CONTROLLED DOCUMENT

University Hospitals Birmingham
NHS Foundation Trust

Ionising Radiation (Medical Exposure) Regulations 2017

Procedure 9: Information and Written Instructions to Individuals after Administration of Radioactive Substances

Required under IR(ME)R 2017 Regulation 6 & Schedule 2 (h)

CATEGORY:	Procedure
CLASSIFICATION:	Health & Safety, Clinical Governance
PURPOSE:	For the giving of information and written instructions as referred to in regulation 12(6).
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Distribution: • **Essential Reading for:**	Staff who are designated as an IR(ME)R practitioner and/or operator working in Nuclear Medicine or PET Managers of IR(ME)R practitioners and operators working in Nuclear Medicine or PET

• **Information for:**	General managers Nuclear Medicine and PET Other IRMER duty holders in Nuclear Medicine or PET.

Contents

1 Procedure Statement

1.1 To identify the groups of individuals who should be given information and written instructions **in order to restrict dose to persons in contact with them** after administration of radioactive materials.

1.2 The procedure also identifies the nature of the advice, who should give the advice, and when it should be given. Note that IR(ME)R Employer's Procedure 14 deals with the provision of information to Carers & Comforters.

2 Scope

2.1 Applies to all individuals who have received a radioactive substance for diagnosis or therapy, including those participating in a research study.

2.2 In this procedure "individual" means the individual who has received an administration of a radioactive substance

3 Responsibility

3.1 The responsibility for issuing the written advice to individuals lies with the following staff:

General Diagnostic Nuclear Medicine Examinations • Advice relating to pregnancy for some long-lived radionuclides and to all breast-feeding individuals	The task may be undertaken by a Clinical Technologist, Clinical Scientist or Radiographer who is competent to give Radiation Protection Advice as demonstrated by competencies listings approved within the department. Written instructions on avoiding pregnancy will be provided in accordance with ARSAC guidance ARSAC notes for guidance: good clinical practice in nuclear medicine - GOV.UK (www.gov.uk) or any relevant procedures identified by the MPE. Advice for outpatients undergoing 18-Fluorine FDG PET scans will be sent with the appointment letter. Advice is emailed to the relevant wards for all In- Patients. Written instructions on breast-feeding will be

• Advice to limit contact as necessary to ensure that a child or an unborn child (the dose to the mother will be used for the latter) does not exceed one millisievert. This will apply to single tests that could give more than one millisievert and to multiple tests that would give more than one millisievert in total even though individual tests would give less than one.	provided and explained by the operator before administering the radioactive material. The operator administering the radiopharmaceutical should carry out a final check to ensure advice has been given. Where the Medical Physics Expert (MPE) deems relevant and appropriate, brief instructions, e.g. on not sharing a bed, will be included in the appointment letter or leaflet sent to the patient. Where a diagnostic investigation requires advice the details given should be noted electronically within the event on the Radiology Information System (RIS).
Radioiodine for treatment of thyrotoxicosis	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the thyroid treatment information leaflet. This contains radiation protection information detailing restrictions to limit other persons' dose. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist or Nuclear Medicine Physician IR(ME)R License holder (ARSAC) in accordance with IR(ME)R Employer's Procedure 12. Patients treated with 131-Iodine for thyrotoxicosis are provided with an Instruction Card and Laminated Warning Card by the person administering the 131-Iodine according to Nuclear Medicine Standard Operating Procedures. Additional or modified written instructions may be provided by a Clinical Scientist as a result of a Risk Assessment based on typical dose rates and the individual patient circumstances for example; contact time at work, return to care home or acts as carer. An Instruction Card and laminated Warning

	Card is given to the patient by a trained operator at the time of patient discharge. This details contact restrictions to limit radiation exposure to others. Details of any non-standard advice given are recorded on the Radioiodine treatment record sheet
Radioiodine treatment of thyroid cancer, 131-Iodine mIBG therapy, 177-Lutetium peptide receptor therapy	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the pertinent treatment information leaflet. This contains radiation protection information detailing restrictions to limit other persons' dose. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist or Nuclear Medicine Physician IR(ME)R License holder (ARSAC) in accordance with IR(ME)R Employer's Procedure 12. An Instruction Card and laminated Warning Card is given to the patient by a trained operator at the time of patient discharge. This details the contact restrictions to limit radiation exposure to others. (according to methods agreed by the MPE and in the relevant Nuclear Medicine Standard Operating Procedures. In all cases, additional written instructions may be provided by the Clinical Scientist as a result of a Risk Assessment of the individual's circumstances e.g. contact time at work, return to care home or acts as carer. Details of any non-standard advice given are recorded on the therapy treatment sheet.
223-Radium chloride treatment of bone metastases	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the pertinent treatment information leaflet

	(manufacturer information booklet). Information about radiation protection. This contains radiation protection information detailing restrictions to limit other persons' dose. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist or Nuclear Medicine Physician (IR(ME)R License holder (ARSAC) in accordance with IR(ME)R Employer's Procedure 12 The operator in Nuclear Medicine provides the patient with a laminated Warning Card before the injection at each treatment cycle. Details of any non-standard advice given are recorded on the therapy treatment sheet.
32- Phosphorus therapy, 90-Yttrium radiation synovectomy 89-Strontium therapy	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the pertinent treatment information leaflet. Information about radiation protection. This contains radiation protection information detailing restrictions to limit other persons' dose. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist or Nuclear Medicine Physician IR(ME)R License holder (ARSAC). An Instruction Card and laminated Warning Card are given to the patient by a trained operator at the time of patient discharge. This details contact restrictions to limit radiation exposure to others. (according to methods agreed by the MPE and in the relevant Nuclear Medicine Standard Operating Procedures). Details of any non-standard advice given are recorded on the therapy treatment sheet.

90-Yttrium microspheres (clinical rather than research)	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the pertinent treatment information leaflet. Information about radiation protection. This contains radiation protection information detailing restrictions to limit other persons dose. The patient is provided with an information leaflet and/or 90-Y microspheres manufacturer's information booklet. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist, Interventional Radiologist or Nuclear Medicine Physician IR(ME)R License holder (ARSAC). Contact restrictions are calculated based on measured bremsstrahlung dose rate and an Instruction card and warning card is given by an operator undertaking the patient discharge. This details contact restrictions to limit radiation exposure to others. (according to methods agreed by the MPE and in the relevant Nuclear Medicine Standard Operating Procedures) Details of any non-standard advice given are recorded on the therapy treatment sheet.

Novel Research Therapies	Patient Information Sheets for therapies may include radiation protection advice. These would be provided to the individual by the person obtaining consent. In addition, an instruction card and warning card may be provided at the time of treatment. Details of any non-standard advice given are recorded on the therapy treatment sheet.
153-Samarium therapy	At the time of booking the appointment the relevant staff member will send an appointment letter and will include the pertinent treatment information leaflet. This contains radiation protection information detailing restrictions to limit other persons dose. Risk and benefit information for these patients is provided at the time of Consent by the Consultant Oncologist or Nuclear Medicine Physician IR(ME)R License holder (ARSAC). An Instruction Card and laminated Warning Card is given to the patient by a trained operator at the time of patient discharge. This details contact restrictions to limit radiation exposure to others(according to methods agreed by the MPE and in the relevant Nuclear Medicine Standard Operating Procedures). Details of any non-standard advice given are recorded on the therapy treatment sheet.

4 Practice

4.1 In practice, the radionuclide, radiopharmaceutical and level of administered activity will determine what, if any, advice needs to be given. The individual's circumstances must also be taken into consideration, for example if the patient is breast-feeding, or in close contact with children for extended periods soon after administration, or in need of intensive nursing care. Contact restrictions may also be modified based upon the patient's medical status e.g. renal impairment reducing clearance of the radiopharmaceutical from the body.

4.2 The individual should be informed in advance of their diagnostic test or treatment, if restrictions may apply. These are based upon standard restriction conditions and advice. These will subsequently be tailored to the individual based upon the residual activity at the time of departure.

4.3 The information given to the individual will specify the risks to persons from the radiation dose that they could get from being in contact with them. It will also include how these doses can be restricted as far as reasonably practicable.

4.4 The information should be given to the most appropriate person:

4.4.1 The individual (including children if they are capable of consent), where they have the capacity to consent to the treatment or diagnostic procedure.

4.4.2 The person with parental responsibility, when the individual is a child who is incapable of consent.

4.4.3 The carer, or other appropriate person, when the individual lacks the capacity to consent.

4.5 If written instructions are required, they will be issued to the patient **prior** to the individual leaving the department or ward.

4.6 In addition, information and instructions will be given to the following groups of patients:

4.6.1 Breastfeeding individuals and individuals to whom possible restrictions on pregnancy may apply

4.6.2 Individuals given 131-Iodine radiopharmaceuticals above 10 MBq. In particular tests using I-131 greater than 30 MBq should be treated as therapy and patients should be advised to avoid pregnancy in accordance with current ARSAC guidance (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1049915/Notes_for_guidance_on_the_clinical_administration_of_radiopharmaceuticals_and_use_of_sealed_radioactive_sources.pdf)

4.7 The person providing instructions must document any non-standard instructions given and the individual should sign the pre-printed sticker on the request card/ referral letter to confirm that they have received and understood these instructions.

5 Contingencies

5.1 Any failure in compliance with this procedure must be reported to the relevant Divisional General Managers or Medical Physics Expert in their absence. Failure to comply with the above procedure may result in the Trust's Disciplinary Policy being invoked.