


*CIPLET
WELLS*

17303-27

	BRIEF FOR DGGHO	
	JOINT HEALTH COMMAND (JHC) - 2GHB INCIDENT CLOSURE PACK	
Branch / Directorate: DSCA	Reference: R21978205	
Timing: Routine	Action required by:	
Copies: 1		

Recommendations:

That you:

- i. **note** the 2 GHB Radiation Incident Closure Pack provided with this brief.
NOTED/PLEASE DISCUSS
- ii. **note** that Director Army Health (DAH) has agreed to develop a Health Instruction that directs compliance with the ADF Radiation Safety Management Plan and Radiation Management Plan (RSMP&RMP) and to meet with you to finalise NLT 30 November 15.
NOTED/PLEASE DISCUSS
- iii. **agree** to the closure of this issue as the JHC Nominee.
AGREE/NOT AGREED/PLEASE DISCUSS

Key Points

1. Although the initial email from [redacted] on 17 Sep 13 notified ARPANSA of an 'accident' involving the use of the Dynarad, the matter was redressed by Director DRSE and reduced in severity to an incident in an email dated 01 Oct 13. ARPANSA has not asked for any further information on the incident, although they have the regulatory right to do so in the future. Such a request may be triggered by the current AHPRA inquiry but has not done so yet.
2. The incident was treated as a 'near miss', both in regard to the health risks of exposing patients to Radiography from a defective x-ray set, and to the regulatory risk of using an x-ray set that was out of compliance. There are many lessons to be learned and the appropriate response is to ensure that the RMP and the RSMP are amended to ensure that a repeat incident cannot reoccur. Once this is done, DDRSE will update the incident response in the Quarterly Report and draw it to a close.
3. ARPANSA's main concerns are that the incident is properly dealt with. If that is done internally, by DRSE acting as the Internal Regulator and JHC acting as a responsible Nominee, then ARPANSA will not have to act. It is only if the Licence Holder is unwilling or incapable of acting, that ARPANSA will find it necessary to intervene. ✓
4. A quick presentation to the next DRSAAC, illustrating how JHC has been able to exert effective control over its medical radiography organisation, will reinforce the message to the other Nominees and show JHC in a good light.



*Just make
file for presentation
to DRSAAC
close to 2014*


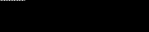
Resources

5. There are no additional financial or workforce resource implications associated with this brief.

Consultation

7. DRSE as the internal regulator were consulted and provided input to this brief.

Cleared by: M. WALKER GPCAPT DSCA 01 May 15	
Contact Officer: LCDR Tracey Elliott	Phone: 


Approved by: G.M. Whelan BRIG DGGHO <i>good ok</i> 6 May 15	
Contact Officer: LCDR Tracey Elliott	Phone: 

Enclosures:

1. Brief for DGGHO – Radiation Medical Practitioner Response to Routine Investigation into the 2GHB Radiation Accident.
2. 2GHB- Quick Assessment- Damage to medical equipment AACAP 2013
3. DAH Minute - AACAP 13 Dynard Radiation Incident (covering Routine Inquiry and Follow up actions).
4. Related emails.

please package

*QA, RI, Minute from DAM, GHO Brief w/ ARPANSA
letter to package w/ class of the report 16/4/15*

	BRIEF FOR DGGHO RADIATION MEDICAL PRACTITIONER RESPONSE TO THE ROUTINE INVESTIGATION INTO THE 2 GHB RADIATION ACCIDENT	
	Branch: GHO	Reference: DSCAR
	Timing: Routine	Action required by:
	Copies: DAH, DDRSE, Deputy RMP, Chair MICO	

Recommendations

That you:

- i. Approve the radiation breaches identified in this brief for Army to address.

APPROVED / NOT APPROVED / PLEASE DISCUSS

References:

- A. DGPERS-A/OUT/2014/R19302092 of 19 Aug 14
- B. JHC Radiation Safety Management Program and Radiation Management Plan of 12 Nov 12
- C. Army Radiation Safety Management Plan
- D. DSCA/OUT/2013/R15863018 Minutes of the Army Stakeholder Medical Radiation Safety and Technical Lines of Communication Meeting Held by Teleconference on 20 Sep 13 of 02 Oct 13
- E. Defence Radiation Source Licence
- F. Health Practitioner Regulation National Law Act of 2009
- G. 2GHB SOP 026 Medical Imaging Department of Mar 2013
- H. DSCA/OUT/2013/R15135406 Radiology and Radiation Safety Cell Preliminary Report on 2GHB JHC RSMP and RMP Health Check 04 Jun 13 of Aug 13
- I. Defence Safety Manual (SAFETYMAN)
- J. Defence Radiation Safety Manual
- K. Radiation Protection Series No 6 - National Directory for Radiation Protection
- L. ARPANSA - Regulatory Guide: Reporting an Accident 4.1.
- M. Radiation Protection Series No.14, Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation, 2008.
- N. 2GHB/2013/03921563 Response to Preliminary Report 2GHB JHC RSMP and RMP Health Check 04 Jun 13 of 13 Sep 13
- O. SOP 041 Medical Imaging Department, 2GHB

Background

1. During AACAP13, Army utilised a damaged Dynarad x-ray machine in the provision of medical imaging services to Defence members for several months, before the damage was noted by the Command team during a visit to the deployed location. This was subsequently reported incorrectly as an accident directly to the CEO of ARPANSA, bypassing established reporting chains and responsible personnel for such incidents.
2. A quick assessment (QA) and Routine Investigation (RI) were subsequently carried out with the RI being completed in Oct 13. A copy of the RI was provided to the ADF Radiation Medical Practitioner (RMP) (the authorising officer for all medical radiation exposures in the ADF and technical authority for such matters, through reference A) nearly 12 months after completion.

3. 12 recommendations were made in the RI, which were accepted by CO 2GHB. An additional three recommendations were made by CO 2GHB.

4. DAH has accepted all recommendations and has asked that the Army Health Steering Group consider whether compliance with reference B should be articulated as a mandatory requirement for Army health personnel through promulgation of an Army Health Instruction. This is to confirm compliance with reference B despite it already being outlined as mandatory in reference C, and Army Health personnel across the chain of command, from DAH to 2GHB radiographers, formally agreeing to comply with its provisions through reference D.

5. The recommendations made are supported.

ADF RMP Review of RI Findings

6. The RI narrowly focuses on the events surrounding the damage to the x-ray unit and actions taken in addressing it. There does not appear to have been any action taken to recognise, investigate or address the serious issues subsequently identified by the RI, which include:

- a. the x-ray machine had not undergone regular compliance testing as required by the Defence Radiation Source Licence, at reference E, since 2009
- b. the x-ray machine failed the last compliance test undertaken in 2009, with no record of measures to rectify the failure
- c. evidence in the RI shows that 2GHB staff were aware that the machine was not compliant yet continued to utilise it; representing a contradiction of accepted standards of practice, and notifiable conduct under s140 of Reference F, all of which have not been reported
- d. no evidence exists that any assessment has been undertaken to determine the impact on patients and staff of non-compliant equipment including:
 - 1) determination of locations where the x-ray machine was used
 - 2) identification and assessment of patients and staff exposed to x-radiation produced by the machine
 - 3) calculation of potential radiation exposures each patient and staff member received
 - 4) assessment of Thermoluminescent Dosimeter (TLD) results for all staff potentially exposed to radiation produced by the machine
 - 5) determination of incident notification and health surveillance requirements.
- e. servicing and non-technical inspection routines were not maintained or appropriately documented
- f. inconsistencies exist surrounding the content and application of SOPs where:
 - 1) the SOP included in the RI does not represent the SOP in place at the time of the incident

- 2) the SOP in the RI is dated Aug 13, whilst damage occurred in Jun 13
 - 3) a copy of the SOP in place at the time of the incident, reference G, dated Mar 13, was obtained by the Compliance Review Team (CRT) as part of the audit activity undertaken in Jun 2013 and referred to in reference H
 - 4) amendments in the Aug 13 SOP (in the RI) from the Mar 13 SOP (Reference H) specifically address the issue of reporting damage and conducting a coin test to assess functionality, although the damage was not reported as an accident directly to the CEO of ARPANSA and bypassing appropriate chain of command until Sep 13.
- g. evidence in the RI exists that 2GHB staff were aware the machine was damaged yet took no action until it was identified by the Battalion 2IC
- h. TLDs were not being managed appropriately during AACAP despite the CRT being assured in Jun 13 that a compliant procedure was in place
- i. inconsistencies in the identification of the seriousness of the incident where:
- 1) evidence identifies 2GHB considered the risk low
 - 2) the risk of exposure was considered so low that dose calculations were not considered necessary
 - 3) the issue was so serious it was considered as an accident rather than an incident
 - 4) the issue was so serious its reporting had to bypass the chain of command to be reported as an accident directly to CEO ARPANSA.
7. These serious issues were identified to Army; however no response has been provided to indicate they have been adequately addressed.
8. Army states in the RI that reference B did not adequately outline incident reporting processes, despite these processes being clearly documented in line with overarching Defence radiation safety policy outlined in references I-K. However, evidence in the RI shows that 2GHB did not refer to reference B IOT determine reporting requirements but rather reference L
9. Communication and reporting of detail associated with this issue by Army has been contradictory to the established and agreed chains of command and technical authority.

Radiation Safety Breaches Identified

10. Review of reference A has identified the following radiation safety breaches:
- a. The DYNARAD X-ray unit (05262-1205) failed a compliance test in 2009 and was not retested, which implies that every patient irradiated by that machine since, represents an unreported radiation safety incident
 - b. The Site Ionising Radiation Safety Folder was out of date and not made available to the investigator
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- c. The damaged X-ray machine was not reported to the JHC RSO or ADF RMP
- d. Irradiation of patients using a damaged x-ray unit represents a practice that is not authorised by the ADF RMP; therefore Army radiographers were acting without authorisation
- e. The ADF RMP was not appropriately advised of:
 - 1) patients irradiated
 - 2) examinations undertaken
 - 3) radiographer TLD radiation doses.
- f. The ADF RMP's subsequent review of the above and report through Director Specialist Clinical Advice (DSCA) to DAH was not included in the RI
- g. no appropriate medical radiation safety review of patients or staff exposed appears to have been undertaken or documented
- h. the incident was reported directly to CEO ARPANSA as an accident despite multiple radiation incidents involving Army members occurring since the damage occurred
- i. the report to CEO ARPANSA did not go through the appropriate technical chain of command, bypassing:
 - 1) JHC RSO
 - 2) ADF RMP
 - 3) the Nominee (Responsible Person), DGGHO
 - 4) DRSE
 - 5) CJLOG
 - 6) CDF and the Secretary.

Personnel Medical Irradiation

11. It is expected that Defence member medical ionising irradiation doses arising from the breaches which have occurred since 2009, including this incident, are unlikely to be of clinical significance; however no definitive evidence is currently available to make such a determination. Except for the AACAP 13 technical record, there is also no information currently available of where the unit was deployed, who was examined, or what staff may have been affected and to what degree.

Facilitation of ADF RMP Review of Equipment Damage

12. The incident of accidental transit damage to the Dynarad unit caused removal of x-ray capability from the operational AACAP 13 unit. If 2GHB had been compliant with Reference B and if immediate review of the situation had occurred as outlined in Reference B, (by the JHC RSO, and ADF RMP as the "qualified expert", in liaison with the deployed Army Radiographer) it may have been that the machine could have been cleared for continued use on the proviso that the equipment be inspected and repaired on return to base. In such a situation, operational capability would not have been lost.

13. 2GHB should utilise this function in the future so as not to unnecessarily withdraw operational x-ray capability unless definitively required following accidental damage.

Broader Army Compliance with JHC RSMP & RMP

14. The Defence Radiation Source Licence, Reference E, was introduced and applicable to Defence medical radiation services on 1 Jul 09. Conditions of this licence included the development and adherence to sufficient plans and arrangements for radiation safety, and adherence to Reference M, which requires x-ray examination authorisation through a Radiation Medical Practitioner.

15. Army was advised of the requirements of Reference E; however did not implement RMP authorisation examinations, or establish sufficient plans and arrangements. All exposures undertaken by Army between 1 Jul 09 and Nov 12 were unauthorised and therefore in breach of reference E.

16. Reference B was subsequently introduced to ensure Defence compliance with Reference E. From the perspective of the ADF RMP, given the legislative duty and responsibility requiring RMP justification and authorisation of each and every medical x-ray exposure under Reference E, mandatory compliance with reference B has been a legislative requirement for Army health personnel since Nov 12. This was when reference B was promulgated by CJHLTH following its endorsement by the single Services.

17. As a result of the JHC CRT audit of 2GHB Medical Imaging in Jun 13, multiple areas of non-compliance were identified and reported through reference H.

18. At a conference held on 20 Sep 13 between JHC and Army stakeholders, and detailed at reference D, it was made clear that Army authorisation to irradiate patients on medical grounds would be withdrawn by the ADF RMP if Army did not comply with reference B. All Army stakeholders present agreed to comply with reference B; including the acceptance of the technical authority of CJHLTH and appointed officers for operation and implementation of Reference B.

19. Despite such agreement, Army personnel did not comply with the requirements of Reference B IRT this incident, or its subsequent investigation and remediation. Army failed to:

- a. notify the JHC RSO or ADF RMP, either within the required time frame or ever of the AACAP incident
- b. notify DRSE of the incident
- c. provide DRSE or ARPANSA with the R1 findings within the required two week time frame

- d. provide the ADF RMP with a copy of the RI findings once complete, or in response to multiple requests over a period of almost 12 months
- e. did not adhere to the technical direction provided by the ADF RMP for the incident investigation process
- f. did not respond to the serious matters identified by the ADF RMP upon review of the RI findings.

22. If mandatory compliance with reference B is not, in place; the ADF RMP should withdraw authorisation for any future medical x- ray exposure to be made by Army, which will result in the closure of the Army medical x- ray capability.

23. **Ongoing Administration through Army CoC: not satisfactory.** Analysis of the RI indicates that Army does not recognise the various serious and less serious breaches of radiation safety identified in the RI. The ADF RMP remains uncertain as to whether or not Army COC is in a position to discharge its medical radiation responsibilities and to provide an ongoing medical x-ray capability. However, it is noted that the problem appears to have been resolved at the unit (radiographer) level.

24. **Subsequent Administration with 2GHB Radiographers: Satisfactory.** Significant effort by the JHC RSO and ADF RMP was required to ensure that the non-compliances identified through the CRT audit activity were appropriately addressed. Since this was achieved, ongoing communication with 2GHB radiographers has been satisfactory.

25. **The current 2GHB Medical Imaging SOP, reference O, has been reviewed.** Some minor amendments will be suggested shortly as a result of the current review Reference B and assessment of Navy and Air Force SOPs. Relevant sections of the Services SOPs are being reviewed with the aim of ensuring they function in parallel so as to streamline the professional relationships between the ADF RMP and ADF radiographers, and to better enable the undertaking of the ADF RMP's duties and responsibilities.

Serious Radiation Safety Breaches Requiring Actioning

26. The 2GHB RI report at Reference A, and ADF RMP analysis thereof indicates the responsibilities of the JHC RSO, ADF RMP, and Nominee / Responsible Person (DGGHO) have been transgressed by Army through the radiation safety breaches identified in this document, including the following significant radiation safety management issues, which remain unaddressed:

- a. ionising irradiation of ADF members in 2013 using a machine which failed its compliance test in 2009, which was not rectified for at least four years and only when the non-compliance was widely evident
- b. ionising irradiation of ADF members using the above machine since 2009
- c. evidence that illicit irradiation of ADF members was undertaken knowingly
- d. lack of acknowledgment that the above did occur
- e. lack of any measures since 2009 to address points above.

27. The majority of the administrative breaches of reference B noted have since been addressed through the persistence of JHC personnel.

Conclusion


28. Review of the 2GHB incident RI, reference A, has identified a number of radiation safety breaches and items of concern that must be addressed.

29. The most significant issue identified is the despatch by 2GHB on AACAP 13 of an x-ray unit for medical irradiation of Defence members that was knowingly not compliant with mandatory safety standards and references B and E, and the failure to rectify these non-compliances.

30. It is the view of the ADF RMP as technical authority of the Radiology and Radiation Safety Cell of JHC, that the RI has identified a significant breach of radiation safety and professional standards, and it is noted also that the responsibility of the Nominee (DGGHO) to ensure health radiation safety within Defence has also been breached.

- all outstanding issues in RI addressed 16/4/15

Approved by: G.M. CONSTANTINE COL DSCA	
Nov 14	
Contact Officer: GPCAPT P. J. Duffy	Phone: [REDACTED]

DGGHO Comments:  G.M. WHELAN BRIG DGGHO 20 Nov 14	<i>Cor - Constantine Acta req is follow:</i> <ol style="list-style-type: none"> ① JHC brief to OAM ② Good meeting over OAM to discuss content over views to address AMI to address shortfalls of Army compliance ③ pls explain content of para 30 ARAF
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16 Apr 15 - follow up meeting over DAM. Army agree to develop AMI to address issues identified in para 26 and 30. DGGHO will meet with Army NI 30 Nov 15 & finalize the AMI





DGPERS-A/OUT/2014/R19302092

DGGHO

For information:

DSCA (Attention: COL Constantine)
DRSE (Attention: Mr Mills-Thom)

AACAP 13 DYNARAD RADIATION INCIDENT

References:

- A. 2 GHB Instrument of Appointment – *Appointment of a Routine Inquiry Officer* dated 24 Sep 13
- B. 2 GHB/2013/RI 002/13 – *Inquiry into damage to X-Ray device on AACAP 13* dated 11 Oct 13
- C. 2 GHB/2014/O7994281 – *Compliance with AACAP 13 Dynarad Inquiry Recommendations* dated 16 Jul 14
- D. Email CHO FORCOMD/SOI Health Governance – *FW: Compliance with Dynarad AACAP13 Inquiry Recommendations* dated 21 Jul 14
- E. Telecon LTCOL Seidl / MAJ Strong dated 18 Aug 14
- F. Joint Health Command *Radiation Safety Management Program and Radiation Management Plan for Diagnostic Radiology* dated 05 Nov 12

1. During AACAP 13, it was identified that a Dynarad x-ray apparatus had been damaged during transit from the unit lines of 2nd General Health Battalion (2 GHB) and the deployed location in Fregon, South Australia, on or about 11 Jun 13. The matter was not formally notified to the chain of command until 16 Sep 13, during a visit by the Command Team to the deployed location.

2. At reference A, on 24 Sep 13, the Commanding Officer (CO) 2 GHB initiated a Routine Inquiry (RI) in accordance with extant Defence policy for the conduct of such investigations. The RI Officer reported on 11 Oct 13, and made a number of recommendations, see reference B, all of which were accepted, and to which the CO added additional actions to be completed. The CO's annotated version of the RI report is at enclosure 1.

3. The recommendations, including the CO's additional actions, have been actioned as per reference C. The recommendation matrix, received by this Directorate at reference D, is at enclosure 2.

4. At reference E, it was confirmed that [REDACTED] dosimetry report was within normal limits. It was also acknowledged that [REDACTED] had erroneously used his TLD monitor from his civilian workplace, and that he had been counselled about this non-compliance with reference F.

5. In addition, as a result of participation in the process to ratify a 2014 edition of reference F, involving Senior Army Radiographer and other members of her staff, I am confident that awareness of this policy and specifically, the reporting requirements, has been raised. Moreover, I have directed my staff to raise, at Army Health Service Steering Group, the question of whether compliance with reference F should be articulated as a mandatory requirement for Army health personnel, through the promulgation of an Army Health Instruction.

6. My point of contact for this matter is the SOI Health Governance, [REDACTED], who can be reached on [REDACTED] or via [REDACTED].

[REDACTED]

AM Williams
COL
DAH

Tel: (02) 6265 5172

19 Aug 14

Enclosures:

1. 2 GHB/2013/RJ 002/13 – *Inquiry into damage to X-Ray device on AACAP 13* dated 11 Oct 13 and annotated by CO 2 GHB
2. Action Item Matrix – *Inquiry into Damage to X-Ray Device on AACAP 13* dated 11 Oct 13 – actual document undated