nuclear Medicine and the Department of Radiation Oncology. Radiation Safety Division staff provide rotating on-call coverage at all times. Supplementary information regarding the response of hospital employees and Radiation Safety Staff to radiation contingencies (including spills, waste monitor alerts, fires, injuries, exposures during pregnancy, and Code Blue procedures) has been made available on the OESO Web site.

Emergency Medical Services possesses a "portal monitor" to facilitate rapid surveillance of patients potentially contaminated with radioactive material as the result of an industrial accident or a terrorist-launched radioactive dispersal device ("dirty bomb"). The Radiation Safety Division supports the Emergency Department by (a) performing initial operational checks on the equipment; (b) developing procedures and brief written "quick reference" guides for attachment to the monitor; (c) Integrating into ED response training; and (d) providing operational support.

In response to 2005 published directives from the US Nuclear Regulatory Commission (NRC) and their incorporation into 10 CFR Part 37, the Radiation Safety Division implemented a management system for increased control of access to and operation of encapsulated radiation sources that contain quantities of radioactive material that exceed NRC's "quantities of concern". Management activities included development of an on-line personnel registry, developing and implementing criteria for personnel access, and training users of sources and the Duke Police regarding safety, security and emergency response issues.

E. Training. Policies and procedures for handling radioactive materials and for caring for patients with radioactive implants or internally-deposited radionuclides are included in the new employee Orientation and annual update training programs. Orientation training includes all required training, such as hazards, selection of personal protective equipment, exposures and reporting, spill clean ups, regulations, and

Methods of exposure control specific to Duke. Update training programs utilize information gathered from audits, exposure data, and PI projects that reflect experience with change in risk or control procedures. Radiation Safety Orientation Training for biomedical research workers and nursing staff is available on-line on the OESO Web site. The Radiation Safety Division conducts didactic and Web-based training in the safe use of medical and research laser systems.

F. Maintenance of Documentation. The Radiation Safety Division maintains documentation of all State permits and licenses for the medical and academic use of radiation sources and radioactive materials. This includes periodic renewal of licenses and amendment of license conditions where necessary to accommodate the needs of the clinical users. The Division maintains documentation of employee occupational exposure to ionizing radiation. In collaboration with the MCRSC and the Radioactive Drug Research Committee, the Radiation Safety Division submits quarterly and annual reports to the Food and Drug Administration regarding research radiopharmaceuticals.

G. Monitoring Compliance. Radiation Safety Division Staff conduct periodic audits of clinical areas and research laboratories that employ radiation sources and radioactive material to ensure compliance with State, Federal and local laws, and institutional policies as set by the MCRSC. Findings of monitoring programs, including personnel external dosimetry and bioassay, are reported to the MCRSC and, where appropriate, the DUSC. Radiation Safety Division staff also conduct periodic audits of clinical laser use areas and formal hazard evaluations of laser systems, in accordance with ANSI Standards and institutional laser safety policies.

V. PerformanceMonitoring.

Performance Improvement Plan. The Director of the Radiation Safety Division is responsible for development of the Performance Improvement Plan, which is based on the priorities identified by the Division, the MCRSC and the DUSC. All plans are developed in collaboration with the Office of Accreditation and Patient Safety to assure that the PI activities are appropriately integrated into the Quality Improvement Plan for Duke University Hospital. The DUSC approves the Plan each year, and all PI activity is reported to the DUSC.

Effectiveness Monitoring. In addition to the PI activities and reporting, the effectiveness of the Radiation Safety management program is assessed through a number of audits and inspections. All hospital inpatient units, clinics, and support departments are subject to a comprehensive safety audit on a bi-annual basis. These audits (Joint Commission Mock Surveys) assess the hazards, the control measures, and employee knowledge regarding radiation safety in the workplace.

Performance Improvement Standards. Many of the Planning Objectives of the Radiation Safety Division include measurable outcomes, and establish Performance Improvement Standards for the handling of radioactive materials. The Performance Improvement Standards for the handling of radiation hazardous materials in the workplace include the following:

2023 Objectives – The primary planning objectives for the Radioactive Materials Management Plan in 2023 are as follows:

- Continue to support institutional efforts to comply with NRC's orders for increased security of high-activity encapsulated radiation sources.
- Continue to monitor compliance of posting requirements for clinics and laboratories where radioactive materials are used or stored.
- Continue to monitor the effectiveness of periodic inspections of clinical and research laboratories.
- Continue to support the medical use of radionuclides, and to ensure compliance with regulations governing the release of patients containing radioactive material.
  Specifically, data is being collected regarding patient release to the community that will facilitate planning to minimize radiation exposure to the community and the environment.

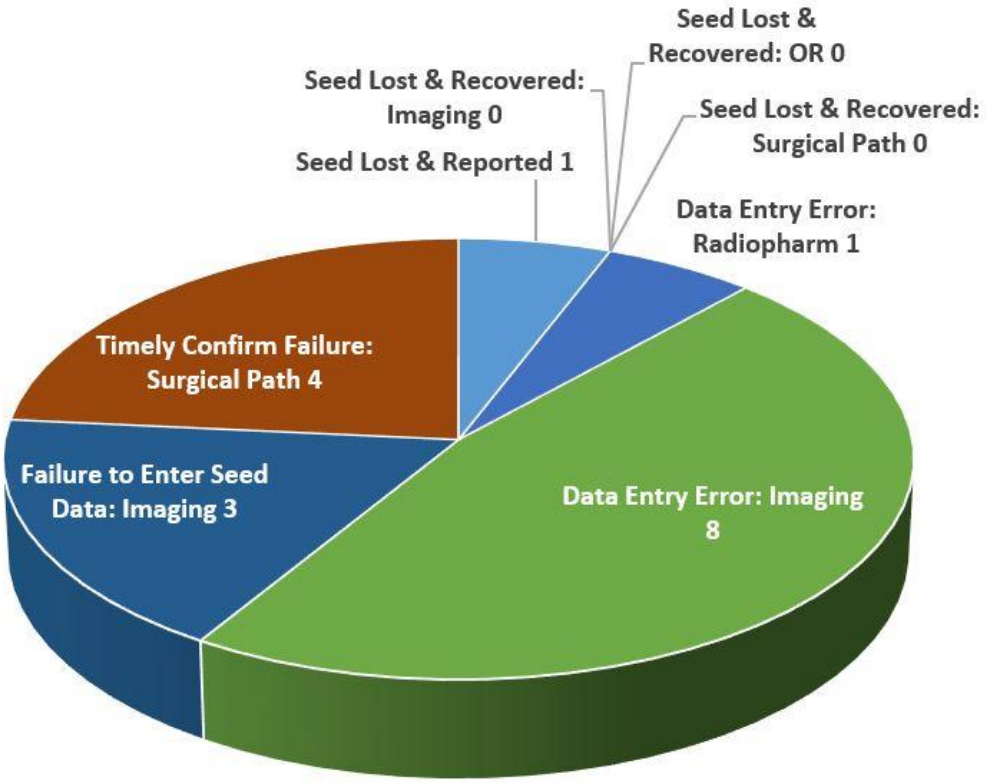
- Continue to assist the Nuclear Medicine Division and the Clinical Imaging Physics Group in updating or establishing institutional policies and practices that ensure compliance with the applicable Joint Commission EOC standards for radiology facilities.
- Continue to provide consultative services regarding radiation and laser protection to faculty and staff of Duke University Medical Center, Durham Regional Hospital, Duke Raleigh Hospital, and associated Duke Facilities and outside institutions.

2023 Performance – Our performance improvement efforts for 2023 will focus on regulatory compliance issues involving the loss of control of encapsulated radiation sources that are used in radioactive seed localization (RSL) procedures. RSL procedures involve the implantation of tiny radioactive "seed-type" sources into non-palpable breast or body masses under imaging guidance, with subsequent detection in the operative suite using a hand-held radiation detector. The goals of RSL are to reduce the amount of tissue excised during the biopsy, and to provide a better experience for the patient compared to the wire localization technique. The size of the seeds (longest dimension = 4 mm) poses the hazard of loss in the Surgical Pathology suite, where they must be removed from specimens prior to processing. Seeds that are declared lost must be reported to the state radiation control agency, resulting in a significant expense in terms of Surgical Pathology and Radiation Safety staff time, disruption of normal activities and the possibility of unnecessary radiation exposure to staff or the environment. The goal of our 2023 Performance Improvement initiative is to reduce seed loss. Our initial intervention will be to assign a Radiation Safety staff member to continuously monitor the pathway of seeds (Imaging to OR to Surgical Pathology to the regulated waste stream) in our on-line "Seed Tracker" software. The intent is to actively alert Surgical Pathology staff to anomalies in seed tracking. We began this intervention in January 2023 and will use pre-2023 seed tracking data as a baseline to evaluate effectiveness of our intervention. Data collection will focus on identifying "near misses" of and the types and frequencies of near misses that contribute to seed loss.

2022 Effectiveness – The effectiveness in implementing the 2022 planning objectives for the Radioactive Materials Management Plan is as follows:

The chart below shows the types of errors that were identified in 2022 and the frequencies with which they occurred. Although 65% (11/17) of the tracking errors are due to patient and seed data entry errors in Mammography, they have little contribution to actual seed loss. Their adverse effect is mostly the delays and time spent correcting the errors. A common tracking error is failure to confirm the receipt of seeds by Surgical Pathology. This error has contributed to seed loss in the past and should be the focus of identifying and preventing errors.

Distribution of Radioactive Seed Tracking Errors in 2022



VI. Management Plan Evaluation. The Radiation Safety Officer (RSO) will evaluate the Hazardous Radioactive Materials Management Plan annually for its scope, objectives, performance, and effectiveness. Any changes in *scope* will be addressed during the annual update of the Plan, and any changes in the range of application or interactions will be incorporated into the updated Plan. Annual planning *objectives* will be developed through interactions with DUSC members and hospital administration. These objectives will address the primary operational initiatives for maintaining and enhancing the "safety" of the Environment of Care. Progress toward accomplishing these objectives will be reported at least quarterly to the Committee and a year-end summary of the *effectiveness* in accomplishing these objectives will also be presented. The *performance* of the Plan will be assessed through progress in achieving the Performance Improvement Standards defined within the Plan. The annual evaluations, updates, and planning efforts will be presented for Committee review and action during the first quarter of the new calendar year. This information will be provided to the Governing Body through the routine reporting channels.