3 Introduction and Use of Radioactive Substances and Ionising Radiation Generators

Scope

1. This chapter covers the agreement for and assessment of the introduction and use of sources of ionising radiation including radioactive substances. The following information describes the legal and MOD requirements for the introduction and use of such items, materials and sources of radiation, and the procedure to ensure that these requirements are met. The requirement to notify MOD authorities, the Health and Safety Executive (HSE), the Office for Nuclear Regulation (ONR) and the environmental regulators of the devolved administrations in the UK of the occurrence of radiation incidents, accidents, and over exposures is addressed in Chapter 14.

Introduction

2. Before any source of ionising radiation is introduced, permanently or temporarily, (including for trials) into the unit or establishment, a number of requirements must be met.

3. The Radiation Protection Adviser (RPA) must be consulted at the earliest opportunity to advise on regulatory issues associated with the introduction into service of a new source, or modifications to an existing source, of ionising radiation.

Statutory requirements

4. In addition to the general requirements of the Health and Safety at Work etc Act 1974 and the Management of Health and Safety at Work Regulations 1999, the following specific legislation applies directly or is applied indirectly through parallel arrangements designed to achieve equivalent standards:

a. Justification of Practices Involving Ionising Radiation Regulations 2004 (as amended) (parallel arrangements);

b. Ionising Radiations Regulations 2017 (IRR17) (apply directly);

c. The Environmental Permitting (England and Wales) Regulations 2016 (ERP16) (as amended) (parallel arrangements);

d. Environmental Authorisations (Scotland) Regulations 2018 (EASR18) (parallel arrangements);

e. Radioactive Substances Act (Northern Ireland) 1993 (RSA93) (as amended) and associated Exemption Orders (parallel arrangements); and

f. Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR) (apply directly).

5. The requirements for approval and assessment to meet MOD policy and these regulations are set out in the following paragraphs. Advice is to be sought from the appointed RPA on the scope of application of any particular legislation.

Duties

6. Duties as detailed in Chapter 39 apply. In addition, the following duties also apply:

a. **Radiation Safety Officer (RSO)**. If appointed and where authority has been delegated, the RSO will normally discharge the duties of the Commanding Officer / Head of Establishment (CO / HoE) with respect to application for any approval. This will include the actions outlined below under specific legislation; and

b. **Radiation Waste Adviser (RWA)**.The CO / HoE has a duty to appoint an RWA to ensure compliance with the requirements of any approval issued under radioactive waste legislation for the accumulation and disposal of radioactive waste. The RWA for most units and establishments outside the nuclear programmes is provided by DRPS.

Route for Approval and Agreement for Introduction or Modification

7. The requirements of the procurement process to be followed for equipment incorporating sources of ionising radiation are set out in Chapter 1, particularly with reference to Projects where DE&S have responsibility.

8. Units, establishments and sponsors of new equipment are to direct their requests for agreement to introduce or modify equipment through the Top-Level Budget (TLB) Safety Authority (e.g. CESO for the TLB), ensuring that potential issues for radiation safety are raised and an RPA is consulted as appropriate. Routinely, no radioactive material should be procured until it is confirmed (generally in consultation with the RPA) that any necessary approvals are in place. The request for introduction is to include the following information:

a. name and address of the establishment;

b. brief description of the proposed introduction or modification;

c. proposed date of introduction; and

d. Radiation Risk Assessment (see Chapter 2).

9. For installations, e.g. radiography facilities, approvals may be conditional upon confirmatory radiation measurements being taken as part of the commissioning or acceptance procedure.

10. Any request for introduction is to be made at an early stage (before any procurement action commences) and is to include a suitable and sufficient prior risk assessment, where required (see Chapter 2). Where the proposal concerns the design of new equipment, the responsibility lies with the MOD design authority to seek approval for the introduction through TLB Safety Authority, ensuring that radiation safety is addressed, before the detailed design is undertaken.

11. Sponsors of new equipment or components (whether to be introduced permanently or on trial), or individuals making changes to existing apparatus that could have a radiation

health and safety implication, are also to inform and seek approval through relevant channels, including the RPA (see Chapter 1). This is to be undertaken at an early stage (before any firm commitments are entered into) and is to either include a new radiation risk assessment, or an updated version of a previously written prior risk assessment (see Chapter 2).

Actions Required Under Specific Legislation

Justification of Practices Involving Ionising Radiation Regulations (JOPIIRR)

12. Whilst these regulations do not apply directly to Defence activities, it is recognised that justification is the first principle of radiological protection, as recommended by the International Commission on Radiological Protection (ICRP). In accordance with the Secretary of State's Policy Statement, the MOD will develop arrangements that are, so far as reasonably practicable, at least as good as those required by these regulations.

13. The Department for Business, Energy and Industrial Strategy (BEIS) has not yet published an updated list of existing practices that pre-date the requirement of the regulations. Most of the non-nuclear activities carried on by MOD will come under one of these existing practices. Practice has a very wide, generic meaning and does not relate to any particular site or location. It will therefore be unusual for there to be a new type or class of practice.

14. Any unit or organisation intending to introduce a new type or class of practice within the meaning of the regulations is to notify the Head Office CCE Directorate, Ministry of Defence, Floor 3, Zone E, MOD Main Building, Whitehall, LONDON, SW1A 2HB (email Spocce-ep@mod.gov.uk) of details of the activity in good time before its proposed introduction date. Additionally, CCE is to be notified if new and important evidence about an existing practice's efficacy or consequences is acquired.

Ionising Radiations Regulations 2017 (IRR17)

Notification, Registration and Consent (Regulations 5, 6 and 7)

15. Regulatory control over work practices involving ionising radiation is applied using a graded approach of notification, registration and consent that is proportional to the size and likelihood of exposure resulting from the work. Employers notify the HSE or apply for registrations and consents using HSE's RADAN online service at https://www.hse.gov.uk/radiation/ionising/notify.htm. The required detail increases from notification to consent in line with the increasing hazard. There is currently no charge for a notification, a £26 charge for a registration (which can cover multiple practices at multiple sites) and a charge of up to £6k for each consent (specific to a single practice but can cover multiple sites). Very low hazard practices are not subject to any of the above. HSE must also be informed of significant changes (such as undertaking a new practice or ceasing an existing practice) and where this affects a registration or consent an additional fee will be payable.

16. Certificates may contain conditions that must be complied with. For example, consent certificates for industrial radiography where the employer has informed the HSE that they conduct site radiography on the premises of other employers includes a condition requiring the client to provide the consent holder seven days written notice of the work.

17. Practices requiring registration or consent must not take place unless a registration or consent has been issued. Your RPA should be consulted well before making any application. Planning and applying for a consent can take several months and requires detailed information to be provided to the HSE, as well as an HSE site inspection before the consent will be granted and work can commence.

18. In line with MOD policy on who discharges the employer's legal responsibilities it has been decided that MOD submissions will normally be made at TLB level (and Chief Executive for Defence Agencies etc.) by an individual with delegated authority. Hence no action is required at Unit or Establishment level other than to make the necessary information available if requested. This approach will ensure that those responding have appropriate assurance of the information that they are submitting. This is important since the HSE have said that individuals can be held personally liable for the accuracy of the information provided.

19. **Notification** (lowest risk) (Regulation 5) required for all work with ionising radiation except work Specified in IRR17 Schedule 1 or where a registration or consent is required (see below).

20. **Registration** (medium risk) (Regulation 6) required for:

a. work with a radiation generator (including any X-ray set) unless the work is from a practice that requires a consent;

b. work with up to 1000 kg of radioactive material where the activity concentration is above the value in column 4 of Schedule 7, part 1 (if used for their radioactive properties) or column 4 of Schedule 7, part 2 (if not used for their radioactive properties); and

c. work with more than 1000 kg of radioactive material where the activity concentration is above the value in column 2 of Schedule 7, part 1 (if used for their radioactive properties) or column 4 of Schedule 7, part 2 (if not used for their radioactive properties).

21. **Consent** (highest risk) (Regulation 7) required for:

a. industrial radiography;

b. the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of persons is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

c. the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products;

d. the operation of an accelerator (except an electron microscope);

e. any practice involving a high-activity sealed source (other than one within the bullets above);

f. the operation, decommissioning and closure of any facility for the long-term storage or disposal of radioactive waste, (including facilities managing radioactive

waste for this purpose); but not any such facility situated on a site licensed under section 1 of the Nuclear Installations Act 1965; and

g. practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment (generally this applies where an environmental authorisation is required for the discharge).

22. At the time of these regulations coming into force notifications had been submitted and registration and consents obtained, where required, by TLB duty holders and Chief Executives in line with the transitional arrangements. Copies of notification summaries and registration and consent certificates should be held on file by each of the duty holders CESO or equivalent person.

Environmental Permitting (England and Wales) Regulations 2016 (EPR16) (as amended), Environmental Authorisations (Scotland) Regulations 2018 (EASR18) and the Radioactive Substances Act (Northern Ireland) 1993 (RSA93) (as amended) and associated Exemption Orders

Application for Approvals to Regulatory Authorities (EA, SEPA, NRW and NIEA)

23. EPR16 / EASR18 / RSA93 do not apply to premises occupied on behalf of the Crown for defence purposes. However, MOD has a policy to implement parallel arrangements to those required. In England and Scotland these are implemented via MOUs with the EA and SEPA respectively. In Wales and Northern Ireland the need to implement parallel arrangements is considered on a case by case basis. DRPS is tasked to provide advice to CO / HoE on how they comply with such arrangements. When an application for an approval has been made and granted, the key to achieving compliance is to read, understand and act on the conditions contained within any approval issued or exemption order applied.

24. To enable MOD to apply parallel arrangements to those set out under EPR16 / EASR18 / RSA93, DRPS maintains a database of radioactive material holdings for all units and establishments. In order to ensure that this database is accurately maintained, units and establishments are to comply with the following procedure:

a. in January of each year DRPS will send out an Annual Holdings Return (AHR) to all units and establishments that will detail any radioactive material previously notified; and

b. the CO / HoE is responsible for ensuring that the information on the AHR is updated, complete and accurate (nuclear weapons and ammunition containing DU should not be declared). The AHR (including a nil return) is to be returned to DRPS by 30 April of each year. The full detail on the requirements for AHR is detailed in Chapter 9.

25. In addition to the above, within one month of introduction of new types of radioactive materials, a unit or establishment is to submit a revised list of radioactive holdings to DRPS, as detailed in paragraph 24.

26. DRPS can assist in preparing and submitting an application to the relevant environmental regulator. It is the responsibility of the TLB to fund any application and make payment of annual subsistence charges.

27. As a result of applying for an approval to the appropriate environmental regulator, each unit or establishment is issued with an approval detailing the authorised holdings of radioactive materials. The unit should forward a copy of the approval to DRPS. Standard conditions are set out at the beginning of all approvals and must be complied with. It is advised that units liaise closely with their RPA with regards to compliance.

28. Revised approvals are issued to units and establishments when amendments to authorised holdings are required and are not usually reissued on an annual basis.

29. New approvals are issued in the name of the Secretary of State for Defence. If there is a change in the unit holding the radioactive material at the site, the new unit is to notify DRPS and the unit's RPA / RWA (if this is not DRPS) of the change of name forthwith. Both units involved must muster their radioactive holdings and produce a written record, which they are to retain for a minimum period of 2 years from the date of the last entry (see Chapter 9). However, if a unit changes its name, an amendment to the documentation will not be required until the normal review falls due, at which point the name will be amended.

30. Radioactive materials held at units and establishments in accordance with an exemption are exempt from the requirement to apply for an approval from the relevant environmental regulator. However, they are not exempt from the other requirements of the EPR16 / EASR18 / RSA93; in particular, the requirement to keep records. All radioactive materials, including those exempt from the need for an approval, are to be recorded and accounted for in accordance with Chapter 9.

Public disclosure of information

31. The regulatory authorities (predominantly EA and SEPA) place applications for approvals for open sources (but not sealed sources) and disposals on the public record unless specific instructions to the contrary are given. Unless advised that a higher level of protective marking is required the regulatory authority will treat all applications for approval and issue approvals for sealed sources as UK OFFICIAL-SENSITIVE. DRPS is to be advised of any reasons for withholding information from the public record as soon as possible. In the absence of any information to the contrary, DRPS will allow approvals to be placed on the public register.

32. Notwithstanding the above, even where information has been supplied to the regulatory authority but kept off the public register, then that authority may still be obliged to release the information in responding to a Freedom of Information or Environmental Impact Assessment enquiry. A statement to this effect will be sent to all units and establishments with the AHR in January of each year.

Pollution inventory reporting

33. The Environment Agency has expanded the scope of the Pollution Inventory for England and Wales to include radioactive waste. Where a unit or establishment holds an approval for the accumulation and disposal of radioactive waste, the CO / HoE is responsible for ensuring that a Pollution Inventory reporting form (supplied by the EA) is completed and returned on an annual basis. Copies of the forms are to be retained as they will be required from time to time for incorporation into MOD statistics on radioactive waste disposal.

Inspections by the environmental regulatory authorities

34. The environmental regulatory authorities are authorised to inspect those units and

establishments with approvals. CO / HoE must be provided with at least 48 hours notice of an inspection. The visiting inspectors are to be given the fullest co-operation at all times. The CO / HoE is normally to inform the appropriate TLB Safety Authority (e.g. the CESO) and DRPS prior to such visits taking place. The CO / HoE should inform their CESO and DRPS of the outcome of any inspection.

35. Not all inspectors are security cleared for access to classified information and must not be afforded such access unless they are known to have the appropriate security clearance. Inspectors must not, under any circumstances, be made aware of the presence of nuclear weapons or their components during a site inspection. In cases of doubt, the regulatory authority should be denied access and guidance sought, in the first instance, from DSA.

Ships and overseas establishments

36. Approval documents are not required for radioactive material held by HM Ships (other than shore establishments) or overseas Service units and establishments. However, in order to ensure that a complete database of radioactive material is maintained at DRPS, an AHR is to be submitted.

Breaches of arrangement to hold / dispose of radioactive substances

37. Units or establishments that, as a result of an inspection by environmental regulatory authorities, are informed that they are not fully compliant with an approval or exemption must report such non-compliances through the accident and incident reporting systems within the TLBs' business processes. Copies of letters etc. specifying enforcement action should be copied to the DRPS RPA Body.

38. Any MOD unit transferred to the private sector thus becoming a commercial company will likely have to fully comply with the requirements of EPR16 / EASR18 / RSA93, and therefore obtain the necessary 'licenses' (permit etc.) from the relevant environmental regulatory authorities. Prior to transfer of assets, the unit is to notify DRPS of the transfer of radioactive material and waste. The unit is to produce a muster record and preserve it in accordance with the requirements of paragraph 49 unless an alternative period is specified in the registration document.

39. Disposal of radioactive material is addressed in Chapters 11 and 12.

High Activity Sealed Radioactive Sources and Orphan Source (HASS) requirements

40. HASS requirements in England, Wales, and Scotland are incorporated into the EPR16 and EASR18 regulations. The requirement for Northern Ireland is covered by the High Activity Sealed Radioactive Sources and Orphan Source Regulations 2005 (HASS).

41. High activity sealed sources are subject to special authorisation, control and transfer. In addition to the MOD accounting arrangements set out in Chapter 9, high activity sealed sources are to be accounted for on a HASS Record Form. The form is to be obtained from the relevant environment agency and, once completed, should be forwarded to DRPS as well as the appropriate regulator. HASS are to be identified separately on the AHR as advised by DRPS. RPA advice must be sought before acquiring a high activity sealed source.

42. Other than at MOD nuclear authorised sites, arrangements for approval of the environment agencies described under EPR16 / EASR18 / RSA93 above have been

extended to encompass the additional requirements for HASS. The main features which extend or differ from the EPR16 / EASR18 / RSA93 parallel arrangements are:

a. an application for a HASS approval is to be made by the prospective holder direct to the relevant environment agency. The application must include the documentary evidence required by the relevant environment agency. The practice or task for which the HASS will be used shall not commence until the approval has been certified by the relevant environment agency.

b. the certificate of HASS approval, when received, will be accompanied by a set of terms and conditions including the requirement to forward certain records to the relevant agency. Compliance with these terms and conditions is mandatory under the parallel arrangements.

c. arrangements for the physical security of HASS and similar sealed sources (sealed sources individually or in aggregate in IAEA categories 1 to 4) are, so far as reasonably practicable, to parallel those in place on civil sites. The document Security Requirements for Radioactive Sources produced by the National Counter Terrorism Security Office (NaCTSO) sets out the requirements for civil sites. While these explicitly do not apply to MOD, the Secretary of State requires that equivalent standards be applied (JSP 815).

43. Arrangements for the control of HASS held by MOD nuclear Authorisees mirror those applicable to civil nuclear licensees. The arrangements are administered by the Defence Nuclear Safety Regulator (DNSR). These arrangements do not extend to mobile HASS held by Authorisees or to HASS held beyond the nuclear authorised site boundary. In these cases, the normal parallel arrangements pertaining to non-nuclear sites apply with HASS reports being submitted to the appropriate environmental regulator as a condition of the approval.

44. Any unit or establishments holding HASS should expect to be visited on an annual basis by the regulatory authority. The CO / HoE should inform the appropriate TLB Safety Authority (e.g. the CESO), the RPA and the NaCTSO Police Officer prior to such visits taking place. The CO / HoE should inform DSA, their CESO and DRPS of the outcome of any inspection.

Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR)

Provision of Hazard Evaluation and Consequence Assessment to HSE

45. Where radioactive materials in excess of the quantities contained in REPPIR Schedule 1 are held on premises or transported then the CO / HoE or carrier, as appropriate, shall make or ensure that Hazard Evaluation and Consequence Assessment has been made and a report produced. This will normally be made in collaboration with the RPA and will affect very few units and establishments. The assessment is to demonstrate that all hazards arising from the work with the potential to cause a radiation emergency to have been identified and the nature and the magnitude of risks to employees and other persons arising from those hazards have been evaluated. Where the assessment shows that a radiation risk to employees or others exists from a radiation emergency, the operator or carrier is to take all reasonably practicable steps to prevent such an emergency and to limit the consequences of any such accident that could occur.

46. The Hazard Evaluation and Consequence Assessment is to be sent direct to HSE or ONR as appropriate but guidance and direction should be obtained from the RPA. Any reports for the Naval Nuclear Propulsion Programme (NNPP) should also be copied to the Defence Nuclear Safety Regulator (DNSR).

47. The documentation is to be reviewed every three years or whenever there is a material change in the work with ionising radiations. This may require a further assessment or, where there are no changes, the CO / HoE (or the carrier), shall sign a declaration to that effect. The revised documentation or declaration is to be made to the HSE within 28 days of the review or declaration being made.

48. The RPA should be contacted at the first opportunity if there is reason to think that REPPIR is applicable to a particular site.

Records

49. Any records generated shall be retained in accordance with MOD record retention policy (see JSP 392 Volume 1, Chapter 3).