**Employer’s Written Procedure 14**

**Reporting of Radiation Incidents Involving Unintended Exposures**

1. **Objectives**
* To ensure that radiation incidents involving unintended exposures of patients are properly classified and investigated
* To ensure that externally reportable radiation incidents are reported to the appropriate statutory authority promptly and in accordance with this procedure.
1. **Terminology**

The extant guidance from Healthcare Improvement Scotland (HIS) on Significant accidental and unintended exposure (SAUE) under IR(ME)R will be followed. This will include clinically significant exposures (CSAUE).

An *accidental exposure* means an exposure of an individual as a result of an accidental over-exposure of an individual to radiation.

An *unintended exposure* occurs when an exposure to ionising radiation is significantly different from the exposure intended for a given purpose. This may occur as a result of a fault in equipment or as a result of a failure of procedures and would include unintended exposures where a patient receives a dose of radiation intended for another person. Unintended exposures which occur as a result of a fault in equipment are now covered by the Ionising Radiation (Medical Exposures) Regulations 2017 having been previously included in the Ionising Radiations Regulations 1999.

Not all mammograms which are repeated are to be classified as radiation incidents. Version 2 of Good Practice Guide No. 4, *Collecting, Monitoring and Reporting Repeat Examinations*, published by the NHS Cancer Screening Programmes in November 2006, divides repeat examinations into two categories:

* A *technical repeat* - where a mammographer decides to repeat the same projection(s) after identifying an error
* A *technical recall* - when a woman is asked to re-attend for the same projections to be repeated because the current screening examination is technically inadequate for reporting or is missing.

The total number of technical repeats and technical recalls is known as *repeat examinations*.

Table 1 lists some of the occurrences which can occur in digital mammography and gives guidance as to whether they should be considered as radiation incidents.

Note that “near misses” where there is no actual irradiation of the patient are not included as the occurrence would not be a radiation incident. Also note that local procedures relating to technical recalls, repeats and near misses still need to be followed.

NSS does not own or operate any dental X-ray equipment. However, the Dental Reference Service, Dental Advisers and Orthodontic Advisers evaluate clinical images and can act as referrers for additional radiographs to be taken by the public dental services or independent dental contractors. Incidents involving equipment failure or incidents involving failure of procedures can apply to these radiographs. The implications are discussed in sections 4 and 5 below.

Employers have a statutory duty to report certain over-exposures to external bodies such as the Health and Safety Executive or the Scottish Ministers. For this reason, it is important to be clear about initial reporting routes within the Scottish Breast Screening Programme in order that advice may be obtained promptly.

1. **Responsibilities**

The person responsible locally for the authorisation of IR(ME)R procedures, in conjunction with the medical physics expert (MPE) for breast screening shall authorise a Level 2 procedure that sets out the actions to take when a radiation incident is suspected in the Scottish Breast Screening Programme. See Level 2 procedure NSS100-014.01 for NSS Medical Physics. Similarly, the Director of Dentistry shall authorise a Level 2 procedure that sets out the actions to take when a radiation incident is suspected involving the NSS dentists.

* + Breast screening

IRMER cooperation agreements set out who will carry out the investigation and dose assessment for incidents in each of the six health boards that provide breast screening programmes. If it is NSS then MSS MPEs will follow NSS100-014.01.

For all health boards the local health board IRMER Employers Procedure for incidents will be followed, including for any CSAUE incidents. Any reportable incidents will be reported through the health board to HIS.

* + Dental

For dentistry, all of the incidents categorised under *equipment* in Table 1 could occur. Any such incidents would be subject to the IR(ME)R procedures of the public dental service or independent dental contractor involved. Section 3.2 of the NSS Adverse Events Management Policy categorises such incidents as *external adverse events* where NSS has no responsibility for causing the error. According to the policy, the NSS staff member who discovers/highlights the incident must report these external adverse events, make the originating organisation aware of the error and take action to minimise the impact of the error.

The MPE in NSS should be informed of these dental incidents but investigation will normally be left to the MPE for the public dental service or for the independent dental contractor. However, *incorrect patient demographics* is a category where the fault may lie with NSS rather than with the external dentist. An example would be where the wrong radiographs are taken or the wrong patient has a radiation exposure because the NSS dentist has requested the wrong radiographs or made a request for the wrong patient. Such occurrences should be reported to the MPE in NSS Medical Physics by NSS dental staff.

1. **Advice on Reporting to External Bodies**

For all mammography incidents that result in a clinically significant exposure the MPE in NSS, in consultation with the MPE in the host board will advise management in the local health board as to whether the incident is reportable to HIS. This decision will be based on current guidance from the HSE, CQC, HIS and professional bodies. HIS expect that all incidents involving multiple patients within the same incident / theme should be notified to them regardless of the dose.

SRPA have agreed a definition for a “theme” -

*six or more incidents in one year on one site with the same root cause” (at the discretion of the MPE with special attention to paediatrics, higher dose modalities, screening etc)*

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Any mammograms taken within six months of a previous mammogram are reportable. This may differ for symptomatic and research trial mammograms.

For dental incidents where the fault lies with NSS, the MPE in NSS will advise management in NSS as to whether reporting to the Scottish Ministers is required. Otherwise, the MPE for the public dental service or for the independent dental contractor will advise on whether external reporting is required.

1. **Advice on Reporting to External Bodies - IRMER**

If an incident is reportable under the IR(ME) regulations then the HIS notification form should be completed and emailed to - hcis.irmer@nhs.net. This will be completed by the local health board where the incident occurred.

The form and guidance are available on the HIS website -

<http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx>

1. **Advice on Reporting to NSD**

For all mammography incidents, where it is considered to be an Adverse Event, the NSD procedure will be followed (NSS100-014.01).

**TABLE 1. Categorisation of Occurrences**

|  |  |  |  |
| --- | --- | --- | --- |
| **Category** | **Reason** | **Example** | **Radiation incident** |
| Equipment | Detector artefact | Dead pixels | If repeat necessary |
| Grid artefact | Grid lines | If repeat necessary |
| Cut-off | Part of breast not imaged – e.g. nipple, chest wall | If due to equipment and a repeat is necessary. Would not be a radiation incident if cut-off was due to an operator error.  |
| Over-exposure | Displayed dose higher than expected – e.g. higher than twice the mean dose for the compressed breast thickness. See graph displayed in viewing area. | If related to equipment – e.g. AEC. if exposure factors set incorrectly (e.g. AEC set incorrectly) and high dose to patient occurs. Also a radiation incident if incorrect technique factors selected. (See below) |
| Under-exposure | Noisy image and displayed dose lower than expected | If image quality is unacceptable and a repeat is necessary |
| No image | Blank screen | If exposure occurred. (See the post-exposure readings of dose or mAs. Report also in cases when the readings cannot be seen.) |
| Lost image | Cannot retrieve image – e.g. from PACS | If repeat necessary |
| Image processing | Poor resolution and/or contrast | If additional processing does not result in an acceptable image and a repeat is necessary |
| Non-termination of exposure | Exposure has to be terminated manually – e.g. by removing power to unit | Always |
| Equipment failure | Unit not responding.Software not working correctly.No electrical power. | If a repeat is necessary |
| Operator | Blurring | Poor resolution and/or contrast | Not if due to poor set-up – e.g. inadequate compression |
|  | Incorrect patient demographics | Wrong name. Names interchanged.Incorrect labels on image | Only if situation cannot be rectified prior to further exposure  |
|  | IR(ME)R procedures not followed | Identification procedure not followed.Incorrect view – e.g.2 x LCC | Only if unintended exposure occurs – e.g. wrongly identified individual actually irradiated or double exposure made  |
|  | Over-exposure | Displayed dose higher than expected | Yes – if exposure factors set incorrectly (e.g. AEC set incorrectly) and high dose to patient occurs |
|  | Under-exposure | Noisy image and displayed dose lower than expected because of incorrectly set exposure factors | If image quality is unacceptable and a repeat is necessary |
|  | Incorrect use of equipment | Wrong breast paddle used.No compression applied | If a repeat is necessary or if a high dose to the client occurs. |
| Client | Inadequate position | Physical difficulties experienced in obtaining adequate images | No |