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59TH MEDICAL WING

59TH MEDICAL WING INSTRUCTION
48-104

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MEDICAL AND DENTAL IONIZING RADIATION PROTECTION

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This instruction implements Air Force Policy Directive 48-1, *Aerospace and Operational Medicine Enterprise* and AFMAN 48-148, *Ionizing Radiation Protection*. This medical wing instruction (MDWI) establishes procedures for the safe use of all medical and dental radiography equipment at the 59th Medical Wing (MDW). This instruction applies to all personnel assigned, attached, or under contract to the 59 MDW (with the exception of individuals/organizations in which the 59 MDW only exercises Administrative Control and Operational Control is exercised by other command authorities) or any other functional unit that produces and/or utilizes ionizing radiation within the 59 MDW. This instruction does not apply to the Air National Guard or Air Force Reserve. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. Requests for waivers must be submitted to the OPR listed above for consideration and approval. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW Air Force Manual (AFMAN) 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System (AFRIMS) Records Disposition Schedule (RDS).

SUMMARY OF CHANGES

59 MDWI 48-104 has been revised. Changes made include: Removal of sections taken directly from AFMAN 48-148. Updated Medical Director of Radiology requirements. Removes the requirement for a Radiation Safety Committee (RSC) since the 59 MDW does not have a Medical Radioactive Material (RAM) permit anymore and does not use RAM to diagnose or treat patients. Changes the title of RSO from Site Associate RSO to Wing RSO to better reflect the unit RSO

concept in AFMAN 48-148 and to differentiate from Associate RSOs in DHA-AI 087 which is associated directly with a RAM permit. Introduces the concept of a Unit Radiation Safety Officer whereby personnel in each section utilizing machine produced radiation assists the Wing radiation safety program.

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Chapter 1

GENERAL ROLES AND RESPONSIBILITIES

1.1. 59th Medical Wing Commander.

1.1.1. Appoints, in writing, a Wing Radiation Safety Officer (RSO) and alternate Wing RSO for the 59 MDW.

1.1.2. Delegates authority to the Wing RSO to appoint unit radiation safety officers (URSOs) as described in **paragraph 1.6**.

1.1.3. Ensures adequate resources and staffing are available to establish and maintain an effective Radiation Safety Program (RSP).

1.2. Workplace Supervisors of Medical/Dental Radiation Workers/Operators.

1.2.1. Ensure workplace compliance with this instruction, and other pertinent radiation regulations/accreditation requirements in consultation with the Wing RSO.

1.2.2. Ensure workplaces establish written processes aimed at ensuring the safe, effective, and efficient medical/dental use of ionizing radiation. Ensure Wing RSO reviewed/approved these processes before implementation.

1.2.3. Coordinate activities that significantly impact radiation producing device inventory, ionizing radiation usage, engineered radiation controls (e.g., lead shielding), and surrounding area occupancy with the Wing RSO prior to execution.

1.2.4. Promptly notifies the Wing RSO of adverse incidents involving radiation. Provide a written report to the Wing RSO before close of business the next duty day.

1.2.5. Ensure designated radiation workers complete Wing RSO approved initial and annual radiation safety (ALARA) training. Supervisors ensure training completion is appropriately documented.

1.2.6. Ensure all personnel responsible for the application of medical/dental radiation to patients meet the minimum standards for knowledge, skill and experience as outlined in this instruction and AFMAN 48-148, *Ionizing Radiation Protection*.

1.2.7. Ensure all personnel who operate fluoroscopy systems (excluding microampere systems) complete initial and annual ALARA training and fluoroscopy users training utilizing training approved by the Wing RSO. Ensure personnel compliance with other radiation operator's training requirements deemed necessary by the Wing RSO. Supervisors will encourage approved hands-on training when such training is deemed optional by the Wing RSO. Supervisors will ensure completion of this training is appropriately documented.

1.2.8. Support the personnel radiation dosimetry program.

1.2.8.1. Ensure monitored personnel comply with the program.

1.2.8.2. Facilitate the timely exchange of dosimetry devices and promptly notifies the dosimetry manager if any dosimetry device is damaged, lost, or suspected of overexposure. Follow 559 AMDS Bioenvironmental Engineering instructions on wearing, storage, and swap-out of dosimeters. Randolph AFB personnel will follow guidance from 559 MDS Bioenvironmental Engineering.

1.2.8.3. Consider potential mission impact prior to approving requests from members for off-duty employment (moonlighting) where ionizing radiation exposure may occur. (Occupational dose is cumulative across all employers and dose received from other employers can necessitate removing members from normal military duties.) Consult with 559 AMDS Bioenvironmental Engineering for further instructions and for documentation purposes. Randolph AFB personnel will consult with 559 MDS Bioenvironmental Engineering.

1.2.9. Support the radiation Personal Protective Equipment (rPPE) program as described in **paragraph 5.4**.

1.2.9.1. If requested by the Wing RSO, provide a representative to execute the program in their area.

1.2.9.2. Ensure personnel comply with requirements for inventory, wear, and storage of rPPE.

1.2.9.3. Ensure personnel have ready access to appropriate rPPE. Requisitions rPPE as needed.

1.3. Medical/Dental Radiation Workers/Operators.

1.3.1. Comply with pertinent regulations, policies, and procedures.

1.3.2. When issued, use/store dosimeters and rPPE appropriately.

1.3.3. When enrolled in the personnel radiation dosimetry program, supply the Wing RSO with any occupational dose records arising from other agencies (e.g., records from off duty employment).

1.3.4. Perform operations in a manner that optimizes radiation dose to the patient and maintains occupational dose as low as reasonably achievable.

1.3.5. Promptly notify the Wing RSO and workplace supervisors of suspected incidents or unsafe practices/conditions involving radiation. Notify workplace supervisors of changes that could affect exposure to patients/staff or compliance with radiation policy.

1.4. 59 MDW Radiation Safety Office.

1.4.1. For the purposes of this instruction, the Radiation Safety Office and the Medical Physics Office are the same. All Wing RSOs are normally appointed from the Medical Physicists assigned to this Wing. Medical Physicists are experts in ionizing radiation.

1.4.2. The Radiation Safety Office is responsible for the following:

1.4.2.1. Oversight of the 59 MDW Radiation Safety Program.

1.4.2.2. Determination of 59 MDW radiation safety policy/procedures in cases of ambiguity or contention. This includes the authority to temporarily or permanently cease any operations associated with radiation. Decisions in this capacity can only be overridden by the 59 MDW/CC.

1.4.2.3. Advise the Institutional Review Board (IRB) with regards to research involving radiation. See **Chapter 6**.

1.4.2.4. Monitor the radiation safety training program and fluoroscopy users training and attendance rates.

1.4.2.5. Delivering a RSP briefing to ECOMS according to the committee's required frequency. The briefing will include:

1.4.2.5.1. The scope of medical and dental ionizing radiation use in the wing; to include new installation and decommissioning of radiation sources.

1.4.2.5.2. A summary of any significant adverse events or inspection findings related to the medical/dental use of ionizing radiation.

1.4.2.5.3. A summary of occupational dosimetry results.

1.4.2.6. Delivering a WHASC RSP briefing to the DHA Market Radiation Safety Committee.

1.5. The 59 MDW Radiation Safety Officer (Wing RSO).

1.5.1. The 59 MDW Wing RSO is a synthesis of the Unit Radiation Safety Officer defined in AFMAN 48-148 and the Associate RSO defined in DHA AI 087.

1.5.2. Is responsible for ensuring staff/public safety from ionizing radiation hazards produced during the medical/dental treatment or diagnosis of humans.

1.5.3. Has the authority to cease any operations associated with ionizing radiation deemed to be unsafe.

1.5.4. In consultation with the Installation Radiation Safety Officer (IRSO), determines which personnel require dosimetry monitoring. The Wing RSO is the approval authority for radiation worker training in medical/dental facilities. The IRSO is the 559 AMDS Bioenvironmental Engineering Flight Commander. **Note:** DHA AI 087 stipulates a threshold dose for radiation workers of 500 mrem/year. AFMAN 48-148 stipulates a threshold dose of 100 mrem/year. The 59 MDW will utilize the stricter 100 mrem/year threshold until the Air Force relaxes their standard. The IRSO can require monitoring on individuals that do not meet these threshold levels.

1.5.5. Determines which 59MDW personnel require annual radiation safety training and/or fluoroscopy users training and what training satisfies the requirements.

1.5.6. Oversees the rPPE inspection program and is the final arbiter for the need/adequacy of engineered radiation controls (e.g., structural lead shielding) and rPPE.

1.5.7. Reviews and approves all operating instructions pertinent to the medical or dental use of ionizing radiation upon creation/revision.

1.5.8. Assists the IRSO and Bioenvironmental Engineering Flight during shop surveys where ionizing radiation is used in the medical or dental treatment or diagnosis of humans. The Wing RSO can perform additional audits as deemed necessary.

1.5.9. Compiles an annual compliance report summarizing current status and actions of the RSP.

1.5.10. The Wing RSO shall determine any requirements of the Wing radiation safety program beyond requirements already existing in pertinent regulations.

1.5.11. Fulfills other duties as described in DHA AI 087, Enclosure 2, Paragraph 5, except duties specific to RAM, an RSC, or duties assigned to other agencies.

1.6. Unit Radiation Safety Officers (URSOs).

1.6.1. A unit radiation safety officer is an individual appointed by a department utilizing radiation producing devices and approved by the Wing RSO to assist in the execution of the radiation safety program for a given location/specialty. (i.e., dental URSO, Reid Health Services Center URSO, etc.)

1.6.2. URSOs will immediately elevate any operations associated with ionizing radiation deemed to be unsafe to the Wing RSO for review.

1.7. Medical Director of Radiology.

1.7.1. Is a board-certified radiologist that is deemed to be the 59 MDW's competent authority for the medical/dental use of ionizing radiation.

1.7.2. Is the final arbiter for determinations regarding the safety/efficacy/efficiency of ionizing radiation as it relates patient care.

1.8. Qualified Medical Physicist (QMP).

1.8.1. QMPs, as defined in AFMAN 48-148, are experts in the quality control of medical/dental imaging systems that utilize ionizing radiation, ultrasound, and magnetic resonance.

1.8.2. QMPs, operating within their established roles IAW Air Force and DHA regulations, possess the authority to deem equipment/practices as unsafe. Following such a determination, only a QMP can reinstate the equipment/practice.

1.8.3. Conducts room lead shielding designs, room lead shielding integrity surveys and scatter surveys to determine the adequacy and requirements for lead shielding and practices utilizing ionizing radiation sources in order to protect both the public and workers.

1.8.4. Conducts patient and fetal radiation dose assessments.

1.8.5. Has the authority to develop, institute, and require quality control programs, procedures, and tracking by departments operating radiation producing devices and diagnostic imaging equipment.

1.9. Medical Physicist Assistant (MPA). See section 8.3.7. of AFMAN 48-148.

Chapter 2

AUTHORIZED INDIVIDUALS FOR THE MEDICAL/DENTAL USE OF IONIZING RADIATION

2.1. Medical/Dental Ionizing Radiation Use Authorization. The medical/dental use of ionizing radiation can only be authorized (e.g., studies ordered) by individuals meeting the requirements found in AFMAN 48-148 Chapter 4.

2.2. Medical/Dental Ionizing Radiation Use Application. Ionizing radiation for medical/dental use can only be applied by Radiological Medical Practitioners, Radiological Dental Practitioners, Diagnostic Radiologic Technologists, Dental Technicians, or other individuals approved by the Medical Director of Radiology for specialty applications. See AFMAN 48-148 section 8.3.2.1 for definitions of the practitioners.

2.2.1. All personnel who operate fluoroscopy systems (excepting microampere systems) and individuals who supervise fluoroscopic procedures must receive initial and annual ALARA training and fluoroscopy users training approved by the Wing RSO. For credentialed providers, the fluoroscopy credential is contingent upon this training requirement.

2.2.2. Additional, modality-specific and time-variant requirements for radiation operators exist and are adopted when required by applicable regulation or accreditation program. The Wing RSO can levy additional radiation operator training requirements as deemed necessary.

Chapter 3

ADMINISTRATIVE REQUIREMENTS

3.1. Workplace Processes. Each workplace must establish written processes aimed at ensuring the safe, effective, and efficient medical/dental use of ionizing radiation. These written processes are to be certified by the applicable lead Radiological Medical/Dental Practitioner, coordinated with the Medical Physics Office, and reviewed/approved by the Wing RSO prior to implementation/change. These processes will include, but are not limited to, the following:

3.1.1. Protocols for the authorized usage of ionizing radiation. If applicable, these should include information regarding who can authorize deviations from standard procedures/protocols.

3.1.2. Procedures for pregnancy screening and management of pregnant patients. (Not required for dental applications).

3.1.3. When applicable, procedures associated with the use of rPPE by either the staff or patients.

3.1.4. Quality assurance procedures that are standard-of-care for the subject modality. (e.g., repeat rate analysis, computed tomography dose alerts, logging of fluoroscopy dose records).

3.1.5. Quality control procedures for equipment involved in the generation/detection of ionizing radiation and the transmission/storage/display of images pertinent to medical/dental imaging IAW AFMAN 48-148.

3.2. Equipment Failures. AFMAN 48-148 stipulates requirements for the testing of numerous systems associated with the medical/dental use of ionizing radiation. When failures arise, the following apply:

3.2.1. Applicable regulatory or accreditation correction timelines are adopted.

3.2.2. Deficiencies that can have a significant adverse impact on clinical efficacy and/or safety for the patient/staff/public must have the affected component removed from clinical use until repairs are made and verified.

3.2.3. Deficiencies having no regulatory/accreditation/clinical/safety impact (as determined by a QMP) can be evaluated by the equipment owning organization to ascertain whether repair is prudent and, if so, on what timetable.

3.2.4. Other deficiencies should be corrected within 30 days.

3.3. Equipment Acquisition/Replacement. Requests for new or replacement equipment that produce ionizing radiation must be coordinated with the Wing RSO. The 59 MDW Medical Equipment Management Office will not accept such equipment packages without confirming Wing RSO coordination. notify 559 AMDS BE when acquiring new x-ray equipment or when performing scatter surveys to certify new instruments.

3.4. Facility Construction/Modification. Facility construction/modification that involves the install/relocation of ionizing radiation equipment (excluding devices designed to be portable), can impact engineered radiation controls (e.g., structural lead shielding), or the nature of occupancy of areas adjacent to radiation areas (e.g., changing a storage closet adjacent to a radiographic room to an office) must be coordinated with the Wing RSO. The 59 MDW Facilities Management Office will not affect/authorize these changes without confirming Wing RSO coordination.

Chapter 4

CLINICAL REQUIREMENTS

4.1. Informed Consent.

4.1.1. Informed consent from the patient, or a surrogate when appropriate, shall be obtained and documented in accordance with 59 MDWI 51-302, *Informed Consent and Refusal of Care*. In emergency situations, informed consent may be implied by law. See 59 MDWI 51-302 paragraph 6 for further guidance on emergencies.

4.1.2. For procedures known to potentially involve high radiation doses, an estimation of the anticipated risks from the radiation dose shall be communicated to the patient. See 59 MDWI 51-302 for further guidance on what must be communicated to the patient."

4.2. Pregnant Patients (not applicable for dental applications).

4.2.1. No screening (without clinical indication) examinations involving ionizing radiation shall be performed on a pregnant woman. Screening mammography exams may be conducted on a pregnant patient if approved by a radiologist. Exceptions may be granted by the Medical Director of Radiology.

4.2.2. Each workplace will establish and implement procedures to determine, before conducting an examination or procedure, whether a female patient of childbearing age may be pregnant.

4.2.2.1. Each workplace will utilize their most current questionnaire/consent form. For medical radiography, fluoroscopy and computed tomography, that form will be scanned into the Picture Archiving and Communication System (PACS).

4.2.2.2. Signs must be posted in suitable locations, such as patient reception areas or procedure rooms, asking female patients to notify staff if they might be pregnant.

4.2.3. If a patient is pregnant, and a study/procedure using ionizing radiation is deemed necessary, the following apply:

4.2.3.1. A Radiological Medical Practitioner knowledgeable in the associated radiation risks will review the risks with the patient as part of the decision process on whether to proceed. (Excepting situations where emergent need, or the patient’s condition, precludes this discussion.)

4.2.3.2. Every effort should be made to keep the fetus out of the direct radiation beam unless doing so is exclusive of clinical objectives.

4.2.3.3. The referring physician shall contact the Wing RSO and/or medical physicist at the RSO Office (292-7957) to determine if a fetal dose estimate is needed. A fetal dose estimate is required in cases where the fetus was in the imaging field of view.

4.2.4. If a pregnancy is discovered after a study/procedure using ionizing radiation; the referring physician will contact the Wing RSO and/or medical physics within 24 hours. A determination will be made as to whether a fetal dose estimate is required.

4.2.5. The Radiation Safety Office shall notify the 59 MDW Risk Management Office within 24 hours of any fetal dose that exceeds 0.05 Gray (Gy) (5 rad).

4.2.6. AFMRA/SG3PB shall be notified of any fetal dose that exceeds 0.05 Gy (5 rad) that was not approved, in advance, by a physician. The notification will be made within seven calendar days after discovery.

4.3. General Study/Procedure Requirements.

4.3.1. Studies/procedures will be performed in accordance with pre-approved imaging protocols unless deviations are made consistent with approved departmental policy. Technologists will not perform any examination which has not been requested by an authorized provider. Standardized authorizations for bulk processing of military personnel are acceptable for military specific applications (e.g., the acquisition of baseline dental panoramic images on basic trainees).

4.3.2. Beam collimation should be used to exclude anatomy not requiring exposure from the primary beam. Digital masking will not be a substitute for proper collimation and shall not be applied to cover any exposed anatomy.

4.3.3. If it does not interfere with the examination, leaded aprons or other shields should be used to protect radiosensitive anatomy (e.g., thyroid, breasts, etc.). IAW AAPM position statement PP 32-A, patient gonadal/fetal shielding use in the primary field for radiography/fluoroscopy is no longer encouraged. Use of shielding in these situations yields little benefit and may obscure important anatomy, increase dose through its impact on the automatic exposure control circuitry, and/or negatively impair image processing. Shielding may still be used in these situations if it will provide comfort to the patient. When used in the primary field, care should be made to ensure shielding does not adversely affect the imaging technique by selecting an unobstructed automatic exposure control sensor or using a manual exposure technique. Appropriateness of shields should be determined in consultation with a QMP. Care shall be taken that shielding does not cover an active sensor when Automatic Exposure Control (AEC) is in use, thereby driving patient dose up unnecessarily.

4.4. Additional Fluoroscopy Specific Requirements (not applicable for microampere systems).

4.4.1. Fluoroscopic procedures that deliver a machine-reported air-kerma/dose exceeding 3 Gy or a kerma-area product above 300 Gy-cm2 may result in a temporary or permanent deterministic skin injury. Procedures below these levels are unlikely to produce a deterministic injury. If these machine reported levels are exceeded, the following apply:

4.4.1.1. The medical practitioner who performed the procedure will advise the patient of the situation, place an appropriate notation in the patient's medical record, coordinate a consult with dermatology, and request a skin dose estimate from the Wing RSO. The dermatology consult and the Wing RSO notification must be within 24 hours.

4.4.1.2. The situation must be evaluated against this Instruction's **Chapter 7** reporting requirements.

Chapter 5

STAFF RADIATION PROTECTION

5.1. Direct Exposure of Individuals. See section 8.7.1. of AFMAN 48-148.

5.2. Indirect Exposure. Excluding the patient (and a family member if needed for patient positioning/restraint), only staff and ancillary personnel required for the procedure, or those in training, should be in the room during procedures using ionizing radiation. Exceptions and pertinent details are as follows:

5.2.1. When performing portable examinations, other patients should be removed from the room. If not possible, they shall be provided with protective aprons or whole-body shields of not less than 0.25 mm of lead-equivalent material (0.35 mm recommended for medical applications). If shielding is not available or practical, they shall be positioned at least six feet away from both the radiation source and the patient being imaged.

5.2.2. Staff and ancillary personnel in the room should be protected from scatter radiation by protective aprons or whole-body shields of not less than 0.25 mm of lead-equivalent material (0.35 mm recommended for medical applications). Thyroid and eyes should be protected if potential exposure exceeds 25% of the annual regulatory organ dose limits.

5.3. Personnel Radiation Dosimetry Program. The IRSO will oversee a personnel radiation dosimetry program. Pertinent details include:

5.3.1. This dosimetry monitoring program will be conducted in accordance with DAFMAN 48-125, *Personnel Ionizing Radiation Dosimetry* and DHA AI 087, *Radiation Safety Program and Radiation Safety Committee.*

5.3.2. Complete dosimetry results of Wing personnel on the dosimetry program will be shared by the IRSO with the Wing RSO.

5.3.3. The Wing RSO, in consultation with the IRSO, will identify which personnel require radiation dosimetry monitoring.

5.3.4. Staff not identified as requiring radiation dosimetry may self-elect to be monitored. Self-elected individuals are bound to comply with the rules of the dosimetry program.

5.3.5. When a radiation worker formally declares her pregnancy (i.e., becomes a “declared pregnant woman”), she will be issued radiation dosimetry on a monthly cycle in accordance with DAFMAN 48-125. The applicable occupational dose limit is reduced to 5 mSv (500 mrem) over the course of gestation.

5.3.6. Following unusual dosimetry results or missing/not-returned devices, the IRSO or Wing RSO may need/elect to conduct an investigation. Individuals enrolled in the dosimetry program are required to support the investigation. In the event a work center develops a trend of losing dosimeters, members may be responsible for replacing their lost dosimeters as an out-of-pocket expense. **Note:** Investigational limits and actions are prescribed in DHA AI 087, Enclosure 4.

5.3.7. The IRSO or Wing RSO can require work sections to provide a representative to execute the dosimetry program in their area. Ideally this will be the appointed URSO for that section.

5.3.8. If deemed necessary, the IRSO or Wing RSO can impose duty limiting restrictions on personnel to prevent occupational exposure in excess of limits. These restrictions will take into account the occupational exposures from any off-duty employment.

5.4. rPPE Program. The Wing RSO will oversee an rPPE program. Pertinent details include:

5.4.1. Sufficient rPPE should be readily available to staff in accordance with approved departmental guidelines. rPPE is purchased by the department in which it will be used.

5.4.2. rPPE should be stored in accordance with manufacturer recommendations.

5.4.3. All rPPE used within 59 MDW (government furnished or personal) shall be uniquely numbered, inspected prior to use, and inspected annually for deterioration. This will be documented on a central inventory and made readily apparent to users by labels on the individual rPPE items.

5.4.4. The Wing RSO can require work sections to provide a representative to execute the rPPE program in their area. Ideally this will be the appointed section URSO.

5.4.5. The Wing RSO is the final arbiter for the adequacy of rPPE. Inspection criteria for rPPE must be approved by the Wing RSO.

5.4.6. It is the responsibility of the owning department to maintain, inspect, and inventory their rPPE , not the Wing RSO or the Radiation Safety Office. The Wing Radiation Safety Office shall have a program for inspection and inventory of rPPE, but the department owning rPPE must identify their rPPE and arrange with the Radiation Safety Office to assist with inspections and inventories.

5.4.7. All newly purchased rPPE shall be tested and inventoried before it is placed into use.

Chapter 6

RESEARCH INVOLVING RADIATION

6.1. Human Subject Research Requirements. All research involving human subjects that is conducted, supported, or otherwise subject to regulation by any Federal department or agency must conform to the most current version of the Federal Policy for the Protection of Human Subjects. This policy requires approval of research protocols by a properly constituted IRB and obtaining informed consent from the patient or research subject.

6.2. Medically Indicated Radiation. Many protocols use radiation that is *medically indicated* (also referred to as *"standard-of-care*"). Medically-indicated radiation is used to diagnose or guide treatment as a non-research medical procedure for clinical management of the research subject. The radiation dose from a medically-indicated procedure done as part of a research study will not require additional justification, review, and approval by an IRB.

6.3. Indicated For Research Radiation. When the radiation exposure is described as *indicated for research* (the radiation use does not meet the criteria of "medically indicated") it must be reviewed and approved. The IRB has responsibility for oversight of research involving human subjects, but will seek the advice of the 59 MDW Radiation Safety Office regarding the radiation risk from any non-medically indicated radiation use that is a component of the research. Research involving the following must be reviewed/approved by the DHA RSC: use of RAM on nursing mothers, exposures of pregnant individuals and minors to radiation, exposures of any human in excess of 50 mSv.

6.4. Risk Consultation. Investigators assembling a radiation protocol application for submission to the IRB are encouraged to consult with the 59 MDW Radiation Safety Office (210-292-7957) for assistance with the calculation of dose and a determination of risk for stochastic and deterministic effects.

Chapter 7

REPORTING OF ADVERSE INCIDENTS INVOLVING IONIZING RADIATION

7.1. Employee Reporting. Employees should promptly report any perceived concerns to the Wing RSO for determination against reporting criteria. Employees making such reports shall not be subject to reprisal. To facilitate timely reporting; the following simplified/conservative, instructions are given below:

7.1.1. Take immediate action, if necessary, to protect staff/patients/public from ongoing hazards.

7.1.2. Verbally notify the Wing RSO immediately upon suspicion of an incident or adverse patient consequence involving ionizing radiation or radioactive material. Provide all known details. The Radiation Safety Hotline is 292-7957. Additional contact information is maintained by the Hospital Automated Resource Protection System at 292-6070.

7.1.3. Unless otherwise instructed, provide a written report the next day.

7.2. 59 MDW Reporting. The 59 MDW will comply with all applicable radiation reporting criteria levied by Air Force instruction, federal regulation, DHA Administrative Instructions or accreditation agency. Pertinent examples of such reporting criteria include:

7.2.1. AFMAN 48-148 details several reporting criteria pertaining to ionizing radiation. This includes reporting of high occupational exposures to radiation; reporting of cumulative doses in excess of 50 mSv (5 rem) to an embryo/fetus/nursing child unless specifically approved in advance by a physician; and reporting of medical events (adverse events from the medical application of radiation which places the patient at risk of injury, unless it resulted from patient intervention).

7.2.2. AFMAN 40-201, *Radioactive Materials Management,* details several reporting criteria pertaining to radioactive material.

7.2.3. 21 CFR 803 details several reporting criteria pertaining to serious injuries and deaths associated with medical devices.

7.2.4. The Joint Commission requires reporting of “sentinel events”. Serious injuries from ionizing radiation and skin doses in excess of 15 Gy constitute sentinel events.

7.2.5. DHA AI 087 details several reporting criteria pertaining to unsafe conditions and unsafe practices.

7.3. Internal Coordination. Radiation related reporting to external agencies will be coordinated between the Wing RSO, 59 MDW Risk Management Office, and Patient Safety Manager (as appropriate) to the greatest extent feasible within applicable reporting times.

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Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

AFPD 48-1, *Aerospace and Operational Medicine Enterprise*, 6 June 2019

AFMAN 40-201, *Radioactive Materials Management,* 29 March 2019

AFMAN 48-148, *Ionizing Radiation Protection*, 20 July 2020

59 MDWI 51-302, *Informed Consent and Refusal of Care,* 10 April 2017

AFI 91-108, *Air Force Nuclear Weapons Intrinsic Radiation and 91(B) Radioactive Material Safety Program*, 14 May 2020

AFMAN 48-125, *Personnel Ionizing Radiation Dosimetry*, 27 October 2020

DHA AI 087, *Radiation Safety Program and Radiation Safety Committee*, 1 August 2019

Title 29, Code of Federal Regulations, Part 1910.1096, Standards of Conduct, *Ionizing Radiation,* Current Edition

Adopted Form

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

AEC—Automatic Exposure Control

ALARA—As Low As Reasonably Achievable

RSO—Radiation Safety Officer

DHA—Defense Health Agency

Gy—Gray

IAW—In Accordance With

IRB—Institutional Review Board

IRSO—Installation Radiation Safety Officer

MDW—Medical Wing

MDWI—Medical Wing Instruction

MP—Medical Physicist

MPA—Medical Physicist Assistant

PACS—Picture Archiving and Communication System

QMP—Qualified Medical Physicist

RAM—Radioactive Material

rPPE—Radiation Personal Protective Equipment

RSP—Radiation Safety Program

URSO—Unit Radiation Safety Officer

Terms

Air Kerma—Sum of the kinetic energy released in a small volume of air at a specific point in space during a specified event or time frame when irradiated by an x-ray beam.

ALARA (as low as reasonably achievable)—A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account. The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Ancillary Personnel—Personnel beyond the operational medical staff who provide support services.

Annual—For the purposes of periodic requirements, annual refers to the completion of a requirement within a period of 14 months from the last day of the month in which it was previously accomplished. (Unless otherwise specified/required).

Bone Densitometry—The noninvasive measurement of certain physical characteristics of bone that reflect bone strength (typically reported as bone mineral content or bone mineral density); used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

Declared Pregnant Woman—A woman who is an occupational radiation worker and has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Deterministic Effects—(**also called tissue effects)**—Effects that occur in all individuals who receive greater than the threshold dose and for which the severity of the effect varies with the dose (NCRP 2003).

Diagnosis—The determination of the nature of a disease, injury, or congenital defect.

Direct Supervision—The supervising individual must be present in the local area (for physicians, in the office suite) and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the supervising individual must be present in the room when the task is performed.

Dose—A measure of the energy deposited by radiation in a target per unit mass.

Dosimeter—Dose measuring device.

Exposure—In this report, exposure is used most often in its general sense, meaning to be irradiated. Exposure is also a measure of the ionization produced in air by ionizing radiation.

Fluoroscopy—The process of producing a real-time image using x-rays.

Gray (Gy)—The international unit for absorbed dose and air kerma that is equivalent to 100 rad.

General Supervision—The procedure is furnished under the supervising individual's overall direction and control, but the supervising individual's presence is not required during the performance of the procedure. Under general supervision, the training of the personnel who actually perform the task and the maintenance of the necessary equipment and supplies are the continuing responsibility of the supervising individual.

Health Professional—An individual who has been formally recognized through appropriate national procedures to practice a profession related to health (e.g., medicine, dentistry, chiropractic, podiatry, nursing, veterinary medicine).

Informed Consent—Voluntary agreement given by a person or that person's legally authorized representative (e.g., a parent) for participation in a study, immunization program, treatment regimen, invasive procedure, etc., after being informed of the purpose, methods, procedures, benefits, and risks. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the patient. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiologic Studies.

Intervention—Any measure taken to alter the course of medical diagnosis whose purpose is to improve a health outcome.

Justification—The process of determining for a planned exposure situation whether a practice is, overall, beneficial, i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

Medical Exposure—Exposure incurred by patients for the purpose of medical or dental diagnosis or treatment; by caregivers associated with medical, dental, and veterinary procedures; and by volunteers in a program of biomedical research involving their exposure as research subjects.

Medical Physics—An applied branch of physics concerned with the application of the concepts of physics to the diagnosis and treatment of human disease. It is allied with medical electronics, bioengineering, and health physics. The Medical Physicist's clinical practice focuses on methods to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care.

Medical Physicist—A health professional, with education and specialist training in the concepts and techniques of applying physics in medicine, competent to practice independently in one or more of the subfield specialties of medical physics.

Medical Physicist Assistant—An individual that may perform certain medical physics functions under the general supervision of a QMP. Allowable functions are those that they have been deemed qualified for by the supervising QMP and are not precluded by applicable regulations.

Occupational Exposure—Exposure to an individual that is incurred in the workplace as a result of situations that can reasonably be regarded as being the responsibility of management (exposures associated with medical diagnosis or treatment of the individual are excluded).

Picture Archiving and Communications System (PACS)—Electronic system for the archival storage and transfer of information associated with x-ray images.

Potentially-High Radiation Dose Procedure—A procedure for which more than 5% of cases of that procedure result in a cumulative air kerma exceeding 3 Gy or a kerma area product exceeding 300 Gy·cm^2.

Qualified Medical Physicist (QMP)—An individual who is competent to practice independently in the relevant subfield of medical physics. For the purposes of this document, the relevant subfield is diagnostic radiological physics or medical health physics. Board certification and continuing education and experience in the relevant subfield is one way to demonstrate that an individual is competent to practice in that subfield of medical physics and to be a QMP. Due to their unique mission requirements, the uniformed services may need to develop their own criteria for determining when a physicist is a "Qualified Medical Physicist" as defined in this document (**http://www.aapm.org/medical_physicist/fields.asp**).

Quality Assurance—The function of a management system that provides confidence that specified requirements will be fulfilled. In medical imaging, quality assurance refers to those steps that are taken to make sure that a facility consistently produces images that are adequate for the purpose with optimal patient exposure and minimal operator exposure. It includes those organizational steps taken to make sure that testing techniques are properly performed and that the results of tests are used to effectively maintain a consistently high level of image quality. An effective program includes assigning personnel to determine optimum testing frequency of the imaging devices, evaluate test results, schedule corrective action, provide training, and perform ongoing evaluation and revision of the program.

Quality Control—In medical imaging, quality control comprises the procedures used for the routine physical testing of the components of the imaging chain from x-ray production, through the viewing of images.

Rad—The traditional/historical name for the unit of absorbed dose and air kerma.

Radiation Operator—An individual who operates radiation producing equipment or handles radioactive material in the performance of his/her duties.

Radiation Personal Protective Equipment—Specialized clothing or equipment (e.g., lead or lead equivalent radiation protection apron, gloves, thyroid collar, eyeglasses) worn by an employee to protect against a radiation hazard. General work clothes not intended to serve as a protection against a radiation hazard are not radiation personal protective equipment.

Unit Radiation Safety Officer—An individual from a department utilizing radiation producing devices that is assigned by the department or appointed by the Wing RSO to work with the Wing RSO to monitor radiation safety practices in their department and to carry out the Wing radiation safety program.

Radiation Worker—An individual who may be occupationally exposed to ionizing radiation in the course of their duties as determined by the IRSO and/or Wing RSO.

Radiological Medical Practitioner—A health professional with specialist education and training in the medical (also, dental or veterinary) uses of radiation, who is competent to perform independently or to oversee procedures involving medical exposure in a given specialty (See licensed independent practitioner).

Rem—The traditional/historical name for the unit of dose equivalent and effective dose.

Research—A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this document, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. "Research subject to regulation," and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (e.g., Investigational New Drug and Investigational Device Exemption requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage and Hour requirements administered by the Department of Labor).

Risk—The probability or quantifiable likelihood that a detriment to health will occur as a result of performing or not performing a medical procedure.

Screening—The evaluation of an asymptomatic person in a population to detect a disease process not known to be present at the time of evaluation.

Serious Injury—A serious injury is one that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent damage or impairment.

Sievert (Sv)—The international unit for dose equivalent and effective dose that is equivalent to 100 rem.

Skin Dose—Radiation dose to the dermis, may be quantified as entrance or peak skin dose.

Stochastic Effects—Effects, the probability of which, rather than their severity, is a function of radiation dose, implying the absence of a threshold.