DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

DHA-IPM 21-001
April 23, 2021

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Notifications and Reports for Radiation Safety Unusual Occurrences at Military Medical Treatment Facilities (MTFs)

References: See Attachment 1.

This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (f), establishes the Defense Health Agency's (DHA) procedures for reporting and notification of radiation safety unusual occurrences under the Nuclear Regulatory Commission (NRC) License 45-35423-01.

- The Radiation Safety Director or designee conducts direct communication with the NRC, serving as the DHA Radiation Safety Officer (RSO) and Executive Secretary of the DHA Radiation Safety Committee. A designee can be the DHA Associate Radiation Safety Officer (ARSO), an MTF ARSO, a DHA Health Physicist, etc.

- Unusual occurrences are uncommon occurrences outside the normal or scope of practice, as defined in established protocols, procedures, and regulations. Attachments 2 and 3 include descriptions of unusual occurrences and requirements for notifications and reports. Note that this list is not all inclusive, and there may be other situations that require you to make notifications and/or reports. If it is unclear as to whether or not to make a notification, contact the DHA Radiation Safety Program (RSP) to discuss the issue and determine if a formal notification is required. Submit written reports for unusual occurrences to the DHA RSP. Attachment 4 provides a Radiation Safety Situation Report (SITREP) example.

- Submit all Unusual Occurrence Radiation Safety SITREPs to the DHA RSP by e-mail at: dha.ncr.pub-health.mbx.radiation-safety@mail.mil. Serious or time-sensitive unusual occurrences require immediate telephone notification to DHA. Make telephonic notifications to the DHA Radiation Safety Duty Line at: (703) 681-7881. If you cannot reach a DHA Radiation Safety staff member at the duty line, attempt to contact a staff member directly until you make positive contact. Make telephone reports/notifications directly to a DHA Radiation Safety staff member; it is not sufficient to leave a recorded message. A written SITREP (see example in Attachment 4) must follow telephonic notifications/reports within the required timeframe.

- Notify DHA as soon as practicable to allow adequate time for the DHA RSP to prepare and make official notification to the NRC, if required. To ensure DHA can meet the regulatory timeline requirements, the trigger level timelines for notification to DHA are much shorter than for notification to the NRC. The DHA RSP requires prompt reporting to properly evaluate each incident, identify potential radiation safety risks to workers and members of the public, and to take appropriate actions to minimize the chance of future incidents throughout the DHA RSP. In some cases, initial SITREPs will not contain every fact and issue regarding the unusual occurrence, as concurrent investigations may be underway. For occurrences in which investigations are ongoing or corrective actions are pending, the submission of a follow-up SITREP is required once actions are complete to ensure implementation and future mitigation of similar events.

- The Site ARSO will ensure the briefing of this DHA-IPM, stipulated reporting criteria, and notification procedures to the site Radiation Safety Committee and radiation workers (e.g., radiation safety personnel, authorized users, nuclear medicine technicians, and physicists). Subsequent RSP site visits will verify the delivery of this briefing.

- All Unusual Occurrences will be presented to the MTF's local Radiation Safety Committee (RSC) by the Site ARSO. The RSC management representative (typically the Chief Medical Officer, Chief of Medical Staff, or similar deputy commander) will be notified of the Unusual Occurrence concurrent with notification to DHA. MTF leadership needs to be involved in the notification process to ensure that any additional reporting requirements, such as to accrediting organizations, is also accomplished.

- This DHA-IPM applies to DHA MTFs and all other organizational entities within the DHA.

- This DHA-IPM is not cleared for public release. This DHA-IPM is available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

This DHA-IPM is effective upon signature. If not reissued or canceled, it will expire 1 year from the date of the signature per Reference (c). The point of contact for this DHA-IPM is COL Ricardo Reyes, who may be reached at (703) 681-9292 or ricardo.a.reyes.mil@mail.mil.

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Attachments:
1. References
2. Unusual Occurrences: Notifications and Reports For Reportable (To The Nuclear Regulatory Commission) Events
3. Unusual Occurrences: Notifications and Reports For Other Unusual Occurrences From Military Medical Treatment Facilities To Defense Health Agency
4. Radiation Safety Situation Report Sample
Glossary

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cc:
DHA, Radiation Safety Committee

ATTACHMENT 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) DHA-Administrative Instruction 087, "Radiation Safety Program (RSP) and Radiation Safety Committee (RSC)," August 1, 2019
(e) Title 10, Code of Federal Regulations (CFR), Parts 20, 30, 35, and 71
(e) Title 21, CFR part 803
(f) NUREG-1556, "Consolidated Guidance About Material Licenses, Volume 9, Rev. 3, Program-Specific Guidance About Medical Licenses," September 2019
(g) Nuclear Regulatory Commission (NRC) License 45-35423-01, issued to DHA with the most current amendment

ATTACHMENT 2

UNUSUAL OCCURRENCES: NOTIFICATIONS AND REPORTS FOR REPORTABLE (TO THE NUCLEAR REGULATORY COMMISSION) EVENTS

(Make Notifications to the DHA Radiation Safety Officer and NOT directly to the Nuclear Regulatory Commission (NRC))

<table>
<tr><th>Event
(NOT Limited to the Following)</th><th>Telephone Notification</th><th>Written Report</th><th>Regulatory Requirement</th></tr>
<tr><td rowspan="2">Medical Event (as defined by the NRC) (1)
(i) The total dose delivered differs from the prescribed dose by 20 percent or more; or
(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;
(iv) The total source strength administered differs by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;
(v) The total source strength administered outside of the treatment site exceeds 20 percent of the total source strength documented in the post-implantation portion of the written directive
[Note: Criteria (i) & (iii) above also apply to Linear Accelerator-based external beam therapy]
[Note: Criteria (iv) & (v) above apply to permanent implant brachytherapy only]</td><td>Immediate to DHA

(1 day to NRC)</td><td>10 days to DHA

(15 days to NRC)</td><td rowspan="2">10 CFR 35.3045(a)(1)(i)
10 CFR 35.3045(a)(2)(i)
10 CFR 35.3045(a)(2)(ii)</td></tr>
<tr><td colspan="2">To NRC: if any of the conditions in the column on the left are applicable, <u>and</u> a dose differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

[Note: Linear Accelerator-based Medical Events are not reportable to the NRC]</td></tr>
<tr><td>Medical Event (2)
(i) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;
(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
(iii) An administration of a dose or dosage to the wrong individual or human research subject;
(iv) An administration of a dose or dosage delivered by the wrong mode of treatment;
(v) A leaking sealed source;
(vi) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or
(vii) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue</td><td>Immediate to DHA

(1 day to NRC)</td><td>10 days to DHA

(15 days to NRC)</td><td>10 CFR 35.3045(a)(1)(ii)
10 CFR 35.3045(a)(2)(iii)</td></tr>
</table>

[Note: Criteria (i), (iii), (vi), and (vii) above also apply to permanent implant brachytherapy]	*To NRC: if any of the conditions in the column on the left are applicable, and a dose exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.*		
Medical Event (3) A dose to the skin, an organ, or tissue, other than the treatment site, that exceeds by 0.5 Sv (50 rem) to the organ or tissue, and 50 percent or more of the dose expected from the administration defined in the written directive, prepared or revised before administration	Immediate to DHA (1 day to NRC)	10 days to DHA (15 days to NRC)	10 CFR 35.3045(a)(1)(iii)
Medical Event (4) Any event resulting from the intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician	Immediate to DHA (1 day to NRC)	10 days to DHA (15 days to NRC)	10 CFR 35.3045(b)

Dose to embryo/fetus (1) Any dose to an embryo/fetus that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user	Immediate to DHA (1 day to NRC)	10 days to DHA (15 days to NRC)	10 CFR 35.3047(a)
	To NRC: only if the dose to an embryo/fetus is greater than 50 mSv (5 rem) dose equivalent.		
Dose to a nursing child (2) Any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding mother	Immediate to DHA (1 day to NRC)	10 days to DHA, at their request (15 days to NRC)	10 CFR 35.3047(b)
	To NRC: only if the dose to a nursing child is greater than 50 mSv (5 rem) total effective dose equivalent; or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.		

Any stolen, lost, or missing radioactive material	Immediate to DHA	20 days to DHA	10 CFR 20.2201
	To NRC immediately: only if the radioactive material was in an aggregate quantity ≥ 1,000 times the quantity specified in Appendix C to part 20 under such circumstances that it appears that an exposure could result to persons in unrestricted areas; or		

	To NRC within 30 days: only if the radioactive material was in a quantity >10 times the quantity specified in Appendix C to part 20 that is still missing at this time. *(30 days written report to NRC)*		

Receiving and opening packages: if removable surface contamination exceeds the limits of 10 CFR 71.87(i); or external radiation levels exceed the limits of 10 CFR 71.47	Immediate to DHA and NRC (*also notify final delivery carrier immediately*)	20 days to DHA (30 days to NRC)	10 CFR 20.1906 10 CFR 71.87 10 CFR 71.47

Any event involving radioactive material that may cause an individual to receive a whole-body dose greater than 0.05 Sv (5 rem)	Immediate to DHA	20 days to DHA	10 CFR 20.2202(a)(1)(i); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(i); 10 CFR 20.2203(a)(1)
	To NRC immediately: a whole-body dose greater than 0.25 Sv (25 rem); or *To NRC within 24 hours: a whole-body dose greater than 0.05 Sv (5 rem) received in 24 hours* *(30 days written report to NRC).*		
Any event involving radioactive material, that may have caused an individual to receive a lens dose equivalent greater than 0.15 Sv (15 rem)	Immediate to DHA	20 days to DHA	10 CFR 20.2202(a)(1)(ii); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(ii); 10 CFR 20.2203(a)(1)
	To NRC immediately: a lens dose equivalent greater than 0.75 Sv (75 rem); or *To NRC within 24 hours: a lens dose equivalent greater than 0.15 Sv (15 rem) received in 24 hours* *(30 days written report to NRC).*		
Any event involving radioactive material, that may have caused an individual to receive an extremity dose greater than 0.5 Sv (50 rem)	Immediate to DHA	20 days to DHA	10 CFR 20.2202(a)(1)(iii); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(iii); 10 CFR 20.2203(a)(1)
	To NRC immediately: an extremity dose greater than 2.5 Sv (250 rem); or *To NRC within 24 hours: an extremity dose greater than 0.5 Sv (50 rem) received in 24 hours* *(30 days written report to NRC)*		
Any release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received any intake	Immediate to DHA	20 days to DHA	10 CFR 20.2202(a)(2); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(2); 10 CFR 20.2203(a)(1)
	To NRC immediately: a release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake <u>five times</u> the annual limit on intake; or		
	To NRC within 24 hours: a release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of <u>one</u> annual occupational limit on intake *(30 days written report to NRC).*		

Doses in excess of any of the following: (i) The occupational dose limits for adults in 10 CFR 20.1201; or (ii) The occupational dose limits for a minor in 10 CFR 20.1207; or (iii) The limits for an embryo/fetus of a declared pregnant woman in 10 CFR 20.1208; or (iv) The limits for an individual member of the public in 10 CFR 20.1301; or (v) Any applicable limit in the authorization; (vi) The as low as reasonably achievable constraints for air emissions established under 10 CFR 20.1101(d)	Immediate to DHA (See 10 CFR 20.2202)	20 days to DHA (30 days to NRC)	10 CFR 20.2203(a)(2) CFR 20.1201 10 CFR 20.1207 10 CFR 20.1208 10 CFR 20.1301 10 CFR 20.1101(d)
	To NRC: in addition to the notifications required by 10 CFR 20.2202, each ARSO shall submit a written report within 30 days after learning of any of the occurrences in the 1st column.		
Levels of radiation or concentrations of radioactive material in: (i) A restricted area in excess of any applicable limit in the authorization; or (ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part, or in the authorization (whether or not involving exposure of any individual in excess of the limits in 10 CFR 20.1301)	Immediate to DHA (See 10 CFR 20.2202)	20 days to DHA (30 days to NRC)	10 CFR 20.2203(a)(3)
	To NRC: in addition to the notifications required by 10 CFR 20.2202, each ARSO shall submit a written report within 30 days after learning of any of the occurrences in the 1st column.		
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate to DHA and NRC	20 days to DHA (30 days to NRC)	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	Immediate to DHA (24 hours to NRC)	20 days to DHA (30 days to NRC)	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any authorized material or device, container, or equipment with authorized material	Immediate to DHA (24 hours to NRC)	20 days to DHA (30 days to NRC)	10 CFR 30.50(b)(4)
Defect in equipment that could create a substantial safety hazard	Next day to DHA (2 days to NRC)	20 days to DHA (30 days to NRC)	10 CFR 21.21(d)(3)(i)
Leaking source: leak testing reveals the presence of 0.005 microcuries or more of removable contamination	Next day to DHA (none to NRC)	3 days to DHA (5 days to NRC)	10 CFR 35.3067
Planned special exposures (PSE) (as defined by the NRC)	Immediately upon consideration of conducting a PSE. (none to NRC)	3 days to DHA after completion of PSE	10 CFR 20.1206 10 CFR 20.2204

		(30 days to NRC)	
Any deliberate acts of non-compliance, falsifying records, or any other fraudulent behavior with respect to radiation safety	Immediate to DHA after discovery	3 days to DHA	10 CFR 30.10

ATTACHMENT 3

UNUSUAL OCCURRENCES: NOTIFICATIONS AND REPORTS FOR OTHER UNUSUAL OCCURRENCES FROM MILITARY MEDICAL TREATMENT FACILITY TO DEFENSE HEALTH AGENCY

(Make Notifications to DHA Radiation Safety Officer (RSO) and NOT directly to the Nuclear Regulatory Commission (NRC))

Event (*NOT Limited to the Following*)	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
(1) Any deviant delivery of a radioactive package	Only if there is a loss of control or a dose to an individual	10 days to DHA	None
(2) Any administration of a dose or dosage to the wrong individual, not stated in Attachment 2	At the discretion of the site ARSO	5 days to DHA	None
(3) Any administration of a wrong radioactive drug containing byproduct material or by the wrong route of administration, not stated in Attachment 2	At the discretion of the site ARSO	5 days to DHA	None
(4) Any contamination that requires: (i) Health Physics support or oversight to remove; and (ii) Contamination events reported to the MTF's Command	At the discretion of the site ARSO	10 days to DHA	None
(5) Radiation Waste Alarms involving byproduct material (excluding patient excreta) if more than 1 Alarms occur in 24 hours or if Radioactive Material departs the facility	At the discretion of the site ARSO	10 days to DHA	None
(6) Any radiation-related event that gets reported as a Patient Safety Report	Next day to DHA (the day after Patient Safety Report is submitted)	10 days to DHA	None
(7) Any discrepancy noted on a written directive that does not lead to a medical event or reportable event stated in Attachment 2	At the discretion of the site ARSO	10 days to DHA	None
(8) Any unscheduled event that impacts the MTF's abilities and capabilities in regards to imaging or Radioactive Material use	Immediate to DHA for unplanned events, at the discretion of the site ARSO for planned events	10 days to DHA	None
(9) Any outside inspection (Joint Commission, Occupational Safety and Health Administration, Department of Transportation, etc.) that focuses on or considers the Radiation Safety Program	At the discretion of the site ARSO	10 days to DHA if there were adverse findings, 30 days if no findings were identified	None

**(Make Notifications to DHA Radiation Safety Officer (RSO)
and NOT directly to the Nuclear Regulatory Commission (NRC))**

Event **(*NOT Limited to the Following*)**	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
(10) Any event, occurrence, near miss, etc. that the ARSO believes should be shared with DHA Radiation Safety	At the discretion of the site ARSO	10 days to DHA, at their request	None

ATTACHMENT 4

DHA RADIATION SAFETY SITUATION REPORT SAMPLE

DHA Authorization: *Insert the DHA Authorization number followed by the MTF name*

Type of Incident: *Insert Medical Event, NRC Reportable Event or DHA Notification of Unusual Occurrence*

Brief Description: *Insert a descriptive title for the event; e.g., lost source*

[ ] Initial [ ] Follow-Up [ ] Final [ ] Corrective *Mark appropriate box; the first report of an occurrence which the ARSO believes contains all available information without an anticipated follow-up would be marked Final.*

Notification Prior to Report [ ] DHA Duty line [ ] DHA Staff Member – *include name* [ ] None
Date/time Group of telephonic notification: *Insert date/time of first notification and any follow-up calls*

Date/Time Group of Occurrence: *Date/Time of occurrence and date/time of discovery may be different*

Location Event Occurred: *Insert the location within the MTF where the event occurred*

Date/Time Group of ARSO notification: *Date/Time ARSO or Health Physics was first notified of the occurrence*

Date/Time/Group Event Resolved: *Times need to be in Local Time*

Personnel Involved: *Include Rank/Paygrade, Duty Position, and any other pertinent information about the individuals involved.* ***Note: Do not include Name/personally identifiable information/protected health information.***

Statement of Incident: *Detailed statement of the incident*

Mission Impact: *Detailed statement of mission impact known at the time of submission and potential future impact at this MTF and other MTFs*

Corrective Action Required/Taken: *Report mitigation/corrective actions taken or planned*

Strength of Corrective Action(s): *To be identified by the reporter.* ***Strong Actions****: Architectural/physical plant changes, New devices with usability testing before purchasing, Engineering control or interlock (forcing functions), Simplify the process and remove unnecessary steps, Standardize on equipment on process or caremaps, Tangible involvement and action by leadership in support of patient safety.* ***Intermediate actions****: Redundancy, Increase in staffing/decrease in workload, Software enhancements/modifications, Eliminate/reduce distractions (sterile medical environment), Checklist/cognitive aid, Eliminate look and sound-alikes, Readback, Enhanced documentation/communication.* ***Weak Actions****: Double checks, Warnings and labels, New procedure/memorandum/policy, Training, Additional study/analysis*

DHA Radiation Safety's Assistance Required: *Detail assistance required*

Media Interest: *Yes/No, include local/national media involvement*

Contact Information: *Include local contact information for individuals who may have additional information beyond what the SITREP reporter has access to*

SITREP Reporter Information: *Individual who completed this report*
Name:
Phone:
E-Mail:

ARSO or POC for Further Information: *Insert information of appropriate authority figure if not SITREP reporter*

Name:
Phone:
E-Mail:

GLOSSARY

ABBREVIATIONS AND ACRONYMS

ARSO	Associate Radiation Safety Officer
CFR	Code of Federal Regulation
DHA	Defense Health Agency
DHA-IPM	Defense Health Agency–Interim Procedures Memorandum
MTF	Military Medical Treatment Facility
NRC	Nuclear Regulatory Commission
PSE	Planned Special Exposure
RSO	Radiation Safety Officer
RSP	Radiation Safety Program
SITREP	Situation Report