University of Maryland Baltimore

Radiation Safety Procedure

Procedure Number: 4.2

Title: Control and Optimization of Patient Exposure

Revision Number: 0

Effective Date: October 1, 2001

Technical Review and Approval:

_____ **Date:**_____
Radiation Safety Officer

Radiation Safety Committee Approval:

_____ **Date:**_____
Chair, Radiation Safety Committee

PROCEDURE 4.2, CONTROL AND OPTIMIZATION OF PATIENT EXPOSURE

1.0 Purpose:

This procedure provides guidance for controlling exposure to patients who are exposed to ionizing radiation for therapeutic or diagnostic purposes.

2.0 Scope:

This procedure applies to all uses of ionizing radiation for medical diagnoses or therapy.

3.0 Procedure:

3.1 Responsibilities for Medical Exposure

3.1.1 Patient treatment or diagnosis using sources of radiation will be prescribed only by physicians authorized by the Radiation Safety Committee.

3.1.2 Calibration, dosimetry and quality assurance requirements for radiation diagnosis and therapy are conducted by or under the supervision of a qualified expert in the appropriate areas of medical physics.

3.1.3 Authorized users must make arrangements to ensure an adequate number of trained personnel to discharge assigned tasks.

3.2 Justification of Medical Exposures

3.2.1 The therapeutic and diagnostic benefits of radiation exposure will be weighed against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

3.2.2 Each radiation exposure of humans for medical research will be approved by the Institutional Review Board and the Radiation Safety Committee.

D

3.3 Optimization of Patient Protection

3.3.1 Device for medical exposures:

- Radiation producing devices will conform to applicable standards of the Food and Drug Administration (FDA), the International Electrotechnical Commission (IEC) and the International Organization for Standardization or to equivalent standards as appropriate.

- Performance specifications and operating and maintenance instructions, including protection and safety instructions, will be provided to the users of radiation producing equipment and radioactive sources;

- Where practicable, the operating terminology (or its abbreviations) and operating values will be displayed on operating consoles.

3.3.2 Calibration

- Calibration of sources used for medical exposure will be traceable to a Standards dosimetry laboratory.

- Radiotherapy and diagnostic equipment calibration will be determined and recorded in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions.

- For calibration of a sealed source use and record a reference date, and for radioactivity measurement use at a specific distance either air kerma or absorbed dose rate in a specific medium per recommendations of the AAPM (American Assciation of Physicists in Medicine).

- Calibration will be carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals specified by regulation or by the Radiation Safety Committee.

3.3.3 Clinical dosimetry

- In radiological examinations, representative values will be used for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses.

- For each patient treated with external beam radiotherapy equipment, the authorized user will determine and document the absorbed doses to the treatment area.

- For brachytherapy, the authorized user will determine and document the absorbed doses at selected relevant points in each patient.

3.4 Quality Assurance for Medical Exposure

The University of Maryland, Baltimore has adopted quality management implementing procedures to meet the following specific objectives.

3.4.1 Written Directive

Prior to administration, a written directive will be prepared for:

- Any brachytherapy radiation dose;

- Any administration of quantities greater than 30 microcurie of either sodium iodide I-125 or I-131; or

- Any therapeutic administration of a radiopharmaceuticals, other than sodium iodide I-125 or I-131;

3.4.2 Patient identification

Prior to each administration, the patient's or human research subject's identity will verified by more than one method.

3.4.3 Final treatment plans

Final plans of treatment and related calculations for brachytherapy, teletherapy, and stereotactic radiosurgery will be in accordance with the respective written directives;

3.4.4 Administration of radiation

Each administration will be in accordance with the written directive.

3.4.5 Unintended deviations

Any unintended deviation from the written directive will be identified and evaluated, and appropriate action will be taken.

D

3.5 Investigation of Accidental Medical Exposure

3.5.1 The Radiation Safety Officer will be notified of and will promptly investigate any of the following incidents:

- Any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;

- Any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and

- Any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

3.5.2 The user, with the RSO, will calculate or estimate the doses received and their distribution within the patient.

3.5.3 The user, with the RSO, will indicate the corrective measures required to prevent recurrence of such an incident.

3.5.4 The user, with the RSO, will implement all the corrective measures that are under their own responsibility.

4.0 Records and Reports

4.1 Records

Records will be created and maintained consistent with the requirements of Procedure 1.2, *Radiation Safety Records*.

4.2 Reports

Notifications and reports will be prepared and filed in accordance with Procedure 1.3, *Radiation Safety Reports*.

D

5.0 References:

Code of Maryland Regulation (COMAR) 26.12.01.01
FDA Regulations 21 CFR 800 to 1299
Maryland License MD-07-014-01
UMB Radiation Safety Program