

## Defense Health Agency ADMINISTRATIVE INSTRUCTION

NUMBER 087 August 1, 2019

AD-CS/PHD

SUBJECT: Radiation Safety Program (RSP) and Radiation Safety Committee (RSC)

References: See Enclosure 1.

1. <u>PURPOSE</u>. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) through (e), and in accordance with the guidance of References (f) through (aa):

a. Establishes the Defense Health Agency's (DHA) policy for the RSP and for maintaining occupational radiation exposures to ionizing radiation as low as reasonably achievable (ALARA) associated with the use of radioactive material (RAM) authorized by the Nuclear Regulatory Commission (NRC) license (as well as exposure from ionizing radiation from all other sources such as x-ray generating devices, accelerator-produced RAM, and linear accelerators). The DHA RSP includes ALARA principles, proper use of dosimetry (when required), equipment, transportation of RAM, attendance at required periodic training, periodic reviews, reporting of unsafe conditions or reporting of unsafe practices, and administrative reporting.

b. Outlines DHA's RSP and establishes the DHA RSC in order to oversee the safe use of RAM, machine produced radiation, and non-ionizing radiation within DHA's facilities.

2. <u>APPLICABILITY</u>. This DHA-AI applies to DHA Military Medical Treatment Facilities and all other organizational entities within the DHA (referred to collectively in this DHA-AI as the "DHA Components." Deviation from this DHA-AI requires approval of the Director, DHA through the DHA RSC.

3. <u>POLICY IMPLEMENTATION</u>. It is DHA's policy, pursuant to Reference (j), to reduce occupational exposure to ionizing radiation to a level ALARA. The DHA RSP will be authorized for the use and storage of RAM through an NRC license (*Hub and Spoke* model, with

DHA as the Hub and subordinate organizations under DHA authority (e.g., military medical treatment facilities, Markets, as the Spokes)). A complete list of subordinate organizations is provided in the Appendix. RSP compliance is defined in accordance with References (j) through (o). The RSP will further cover the use of non-ionizing radiation in accordance with References (g) and (w) through (y).

## 4. <u>CANCELLED DOCUMENTS</u>. This DHA-AI cancels:

a. Joint Task Force National Capital Region Medical-Directive 5100.03, "Radiation Safety Work Group Charter," January 20, 2012

b. Joint Task Force National Capital Region Medical-Directive 6470.01, "Lead Apron Program," July 2, 2012

c. Joint Task Force National Capital Region Medical-Instruction 6470.02, "Lead Apron Inspection Procedures," April 8, 2013

d. National Capital Region-Medical Directorate Concept of Operations, September 10, 2013

5. <u>RESPONSIBILITIES</u>. Enclosure 2.

6. <u>PROCEDURES</u>. Enclosures 3 through 5.

7. <u>RELEASABILITY</u>. **Not cleared for public release**. This DHA-AI is available to users with Common Access Card authorization on the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

8. <u>EFFECTIVE DATE</u>. This DHA-AI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (i).

MADM, MC, USN Director

Enclosures

- 1. References
- 2. Responsibilities
- 3. Procedures and Management Commitment to the Radiation Safety Program
- 4. Procedures for Establishment of Investigational Levels
- 5. Defense Health Agency Radiation Safety Committee Function

#### Appendix

Defense Health Agency Subordinate Organization Glossary

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## ENCLOSURE 1

## **REFERENCES**

- (a) DoD Directive 4715.1E, "Environmental, Safety, and Occupational Health (ESOH)," March 19, 2005, as amended
- (b) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
- (c) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (d) DoD Instruction 6055.05, "Occupational and Environmental Health (OEH)," November 11, 2008, as amended
- (e) DoD Instruction 6055.08, "Occupational Ionizing Radiation Protection Program," December 15, 2009, as amended
- (f) DoD Instruction 6055.11, "Protecting Personnel from Electromagnetic Fields," August 19, 2009, as amended
- (g) DoD Instruction 6055.15, "DoD Laser Protection Program," May 4, 2007, as amended
- (h) Deputy Secretary of Defense Memorandum, "Implementation of Military Health System Governance Reform," March 11, 2013
- (i) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
- (j) Code of Federal Regulations, Title 10, Parts 2, 19, 20, 21, 30, 31, 33, 35, 37, 51, 71, 170 and 171, January 1, 2016
- (k) Defense Transportation Regulation (DTR) 4500.9-R, Part II, "Cargo Movement," May 2014, as amended
- (1) Nuclear Regulatory 1516, Management of Radioactive Material Safety Programs at Medical Facilities, May 1997
- (m) Nuclear Regulatory 1556, Volume 7, Rev 1., Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers, February 2018
- (n) Nuclear Regulatory 1556, Volume 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," November 2016
- Nuclear Regulatory 1556, Vol. 11, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," February 2017
- (p) National Council on Radiation Protection and Measurements Report No. 107,
   "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," 1990
- (q) Joint Commission Comprehensive "Accreditation Guide for Hospitals"
- (r) Joint Commission Comprehensive "Accreditation Handbook for Ambulatory Care"
- (s) American College of Radiology Practice Parameters and Technical Standards Development and Revision Handbook
- (t) Code of Federal Regulations, Title 21, Parts 1020-1050
- (u) Code of Federal Regulations, Title 29, Part 1910, Subpart 1096, July 1, 2011
- (v) Code of Federal Regulations, Title 49, Parts 171-178, October 1, 2010

- (w) Technical Bulletin Medical 524, "Occupational and Environmental Health, Control of Hazards to Health from Laser Radiation," January 31, 2006
- (x) Department of Army Pamphlet 40-506, "The Army Vision Conservation and Readiness Program," July 15, 2009
- (y) American National Standards Institute Z136.1-2014, "American National Standard for Safe Use of Lasers," 2007 with a revision in 2014
- (z) Navy Environmental Health Center Technical Manual 6470.1, "Navy Radiological Systems Performance Evaluation Manual, June, 2013
- (aa) Army Regulation 40-38, "Clinical Investigational Program," September 1, 1989

## PART 2. INFORMATIONAL REFERENCES

- (1) Bureau of Medicine Instruction 6470.22A, "Navy Radiological Systems Performance Evaluation Program," October 30, 2002
- (2) Navy Medicine P-5132 CH-1, "Equipment Management Manual," January 3, 2008,
- (3) Technical Bulletin Medical 521, "Occupational and Environmental Health: Management and Control of Diagnostic, Therapeutic, and Medical Research X-Ray Systems and Facilities," February 26, 2002
- (4) U.S. Nuclear Regulatory Commission, "NRC Opinion Regarding the Navy's Permitting of Defense Health Agency Facilities Under the Navy's Master Materials License, License No. 45-23645-01NA," February 23, 2016<sup>1</sup>
- (5) Air Force Instruction 40-201, "Radioactive Materials (RAM) Management," September 14, 2014, as amended
- (6) Air Force Instruction 48-109, "Electromagnetic Field Radiation (EMFR) Occupational and Environmental Health Program, August 1, 2014
- (7) Air Force Instruction 48-139, "Laser and Optical Radiation Protection Program," July 25, 2012, as amended
- (8) Air Force Instruction 48-148, "Ionizing Radiation Protection," September 21, 2011, as amended
- (9) Air Force Manual 48-125, "Personnel Ionizing Radiation Dosimetry," January 9, 2019,
- (10) Department of Army Pamphlet 385-24, "The Army Radiation Safety Program," November 30, 2015
- (11) Department of Army Pamphlet 385-25, "Occupational Dosimetry and Dose Recording for Exposure to Ionizing Radiation," October 2, 2012
- (12) Medical Command Reg No. 40-42, "U.S. Army Medical Command Radiation Safety Program," May 4, 2012
- 13) Bureau of Medicine Instruction 1500.27A, "Radiation Health Training for Designated Medical Department Personnel," June 8, 2016
- (14) Bureau of Medicine Instruction 6470.10B, "Initial Management of Irradiated or Radioactively Contaminated Personnel," September 26, 2003
- (15) Bureau of Medicine Instruction 6470.19A, "Laser Safety at Military Facilities and Research Laboratories," May 23, 2005
- (16) Bureau of Medicine Instruction 6470.20A, "Radioactive Material Permit Program for Medical Use," July 21, 2015

- (17) Bureau of Medicine Instruction 6470.21A, "Establishment, Appointment, Functions, and Responsibilities of Bureau of Medicine and Surgery Radiation Effects Advisory Board," July 16, 2012
- (18) Bureau of Medicine Instruction 6470.23, "Medical Management of Non-Ionizing Radiation Casualties," August 18, 1999
- (19) Bureau of Medicine Instruction 6470.25A, "Navy Medical Physics Advisory Board," May 10, 2017
- (20) NAVMED P-117, "Manual of the Medical Department," August 12, 2015
- (21) NAVMED P-5055, "Radiation Health Protection Manual," February 2011

<sup>&</sup>lt;sup>1</sup>This reference can be found at: http://adams.nrc.gov/wba

## ENCLOSURE 2

#### **RESPONSIBILITIES**

#### 1. <u>DIRECTOR, DHA</u>. The Director, DHA will:

a. Oversee the RSP for DHA Components.

b. Be the DHA NRC license holder.

c. Certify that appropriate DHA facilities will implement the RSP, including procedures for maintaining occupational exposure to ionizing radiation ALARA.

d. Establish the DHA RSC.

e. Appoint, in writing, the Radiation Safety Director, serving as the DHA Radiation Safety Officer (RSO) and Executive Secretary of the DHA RSC.

f. Appoint, in writing, a DHA Associate Radiation Safety Officer (ARSO) to assist the DHA RSO.

g. Participate in DHA RSC meetings or appoint, in writing, an 'Executive Representative' to attend on Director's behalf. Director or Executive Representative will appoint, in writing, permanent members to the DHA RSC.

h. Review and approve all NRC applications, amendments, and renewals (those documents requiring Executive Signature), necessary for the licensure and operations on DHA facilities.

i. Take immediate action(s) against those individuals who willfully and knowingly do not comply with NRC regulations and the RSP.

j. Provide adequate resources (including space, training and travel budget, equipment, qualified personnel, and, if needed, contractors to fill critical skills), to the RSP as deemed necessary by the DHA Radiation Safety Director to ensure the public and staff are protected from radiation hazards and meticulous compliance with regulations is maintained.

## 2. <u>DHA RSC</u>. DHA RSC will:

a. Manage and oversee the safe use of RAM within the DHA's subordinate organizations.

b. Manage and oversee the safe use of ionizing radiation producing devices within the DHA's subordinate organizations.

c. Manage and oversee the safe use of non-ionizing radiation within the DHA's subordinate organizations.

d. Approve appointments of the RSO and ARSOs of subordinate organizations to DHA RSC.

e. Fulfill procedures and functions as detailed in Enclosure 5.

3. <u>DHA RADIATION SAFETY DIRECTOR</u>. The DHA Radiation Safety Director, serving as the DHA RSO, and acting as Executive Secretary of the DHA RSC, will:

a. Provide the Director, DHA, and subordinate Commanders/Directors advice on the medical and health implications of radiation exposure and the use of radiation sources and radiation producing devices.

b. Implement the RSP at DHA headquarters, maintain oversight, and monitor the RSP at other DHA subordinate organizations.

c. Be responsible for the programmatic oversight of all ionizing radiation exposures related to the diagnostic and/or therapeutic administration of radioisotopes to humans and non-ionizing radiation issues.

d. Be responsible for the programmatic oversight of ionizing radiation exposures resulting from radioactive sealed sources, including by-product material, naturally-occurring RAM, and accelerator-produced isotopes.

e. Serve as the primary point of contact between the DHA and the NRC.

f. Manage and oversee DHA's Broad Scope RAM License (*Hub and Spoke* model with DHA as the Hub and subordinate organizations as the Spokes), in accordance with Reference (o).

g. Review appointment of the RSOs and ARSOs of subordinate organizations (i.e., site ARSOs), to DHA RSC in accordance with Reference (j).

h. Stop radiation work if ongoing activities pose undue risk or hazard or if continued radiation work violates conditions of the NRC license or regulations.

i. Provide or coordinate periodic site assistance visits to all DHA facilities operating under the DHA NRC License. Frequency of visits will be based upon program complexity, relative risk of safety, and site compliance with internal and external audits. Site visits will not exceed every 30 months with goal of visitation every 24 months.

j. Review applications of new Authorized Users (AUs), Authorized Medical Physicists (AMPs), and Authorized Nuclear Pharmacists (ANPs) and provide interim approval with final approval at the DHA RSC meeting.

k. Review proposed research protocols for radiation dose impact and risks in accordance with Reference (m).

l. Author and sign correspondence to the NRC (except NRC applications, amendments, and renewals), provided 'By Direction Authority' has been given for such purposes.

m. Maintain records of applications, amendment requests, renewals, and correspondences exchanged with the NRC and other regulatory authorities.

n. Maintain direct access to the Director, DHA, on matters directly pertaining to radiation safety.

o. Coordinate DHA RSC meetings at the required frequency.

p. Coordinate minutes of periodic DHA RSC meetings.

q. Ensure audits and program reviews are conducted to assess compliance with the provision of the NRC's license and regulations.

r. Advise the DHA RSC's Chairman of the results of the audits and program reviews.

s. Inform the DHA RSC and the Chairman regarding the status of the RSP.

t. Advise DHA's Executive Management and RSC of all non-compliance items with NRC Severity Levels I, II, and III.

u. Consult with DHA RSC and AUs on matters related to the use of RAM.

v. Establish procedures for the control, use, acquisition, and accountability of radioactive sources and special nuclear material.

w. Establish procedures that ensure the radiation safety staff are appropriately trained and qualified.

x. Implement the DHA RSC's enforcement sanctions. Investigate incidents per the requirements in the DHA NRC license. Determine the course of corrective action(s) to be taken if applicable and forward any required report(s) to the NRC within required time limits.

y. Prepare reports on non-compliance and forward to the DHA RSC.

z. Follow up and document pertinent actions required and/or requested by governing agencies and information notices.

aa. Ensure completeness and accuracy of radiation safety records and all information provided to the NRC.

ab. Ensure applicable procedures and policies, including site licenses, Standard Operating Procedures (SOPs), and instructions are compliant with current NRC and Department of Transportation's regulations and DHA standards.

ac. Be responsible for the programmatic oversight of all non-ionizing radiation producing devices in accordance with References (g) and (w) through (y).

ad. Be responsible for the programmatic oversight of ionizing radiation producing devices in accordance with References (e), (f), and (l) through (v).

## 4. <u>COMMANDING OFFICERS/DIRECTORS</u>. Commanding Officers/Directors, that possess RAM, will:

a. Designate, in writing, a site ARSO. The ARSO should be approved by the DHA RSC before the appointment is final.

b. Provide management oversight of machine produced radioactivity as well as RAM and ensure implementation of the RSP at their Command.

c. Ensure their Command obtains clearance for RAM possession and their facility is stated by address on the main DHA NRC license unless authorized otherwise; e.g., have a local NRC license specific to their command. A licensing action needs to occur if any Command is planning on or is working with RAM, and should be done prior to receipt, possession, or use of RAM at their facility. Coordination and approval from the DHA RSC is required before RAM is initially ordered.

d. Comply with the conditions of specific DHA RAM license, permits, or other appropriate license, tie-ins, NRC correspondences and regulations (Reference (j)), guidance, and informational notices.

e. Comply with the instructions (Reference (j)), concerning the safe receipt, possession, distribution, use, transportation, transfer, and disposal of RAM.

f. Review radiological incidents within their command; recommend and implement corrective action.

g. Ensure adequate resources and staffing are available to establish and maintain an effective RSP.

h. Operate under conditions specified in applicable RAM license(s), permits, authorizations, applications, and correspondences.

i. Coordinate all questions or reports concerning RAM use with the DHA RSC.

j. Submit all requests for additions, changes, or amendments to the DHA RSC.

k. Establish and maintain an effective RSP as described in Enclosure 3, and in compliance with paragraph 5 below.

1. Review radiological incidents within their facilities in accordance with References (j) and (n), and provide written documentation of radiological incidents to the DHA RSO.

m. Identify and recommend corrective actions to the DHA RSC.

n. Comply with instructions concerning the safe receipt, possession, distribution, use, transportation, transfer, and disposal of RAM in accordance with References (j) through (v).

5. <u>SITE ARSO FOR EACH SUBORDINATE ORGANIZATION</u>. The site ARSO for each subordinate organization will:

a. Be qualified in accordance with Reference (j). The qualifications of the site ARSO will be reviewed and approved by the DHA RSC.

b. Provide the site commanders/directors advice on the medical and health implications of radiation exposure and the use of radiation sources and radiation producing devices.

c. Conduct site RSC meetings at the required frequency as established by DHA or local policy. Membership of site RSCs will be in compliance with Reference (j).

d. Provide minutes of site RSC meetings to DHA RSC through the DHA Radiation Safety Director within 30 days after meeting. Draft minutes may be provided if minutes are unsigned; however, signed minutes will be provided within 10 days of next quarterly meeting.

e. Be responsible for conducting the day-to-day RSP operations.

f. Stop radiation work if ongoing activities pose undue risk or hazard, or if continued radiation work violates conditions of the NRC license or regulations.

g. Develop and implement appropriate instructions, SOPs, and formal procedures for cradleto-grave handling of RAM including procurement and acquisition, receipt, accountability, and distribution of RAM, and surveying of all sources, and use of sealed radioactive sources in accordance with References (j) and (m) through (o).

h. Maintain records in accordance with NRC Regulations (References (j) and (n)), including records of procurement, area monitoring, personnel monitoring, accidents and incidents, inventories, and any other documents required by NRC regulations or guidance.

i. Maintain a current list of quantities, uses, and locations where RAM is received, possessed, used, or stored.

j. Respond to all emergencies involving RAM, and provide expert advice and assistance, as required.

k. Provide a dosimetry program for radiation workers (RWs) which is approved by both National Voluntary Laboratory Accreditation Program and the DHA RSC.

l. Review, at least quarterly, the external radiation exposure (and, if appropriate, the internal monitoring), results of AUs and workers to determine that their exposures are ALARA.

m. Review quarterly dose rates in unrestricted and restricted areas and the annual assessment of public dose in accordance with References (j) and (n), to determine dose rates and amounts of contamination were at ALARA levels.

n. Schedule briefings and educational sessions to inform workers of ALARA program efforts. Ensure AUs, RWs, and ancillary personnel who may be exposed to radiation are instructed in the ALARA philosophy and these personnel are informed that management, the RSC, and RSO are committed to implementing the ALARA concept.

o. Be in close contact with all AUs and workers in order to develop ALARA procedures for working with RAM and ionizing radiation-producing devices.

p. Establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the use of those procedures.

q. Investigate all known instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is known, the site ARSO will require appropriate changes in the program to maintain exposures ALARA.

r. Ensure personnel working in any of the workgroups receive annual ALARA training and other training as required by the RAM license.

s. Instruct workers about the radiation effects on embryos/fetuses and the need to promptly notify their supervisors and site ARSO if they become pregnant (if the worker chooses to formally declare her pregnancy). It is not mandatory for the worker to declare her pregnancy; however, if she does, it must be by her and in writing in accordance with Reference (i).

t. Perform an annual review of the RSP for adherence to ALARA concepts and brief the results of the review to the local RSC.

u. Monitor the RSP routinely for performance. When appropriate, establish and report performance metrics.

v. Provide data outlined in the above requirements in written form, as well as the data surrounding any incidents, other information affecting the RSP, and the outcome/status of any investigations to the RSC at the quarterly meeting and at other times deemed necessary.

w. Develop local procedures to implement DHA instructions; monitor and report all nonionizing radiation activities to the site RSC, in accordance with References (g) and (w) through (z). Prior to the publication of DHA instructions, local procedures must align to policies and procedures established by the Joint Commission in accordance with References (n), (q), and (r).

x. Develop local procedures to implement DHA instructions and monitor and report all ionizing radiation device activities to the RSC, in accordance with References (e), (f), and (l) through (v). Prior to the publication of DHA instructions, local procedures must align to policies and procedures established by the NRC and the Joint Commission in accordance with References (n), (q), and (r).

y. Implement and maintain an effective Lead Apron Personal Protective Equipment Inspection Program as appropriate in accordance with Reference (z), and under other applicable service specific guidance.

z. Review proposed research protocol applications to the site RSC for approval. Prepare AU, AMP, and ANP packets (user qualifications) for DHA RSC approval. When necessary, establish technical ad hoc committee to extend staff capabilities for unique or technically complex problems.

aa. Maintain active communication with DHA Radiation Safety Director.

ab. Report incidents and unusual occurrences to DHA Radiation Safety Director in accordance with Reference (j).

ac. Should coordinate with installation Radiation Safety Officer to attend the RSC as a non-voting member.

ad. Coordinate with Joint Munitions Command for low level waste disposal.

ae. Retain decommissioning documents in accordance with Reference (j).

6. <u>AUs (TO INCLUDE PRINCIPAL INVESTIGATORS), ANPs, AND AMPs</u>. AUs (to include principal investigators), ANPs, and AMPs will:

a. Be qualified in accordance with Reference (j).

b. Receive a copy of the site-specific NRC License/permit from each respective ARSO, which includes the license application, as well as the current amendment for medical or research use of RAM. Follow the NRC regulations (Reference (j)), DHA Instructions, and applicable sections of the Radiation Safety's SOPs.

c. Consult with the site ARSO and DHA RSO and receive the approval of the DHA RSC before using RAM for a new procedure during the planning stage. Specific procedures for adding new uses and new use areas are covered in References (n) and (o). Institutional Review Board and DHA RSC approval is required before any research protocol can proceed.

d. Evaluate all procedures before using RAM to ensure exposures will be kept ALARA.

#### ENCLOSURE 3

## PROCEDURES AND MANAGEMENT COMMITMENT TO THE RADIATION SAFETY PROGRAM

#### 1. MANAGEMENT COMMITMENT

a. DHA Leadership is committed to the RSP and to the principle of keeping occupational exposed individuals and collective radiation exposures ALARA.

b. Executive management and the DHA RSC will support the Radiation Safety Director, site ARSOs, in those instances where it is necessary for the DHA RSO or site ARSO to assert authority. When any RSO or ARSO has been overruled, the DHA RSC will record the basis for its action and/or the basis for executive management's action in the minutes of the DHA RSC's quarterly meeting.

#### 2. DELEGATION OF AUTHORITY

a. Executive management will delegate authority to the DHA RSC for all aspects of the RSP.

b. Executive management will delegate authority to the DHA RSC, and DHA RSO for enforcement of the RSP and implementation of the ALARA policy.

c. Duties and responsibilities of the DHA RSC and RSOs are delineated in Enclosure 2. Additional duties may be assigned.

#### 3. <u>PERSONNEL WHO RECEIVE OCCUPATIONAL EXPOSURE TO IONIZING</u> <u>RADIATION</u>

NOTE: An occupationally exposed employee who receives under five milli-sievert (mSv) (500 millirem (mrem)) per year is a non-radiation worker (non-RW). A personal dosimetry device is not required for non-RW; however, basic radiation safety training is required annually. An occupationally exposed employee who potentially receives a dose of five mSv (500 mrem) per year (or more), is defined as an RW. An RW is required to be issued dosimetry and have additional radiation safety training.

a. Non-RW personnel whose exposure rate is less than five mSv (500 mrem) per year will:

(1) Receive instruction in the ALARA concept including time, distance, and shielding; its relationship to work practices; and available recourses if they believe that ALARA is not being promoted on the job.

(2) Inform their supervisors and the site ARSO in writing if they want to be considered a Declared Pregnant Worker. Although this is a voluntary practice, it is encouraged for any pregnant personnel who receive occupational exposure to ionizing radiation. The estimated date of conception should be included so that an appropriate dose to the fetus and the worker are recorded. Declared Pregnant Workers who are issued dosimetry after their pregnancy declaration will follow b.(2) through (5) below.

b. If a particular employee, job, or job position has historically or is estimated to receive 5 mSv (500 mrem) (or more) per year, or if a specific individual or specific job title is deemed as having the potential of an annual dose of over five mSv (500 mrem) by the RSO, the RW individual will:

(1) Receive instruction in the ALARA concept (including time, distance, and shielding), its relationship to work practices and available recourses if they believe that ALARA is not being promoted on the job.

(2) Be issued and wear a dosimeter. The dosimeter will be worn while performing DHA work around ionizing radiation or when entering areas where RAM are present at DHA facilities. If personal protective shields are used, the main (whole body) dosimeter will be worn under the protective shield. A second dosimeter will be worn at the collar, outside of the personal shield. Ring dosimeters may be used in nuclear medicine and some interventional procedures.

(a) Dosimetry devices will be available for change out at all times. They are to be kept in a designated central storage area (low background).

(b) Personnel leaving the command (or taking leave greater than 30 days) will turn their dosimeter in to the site ARSO prior to departure; if he or she goes on extended leave, temporary additional duty, transfers, separates from the military or termination from employment from the site.

(c) Be subject to appropriate administrative and/or disciplinary action (military members, civilians, and contract personnel), if they do not turn in their dosimeter and/or do not make their dosimeter available for rotation or lose a dosimeter.

(d) As dosimeters are government property, RWs will be subject to administrative discipline for handling dosimeters inappropriately, including, the purposeful exposure of the dosimeter without authorization of the site ARSO.

(e) Inform their supervisors and the site ARSO in writing if they want to be considered a Declared Pregnant Worker. Although this is a voluntary practice, it is encouraged for any pregnant personnel who receive occupational exposure to ionizing radiation. The estimated date of conception should be included so that appropriate dose to the fetus and the worker are recorded.

(f) Provide dosimetry reports from outside employment (i.e., moonlighting) to the ARSO.

4. <u>SUBORDINATE ORGANIZATION SUPPORT STAFF (Ancillary Support Staff)</u>. The Subordinate Organization Support Staff (Ancillary Support Staff), who may come in contact with ionizing radiation sources will:

a. Be trained on the principles of ALARA (time, distance, and shielding), to reduce the potential exposure to staff member(s) from sources of ionizing radiation by maximizing the distance from the source of ionizing radiation, minimizing exposure time, and maximizing the shielding between the source and the staff member.

b. Be aware of, and not linger in, the areas within their facility that have radioactive sources or equipment that produce ionizing radiation, such as: Nuclear Medicine, Radiation Oncology, Radiology, Orthopedics, Urology, Gastroenterology, Main Operating Room, Pain Clinic, etc.

c. Be educated to recognize packages marked with RAM labels or trefoil symbols, and do not receive any package containing these labels.

d. Be able to guide RAM delivery persons to the proper RAM delivery location.

#### 5. PROGRAM AND PROCEDURE

a. Ancillary staff members who work in the vicinity of ionizing radiation-producing equipment or sources, as well as occupational exposed workers, are responsible for following all RSP guidance, including ALARA principles, and will inform appropriate persons in their reporting channels and/or the site ARSO when safe practices involving exposure to ionizing radiation are not followed.

b. An occupational RSP is the sum of all methods, plans, and procedures used to protect the health and environment of personnel from exposure to sources of ionizing radiation. The RSP includes an Occupational Radiation Monitoring Program and a Diagnostic Imaging Equipment Performance Evaluation(s) Program. Reference (j) provides formalization of an occupational RSP for all employees (civilian, military, and contractors), working under an NRC license who are occupationally exposed to ionizing radiation. Reference (j) prescribes regulations, procedures, and responsibilities for use and control of NRC licensed material.

c. The Diagnostic X-ray Survey Program must follow Service Policies until DHA policy is published.

d. The RSP includes all aspects of radiation safety regarding the use of RAM for medical, training, or research use. Regulations establishing standards for the control of by-product material are found in Reference (j). Guidelines and suggested procedures for RAM use are in References (m) through (o). These three Nuclear Regulatory Commission Regulation series provide guidance for licenses of research use, medical use, and broad scope, respectively. Guidelines establishing standards for research are found in Reference (aa).

e. A professional who is familiar with the program requirements will conduct program audits annually. Also, to continually evaluate the effectiveness of the ALARA program, the site ARSO, along with the local RSCs, should conduct periodic reviews of the uses of RAM, radiation-generating devices, and facilities designed for the use of ionizing radiation at their facility.

f. Staff will support the RSP for non-ionizing radiation producing devices in accordance with standards in References (g) and (w) through (y).

## ENCLOSURE 4

#### PROCEDURES FOR ESTABLISHMENT OF INVESTIGATIONAL LEVELS

1. <u>INVESTIGATION LEVELS/GENERAL</u>. DHA hereby establishes investigational levels for occupational external ionizing radiation exposure which, when exceeded, will initiate review or investigation by the site ARSO and/or his staff. The adopted investigational levels are listed in the Table 1 and 2. These levels apply to the occupational exposure of individual workers. The site ARSO will review results of personnel monitoring, not less than once in any calendar quarter, as required by Reference (j). The following actions will be taken at the investigational level as defined by Tables 1 and 2.

a. <u>Quarterly Exposure of Individuals to an Amount of Occupational Dose that is Less Than</u> <u>Investigational Level I</u>. No ALARA Triggers exceeded; thus, no action, investigation, or report necessary.

b. <u>Personnel Exposures Equal to or Greater Than Investigational Level I, but Less Than</u> <u>Investigational Level II</u>. If the quarterly exposure is equal to or exceeds Investigational Level I but remains below Level II:

(1) The site ARSO will review the exposure of the individual within 30 days of dosimetry results and will report the results of such reviews at the site RSC meeting following the quarter when the exposure was recorded (providing that the exposure data is developed and available for the previous quarter).

(2) No further action related specifically to the exposure is required unless deemed appropriate by the site ARSO or the site RSC.

(3) The site RSC will, however, review each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the site's RSC minutes.

c. <u>Exposure Equal to or Greater Than Investigational Level II</u>. If the exposure equals or exceeds Investigational Level II:

(1) In most cases, an investigation is warranted. The site ARSO or designee will investigate the cause(s) of all personnel exposures equal to or exceeding Investigational Level II, to find root cause and, if warranted, take corrective and/or disciplinary action within 30 days.

(2) A report of the individual's Occupational Exposure Record will be presented to the site RSC at the first site RSC meeting following completion of the investigation. The details of these reports will be recorded in the site RSC minutes, as well as forwarded separately to the DHA RSC for review.

# 2. ALTERNATE INVESTIGATIONAL LEVEL DIFFERING FROM THAT LISTED IN TABLES 1 and 2.

a. In cases where exposures of one or more workers need to exceed the standards as set forth in Tables 1 and 2, for investigation level, a new higher investigational level may be established for that individual or that group when it is consistent with good ALARA practices, and when the new investigational levels would not track yearly to or exceed the federal limits of Reference (j).

b. In cases where there are lower federal limits (i.e., involving youth under 18 or in case of declared pregnancy), investigational levels may be lower(ed). For declared pregnant workers, the RSO will implement special monitoring efforts to ensure the dose to the embryo/fetus does not exceed five mSv (500 mrem), over the entire pregnancy. In addition, efforts will be made to ensure the monthly exposure rate does not exceed 0.5 mSv in any 1 month (50 mrem/month). Additional information regarding the dose limit to the fetus may be found in Reference (j), (dose equivalent to an embryo/fetus). Investigational Levels for declared pregnant workers are based on the above criteria and Reference (j).

c. Justification for any new investigational level must be documented and recorded in the site RSC minutes. The site RSC will review the justification for and approve or disapprove all revisions of investigational levels in Tables 1 and 2. The impact of this approved RSC change will be evaluated during the yearly review of the RSP program. Site RSC will approve and send to the DHA RSC for concurrence.

**Tables:** Occupational Exposure Investigational Level (reported as mSv (mrem) per calendar <u>quarter</u>). Set at ten percent of NRC Yearly Dose Limits (based on suggestion in Reference (j)).

PART OF BODY	Yearly	/Year	/Quarter LVL I	/Year	/Quarter LVL II
Whole body; head; tr arms above the elboy	unk including male gonads; v; or legs above the knee (50 mSv; 5000 mrem)	5 mSv (500 mrem)	1.25 mSv (125 mrem)	15 mSv (1500 mrem)	3.75 mSv (375 mrem)
Extremity; hands, el elbow; feet; knee; le	bow; arms below the g below the knee or skin (500 mSv; 50000 mrem)	50 mSv (5000 mrem)	12.50 mSv (1250 mrem)	150 mSv (15000 mrem)	37.5 mSv (3750 mrem)
Lens of eye	(150 mSv; 15000 mrem)	15 mSv (1500 mrem)	3.75 mSv (375 mrem)	45 mSv (4500 mrem)	11.25 mSv (1125 mrem)

PART OF BODY Yearly	/Quarter LVL I	/Quarter LVL II
Whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee (5000)	1.25 mSv (125 mrem)	3.75 mSv (375 mrem)
Extremity; hands, elbow; arms below the elbow; feet; knee; leg below the knee or skin (50000)	25 mSv (2500 mrem)	75 mSv (7500 mrem)
Lens of eye (15000)	3.75 mSv (375 mrem)	11.25 mSv (1125 mrem)

## Table 2. Nuclear Medicine - Double extremity for rings of Table 1.

## ENCLOSURE 5

#### DEFENSE HEALTH AGENCY RADIATION SAFETY COMMITTEE FUNCTION

1. <u>GENERAL</u>. The DHA RSC will oversee all activities related to the NRC license at DHA facilities and make recommendations of qualified individuals to serve on the DHA RSC and to serve as RSOs/ARSOs for each licensed facility. The DHA RSC's recommendations will be forwarded to the Director, DHA, or Executive Representative for approval.

2. <u>MEMBERSHIP</u>. All members of the DHA RSC are selected with guidance found in Reference (i). Executive management specifically selects the Chairperson, Radiation Safety Director, and/or the DHA RSO by providing appointment letters to the individuals. The DHA RSC will consist of the following members:

#### a. <u>Executive Members</u>:

- (1) Chairperson Director, DHA, or Designee (Chief, Medical Officer)
- (2) Co-Chairperson Chief, Public Health Division, or Designee
- (3) Transition Intermediate Management Organization Director/Director Representative
- (4) Executive Secretary Radiation Safety Director
- (5) Resources and Management (J8) Representative
- b. Other Voting Members:
  - (1) Site Command or Management Representative
  - (2) Site ARSOs
  - (3) Authorized User from Nuclear Medicine
  - (4) Authorized User of Radiation Oncology
  - (5) Nursing/Patient Care Representative

c. <u>Contractors</u>: Contractors cannot represent government executive or voting members. Contractors may only advise the RSC in a non-voting member capacity.

NOTE: As necessary, the Chairperson may invite ad hoc participants to provide expertise in health physics, legal, medical, medical physics, radiobiology, radio pharmacy, engineering, radiography, or other professional areas.

#### 3. ADMINISTRATION

a. <u>Meeting Frequency</u>. The DHA RSC must meet at regular frequencies and must establish a quorum to conduct business. The defined quorum is at least DHA's management representative, DHA Radiation Safety Director, three ARSOs, one AU from Nuclear Medicine, one AU from Radiation Oncology, and one Nursing Representative. Any organization having business on the agenda must have a Command or Management Representative and the site ARSO present.

b. <u>Status Reporting</u>. The Radiation Safety Director will manage the RSP and provide all reports to the executive members of the DHA RSC. The DHA RSC will review and approve RSP changes and implementation practices. The DHA RSC will take appropriate actions when best practices and non-compliance items are identified through audits, inspections, notifications, discussions, and documentation. Procedures and timing for all notification of incidents should follow Reference (j).

#### 4. <u>RESPONSIBILITIES</u>. The DHA RSC will:

a. Hold, at a minimum, quarterly meetings and those called by the executive members or the Radiation Safety Director.

b. Review the activities, operations, and compliance to RAM license conditions, as well as review presentations and proposals.

c. Review, vote, and approve in committee: RAM usage.

(1) Institutional Review Board protocols as below:

(a)	Final Approval Authority	Effective Dose Equivalent in any year
(b)	Exempt	0 mSv (entire study)
(c)	Site ARSO	> 0 and $< 30$ mSv
(d)	Site's RSC	$30 \text{ mSv to} \le 50 \text{ mSv}$
(e)	DHA's RSC	Pregnant person, nursing mothers (RAM), and minors $> 0$ mSy
(f)	DHA's RSC	All other patients $> 50 \text{ mSv}$

(2) New areas of use, amendments, renewals,

- (3) AUs, ANPs, and AMPs; and
- (4) DHA and site ARSOs.

d. Monitor the performance of facility audits and implementation of the recommendations of the RSP.

e. Establish a technical ad hoc committee to extend staff capabilities for unique or technically complex problems, when necessary.

f. Review all training programs, equipment, facilities, supplies, and procedures, as required.

g. Approve DHA Authorizations to subordinate commands specifying types, use and possession limits of RAM per facility.

h. Evaluate new uses of RAM.

i. Ensure the use of RAM is authorized by the license and that appropriate radiation safety measures will be taken in accordance with current operating and emergency procedures.

j. Prescribe special consideration to be required for proposed use of RAM (e.g., requirements for bioassays, physical examination of users, special monitoring procedures).

k. Report concerns about the policies and management of the RSP to the Director, DHA.

l. Review procedures for waste management and disposal at all subordinate organizations in accordance with References (j) and (o).

m. Review and approve procedures and plans related to Termination of Activities at all subordinate organizations in accordance with References (j) and (o).

#### 5. SUBORDINATE ORGANIZATION RSCs

a. Subordinate organizations using RAM for patient diagnosis, patient treatment, or conducting research are required to hold local RSC meetings, for which the DHA RSO or designee must participate.

b. Each site must meet at regular frequencies (quarterly) and must establish a quorum to conduct business. The defined quorum is at least one-half of the Committee's rostered membership to be present, including the ARSO and management representative (or designees).

c. Site RSC membership must comply with Reference (j), which "includes an AU of each type of use permitted by the license, RSO, representative of Nursing Service, and representative of Management who is neither an AU nor an RSO."

d. Site RSC minutes will be provided to the DHA RSC through the DHA Radiation Safety Director.

e. Site RSCs will:

(1) Monitor dosimetry reports;

- (2) Monitor the RAM inventory including receipt and disposal of RAM;
- (3) Monitor the training program and attendance rates;
- (4) Review audits and investigation related to the RSP;
- (5) Establish and monitor performance metrics for the local RSP; and
- (6) Conduct other business as necessary to maintain oversight of the local RSP.

6. <u>SUBORDINATE ORGANIZATIONS NOT REQUIRING RSCs</u>. Subordinate organizations not requiring RSCs will:

a. Inform local command of any non-compliance issues with the program.

b. Provide a written report to the DHA RSC through the DHA Radiation Safety Director detailing activities and reports for the previous calendar year by April 1st of the following year.

## APPENDIX

## DEFENSE HEALTH AGENCY SUBORDINATE ORGANIZATIONS

- (a) Walter Reed National Military Medical Center, Naval Support Activity, Bethesda, Maryland
- (b) Fort Belvoir Community Hospital, Fort Belvoir, Virginia
- (c) Medical Education and Training Campus, Joint Base San Antonio, Fort Sam Houston, Texas
- (d) Womack Army Medical Center, Fort Bragg, North Carolina
- (e) Naval Hospital Jacksonville, Naval Air Station, Jacksonville, Florida
- (f) 4th Medical Group, Seymour Johnson Air Force Base, North Carolina
- (g) 81st Medical Group, Keesler Air Force Base, Biloxi, Mississippi
- (h) 628th Medical Group, Joint Base Charleston, South Carolina
- (i) Transitional Intermediate Management Organization/Future Markets

## DHA Projected Subordinate Organizations (October 1, 2019)

- (a) Naval Medical Center Portsmouth, Portsmouth, Virginia
- (b) Naval Medical Center Camp Lejeune, Camp Lejeune, North Carolina
- (c) Naval Air Station Pensacola, Pensacola, Florida
- (d) Wright-Patterson Medical Center, Wright-Patterson Air Force Base, Ohio
- (e) Eglin Air Force Base Hospital, Eglin Air Force Base, Florida
- (f) Eisenhower Army Medical Center (Fort Gordon), Fort Gordon, Georgia
- (g) Moncrief Army Community Hospital (Fort Jackson), Fort Jackson, South Carolina
- (h) Martin Army Community Hospital (Fort Benning), Fort Benning, Georgia
- (i) Blanchfield Army Community Hospital (Fort Campbell), Fort Campbell, Kentucky
- (j) Ireland Army Clinic (Fort Knox), Kentucky
- (k) Darnall Army Medical Center (Fort Hood), Fort Hood, Texas
- (1) Reynolds Army Community Hospital (Fort Sill), Fort Sill, Oklahoma
- (m) Joint Base San Antonio-Fort Sam Houston, Fort Sam Houston, Texas
- (n) Naval Medical Center San Diego, San Diego, California
- (o) Naval Hospital Bremerton, Bremerton, Washington
- (p) Naval Hospital Camp Pendleton, Camp Pendleton, California
- (q) Mike O'Callaghan Military Medical Center (Nellis Air Force Base), Nellis Air Force Base, Nevada
- (r) Joint Base Elmendorf Richardson, Anchorage, Alaska
- (s) David Grant United States Air Force Medical Center (Travis Air Force Base), Fairfield, California
- (t) William Beaumont Army Medical Center (Fort Bliss), El Paso, Texas
- (u) Evans Army Community Hospital (Fort Carson), Fort Carson, Colorado
- (v) Leonard Wood Army Community Hospital, Fort Leonard Wood, Missouri
- (w) Madigan Army Medical Center (Joint Base Lewis McCord), Joint Base Lewis-McCord, Washington

DHA Projected Subordinate Organization (April 1, 2020)

- (a) Tripler Army Medical Center, Honolulu, Hawaii
- (b) Naval Hospital Guam, Tutuhan, Guam
- (c) Naval Hospital Okinawa, Okinawa, Japan
- (d) Landstuhl Regional Medical Center, Landstuhl, Germany

## **GLOSSARY**

#### PART I. ABBREVIATIONS AND ACRONYMS

ALARA	as low as reasonably achievable
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ARSO	Associate Radiation Safety Officer
AU	Authorized User
DHA	Defense Health Agency
DHA-AI	Defense Health Agency-Administrative Instruction
mrem	millirem
mSv	milli-sievert
NRC	Nuclear Regulatory Commission
RAM	radioactive material
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSP	Radiation Safety Program
RW	Radiation Worker
SOP	Standard Operating Procedure
TEDE	total effective dose equivalent

## PART II. DEFINITIONS

These terms and their definitions are for the purposes of this DHA-AI.

<u>Associate RSO</u>. An individual qualified by training and experience in radiation protection in accordance with References (j), (n), and (o), authorized to act as the RSO in the RSO's absence.

<u>byproduct material</u>. RAM that are reactor produced, accelerator produced, discreet source of radium and processed naturally occurring material.

<u>Deep Dose Equivalent (H<sub>d</sub>)</u>. External whole-body exposure based on the dose equivalent at a one-centimeter depth in tissue.

<u>extremities</u>. Extremity; hands, elbow; arms below the elbow; feet; knee; leg below the knee or skin.

<u>Hub and Spoke model</u>. DHA will be issued one NRC License for the subordinate organizations. For RAM usage permissions, DHA will provide each site appropriate RAM authorizations under which to operate.

mSv. Unit of measure for a dose equivalent. Equal to 100 mrem.

<u>non-RW</u>. For dosimetry issuance requirement and any applicable medical physical purposes, those participants who are not estimated to receive, or that receive less than five mSv (500 mrem) on their deep (total effective dose equivalent ((TEDE), total exposure to the body from both internal and external sources) yearly dosimetry badge reading.

<u>NRC Severity Levels (SL) I, II, III, and IV</u>. Describes a graduated system of the seriousness of violations.

Severity Level I is for serious safety or security consequences. Severity Level II is for significant safety or security consequences. Severity Level III is for moderate safety or security consequences. Severity Level IV is for less serious, but are of minor concern that resulted in no safety or security consequences. Minor Violations are those that are less significant than a SL IV violation.

occupationally exposed worker. An employee who in the course of their daily job works with or encounters ionizing radiation.

<u>radiological incident</u>. Occurrences involving licensed material of the following: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material.

<u>RW</u>. For dosimetry issuance requirement and any applicable medical physical purposes, those participants who may receive, or that do receive 500 mrem or more on their deep (TEDE, total exposure to the body from both internal and external sources) yearly dosimetry badge reading.

<u>Shallow Dose Equivalent (H<sub>s</sub>)</u>. Applies to the skin or extremity and is taken as dose equivalent at a depth of 0.007 centimeters averaged over an area of one square centimeter.

<u>TEDE</u>. A total sum measure of deep body dose to include both internal and external radiation exposure. TEDE is the sum of effective dose equivalent from external exposure and committed effective dose equivalent from internal exposure, thereby taking into account all known routes of exposures (total exposure to the body from both internal and external sources).