1. Objectives

To ensure that radiation incidents involving the unintended or accidental exposure of individuals (IRMER17) or the over-exposure/additional exposure of a member of the public or member of staff (IRR17) are properly investigated and recorded in the Datix electronic incident reporting system and ensure that notifiable radiation incidents are reported to the appropriate authority promptly and in accordance with relevant regulations and guidance.

2. Responsibilities

Operator Performing Exposure

The Operator performing the exposure is responsible for recording the data available on the incident by completing a Datix DIF1 form, and for informing the Sector/Site Superintendent / Head of Department and where appropriate the Radiation Protection Supervisor ideally within 2 working days.

Should an accidental or unintended exposure of an individual be discovered subsequent to completion of the medical exposure, then the person making the discovery is responsible for recording the data available on the incident by completing a Datix DIF1 form, and for informing the Sector/Site Superintendent / Head of Department and where appropriate the Radiation Protection Supervisor ideally within 2 working days.

The Operator performing the exposure may inform the individual* of any accidental or unintended exposure at the time of the examination, unless he/she judges that this may be inappropriate.

If the radiation incident is due to operator error, the Operator performing the exposure should complete a factual Incident Management Descriptive Account (EP-GUID-020) and pass this to the Sector/Site Superintendent / Head of Department for upload to Datix.

If the radiation incident is due to operator error, the Operator performing the exposure should also complete a Personal Reflective Account to be kept in their own Continuing Professional Development (CPD) Folder.

Sector Superintendent / Site Superintendent / Head of Department / Head of Service (SeS/SiS/HoD/HoS)

The SeS/HoD is responsible for identifying a Lead Investigator to carry out a more detailed investigation (where appropriate), for collating the reports generated, updating the Datix record, details of the actions taken including any actions taken to reduce the likelihood of a repeat incident.

The SeS/SiS/HoD is responsible for ensuring that the correct members of staff within their sector are given the appropriate responsibilities and permission for Datix.

The SeS/SiS/HoD will work with the MPE/RPA and in collaboration with the equipment company engineer in the investigation of incidents arising from equipment failure.

The SeS/HoS will be the Datix Approver and is responsible for ensuring that the incident investigation is completed.

Medical Physics Expert (MPE)

The MPE under IRMER is responsible for making an assessment of the radiation dose to the individual and for advising the Imaging General Manager whether an incident needs to be notified to the appropriate authority.

The MPE will work with the SeS/HoD/RPA and in collaboration with the equipment company engineer in the investigation of incidents arising from equipment failure.

** or their representative*

Radiation Protection Advisor (RPA)
The RPA is responsible for making an assessment of the radiation dose to a member of staff/outside worker/member of the public, and for advising the Imaging General Manager whether an incident needs to be notified to the appropriate authority.

The RPA will work with the SeS/SiS/HoD/MPE and in collaboration with the equipment company engineer in the investigation of incidents arising from equipment failure.

Radiation Protection Supervisor (RPS)
The RPS should be informed where the incident involves exposure of a member of the public and/or a staff member**.**

Imaging General Manager (IGM)
The IGM is responsible for reporting notifiable incidents to the appropriate authorities when required, requesting written information to complete the investigation and for informing the referrer and practitioner of the notifiable incident and the outcome.

The IGM is also responsible for providing the IRMER Lead with an annual summary of all incidents reported to the statutory authorities and outcomes.

Referrer
Under IRMER the Referrer and/or consultant should inform the individual* , if they were not informed during their visit to the radiology department under Duty of Candour.

The Referrer and/or the consultant, under whom they practice, are responsible for providing the IGM with a factual descriptive account explaining the reason for any incorrect referral, and action they have taken to avoid similar errors occurring in the future.

3. Investigation and reporting

3.1 At the time

Any member of staff who suspects that an accidental or unintended exposure (IRMER2017) or an overexposure/additional exposure (IRR17) has occurred, shall complete a Datix DIF1 form, ideally within 2 working days. They should ensure that the incident is recorded under the Category of Radiation/Imaging Incident and that, where appropriate, the response to question 2.1 “Has an increased radiation dose/exposure taken place?” is YES. The DIF 1 form should include:

- A summary of the incident with sufficient information to describe exactly how the incident occurred and the type of procedure / examination involved
- The age of the individual
- Pregnancy or breasfeeding status if relevant
- *For radiography or fluoroscopy procedures*: the dose-area product, the set kV, the FID, the mAs delivered and set, and other available information where this is relevant, e.g. time for which radiographic exposure appeared to continue if the exposure termination failed, equipment error codes, or unusual signals
- *For CT scans*: the kV, mAs, pitch, collimation, scan length, the field of view and the Computed Tomography Dose Index and Dose Length Product if these are displayed
- *For radionuclide procedures*: the radiopharmaceutical, activity administered and other relevant information

** or their representative*

- *For mammography*: the displayed mean glandular dose, the set kV, the mAs delivered, the target / filter combination, the compressed breast thickness, patient age, and other available information where this is relevant e.g. time for which radiographic exposure appeared to continue if the exposure termination failed, equipment error codes, or unusual signals.

- *For interventional and cardiology:* where the patient dose is 10x the DRL or estimated intended dose any contributory factors e.g. complexity of case, body habitus or training should be identified. The Practitioner carrying out the case or who was responsible for generic justification/authorisation guidelines should be asked to provide additional justification for this dose to the patient and this should be recorded

- *For Incidents involving staff/outside workers/members of the public:* distance from the source, time in presence of the source, estimated contamination activity, PPE, etc should be recorded where relevant

- *Any other relevant information*

3.2 Investigation

The Lead Investigator shall carry out a review of the DIF1 form (ensuring that all necessary fields are completed), undertake a preliminary investigation of the incident, and shall complete the Datix DIF2 form, adding additional information including actions taken, any actions taken to reduce the likelihood of a repeat incident, details of the referrer and practitioner (for IRMER) and attaching relevant documentation to the Datix record. They will ensure that the MPE/RPA is informed that this review has taken place using Datix communications/notifications.

The Datix Approver on receipt of a reviewed Datix record shall consult with the MPE/RPA, in deciding on whether further investigation is required.

It should be noted that psychological harm is included in the criteria for classifying incidents as clinically significant. In rare circumstances an accidental or unintended exposure may be a CSAUE if it affects the individual's quality of life to a level that requires intervention or treatment. Determining if such a CSAUE has occurred will require input from other medical staff involved in the care of the individual.

3.3 Reporting arrangements

The MPE/RPA will provide advice on action to be taken to minimise the consequences and advise on other immediate action.

The MPE/RPA will:

- Make an assessment of the magnitude of the dose to the individual
- For IRMER incidents the MPE will determine if the incident is Notifiable to external authority as a Significant Accidental or Unintended Exposure (SAUE) according to the guidance document "*Significant Accidental or Unintended Exposures under IR(ME)R Guidance for Employers and Duty-holders*"; or is Notifiable as a Clinical SAUE (CSAUE) according to the guidance in "*IR(ME)R Implications for Clinical Practice in Diagnostic Imaging, Interventional Radiology and Diagnostic Nuclear Medicine*"

- Prepare a report on the incident including the dose,an assessment of the risk, and a recommendation on the need to report the incident to the appropriate authority

- Attach the report to the Datix record

- If the incident requires to be reported externally, copies of the MPE/RPA report will be sent to the IGM

The lead investigator will:

- Ensure the referrer, practitioner and patient (or their representative) has been informed of the incident if it has been categorised as a CSAUE by the MPE.

The Imaging General Manager will:

- Notify the appropriate authority of the occurrence of an incident after confirming that for CSAUE incidents the referrer, practitioner and patient (or their representative) has been informed of the incident. If investigation is likely to take some time, an initial report of the occurrence of the incident may be sent, followed later by a more detailed report (EP-Guidance-004) within prescribed deadlines.

- Upload the report and subsequent correspondence to the Datix Incident record and copy this to the relevant General Manager / Clinical Director and for IRMER incidents also to the Referrer and Practitioner

The Referrer will notify the individual (or their representative) of the outcome of the investigation.

4. Investigation and reporting requirements for specific incident types

4.1 Incidents involving duty holder errors or failure of an employer's written procedure

The SeS/HoD will identify a Lead Investigator.

The Lead Investigator will conduct face to face interviews with staff involved to determine the cause of the incident and any contributory factors. Datix will be updated.

The Lead Investigator will include in their report details of what happened and why, any deficiencies in procedures or staff training that contributed to the incident, and recommend actions that should be taken to minimise the risk of a similar incident occurring in the future. The duty holder will be asked to provide a reflective account of the incident which is uploaded to Datix. For incidents in which the cause is complex, the report may be prepared jointly by the Lead Investigator and the MPE/RPA.

The SeS/ HoD will review deficiencies in procedures and training, and ensure necessary changes are implemented. A flow chart setting out the investigation and reporting process is included in Flowchart 1.

4.2 Incidents involving equipment failure

The Ses/HoD will identify a Lead Investigator

The Lead Investigator will arrange for an investigation of the circumstances and causes of the incident, involving the equipment manufacturer's representative, the MPE/RPA, and other agencies as appropriate.

The Lead Investigator will make arrangements for any fault to be repaired and ensure that procedures are in place for any necessary tests to be carried out and satisfactory equipment performance confirmed and documented, before the equipment is returned to clinical service following an incident.

The Lead Investigator will include in their report details of what happened and why, what actions have been taken to minimise the risk of a similar incident occurring in the future, recommendations for any further action, and a recommendation on the need to report the incident to the appropriate authority. For incidents in which the cause is complex, the report may be prepared jointly by the Lead Investigator and the MPE/RPA.

Where the incident requires notification (EP-Guidance-004), the IGM will submit a report to the appropriate authority. A flow chart setting out the investigation and reporting process is included in Flowchart 2.

4.3 Incidents involving loss, release or spill of a radioactive material

The HoD will identify a Lead Investigator

The Lead Investigator will arrange for an investigation of the circumstances and causes of the incident involving the RPS/RPA/RWA as appropriate.

The Lead Investigator will include in their report details of what happened and why, what actions have been taken to minimise the risk of a similar incident occurring in the future, recommendations for any further action, and a recommendation on the need to report the incident to the appropriate authority. For incidents in which the cause is complex, the report may be prepared jointly by the Lead Investigator and the RPS/RPA.

Where the incident requires notification (EP-Guidance-004), the IGM will submit a report to the appropriate authority. A flow chart setting out the investigation and reporting process is included in Flowchart 3

5. Records and Feedback

The SeS/HoD will:

Upload copies of any documents relating to the incident to the Datix Incident record. Reports produced as a result of this investigation should be retained for at least 2 years. (Reports generated under the IRR17 legislation will need to be retained for a longer period – advice should be sought from the RPA).

Ensure that proper arrangements have been made to inform staff of lessons arising, and of any updated documentation.

Log the incident for discussion at an appropriate department staff meeting/radiation safety meetings.

6. Informing the individual (or their representative) and other relevant persons

The Operator performing the exposure may inform the individual* of any accidental or unintended exposure at the time of the examination, unless he/she judges that this may be inappropriate.

If the Operator or IRMER Practitioner has not informed the individual*, the IRMER Practitioner or appropriate line manager will provide sufficient information, including level of risk, for the referrer to inform the individual* at a later stage (this may include liaising with the MPE).

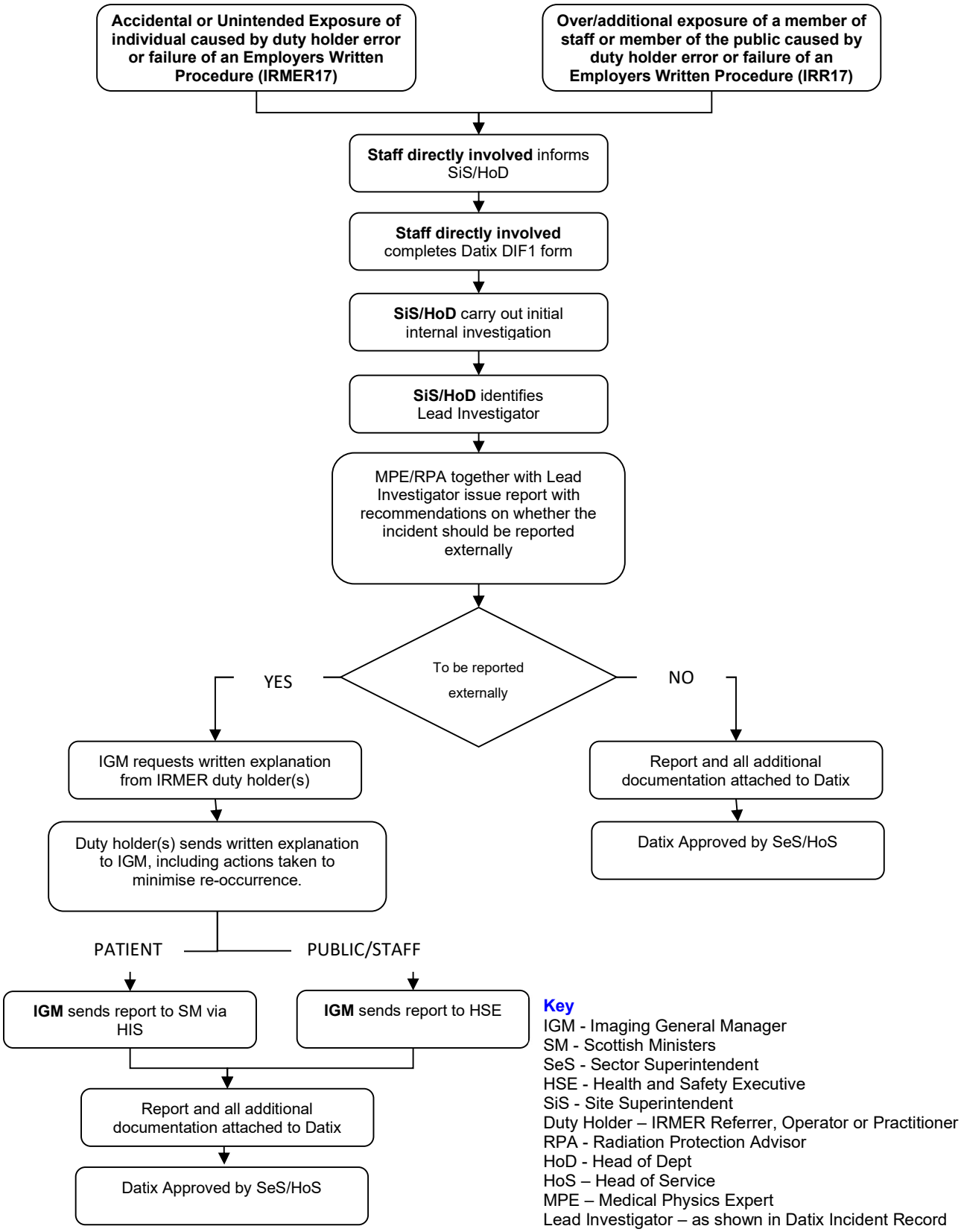
For incidents the MPE has determined are Notifiable as a Clinical SAUE then the referrer, practitioner and the individual involved (or their representative) must be informed. The Imaging General Manager should confirm this has taken place before Notifying HIS of the incident.

An indication of risk will be given in general terms relating to the type of examination (EP-Guidance-004, Table 1). Information on the effective dose, how this compares with doses from other sources such as natural background radiation (EP-Guidance-004, Table 2) and the level of risk can be included. If there is uncertainty about the risk from the exposure, advice should be sought from the MPE/RPA.

A record should be made confirming that the individual* was informed about the incident. The referrer (or the operator/practitioner) is responsible for ensuring that the information is documented via existing Clinical Governance mechanisms.In some circumstances it may be considered that it is not appropriate to inform the patient. If this is the case, the reasons why the patient was not informed should be included on the incident report and in the patient notes.

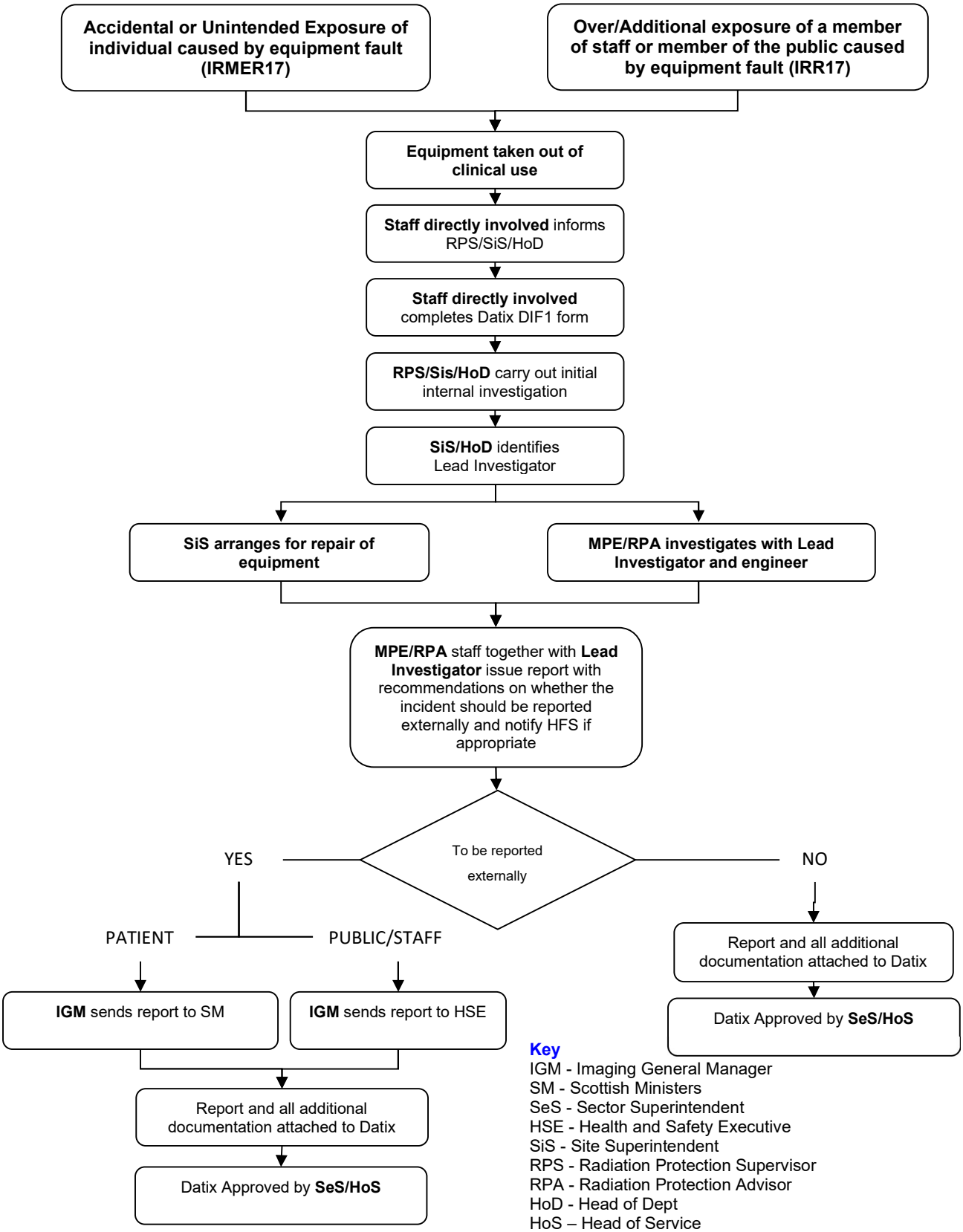
** or their representative*

FLOWCHART 1 Duty Holder Error or Procedural Error



Key
IGM - Imaging General Manager
SM - Scottish Ministers
SeS - Sector Superintendent
HSE - Health and Safety Executive
SiS - Site Superintendent
Duty Holder – IRMER Referrer, Operator or Practitioner
RPA - Radiation Protection Advisor
HoD - Head of Dept
HoS – Head of Service
MPE – Medical Physics Expert
Lead Investigator – as shown in Datix Incident Record

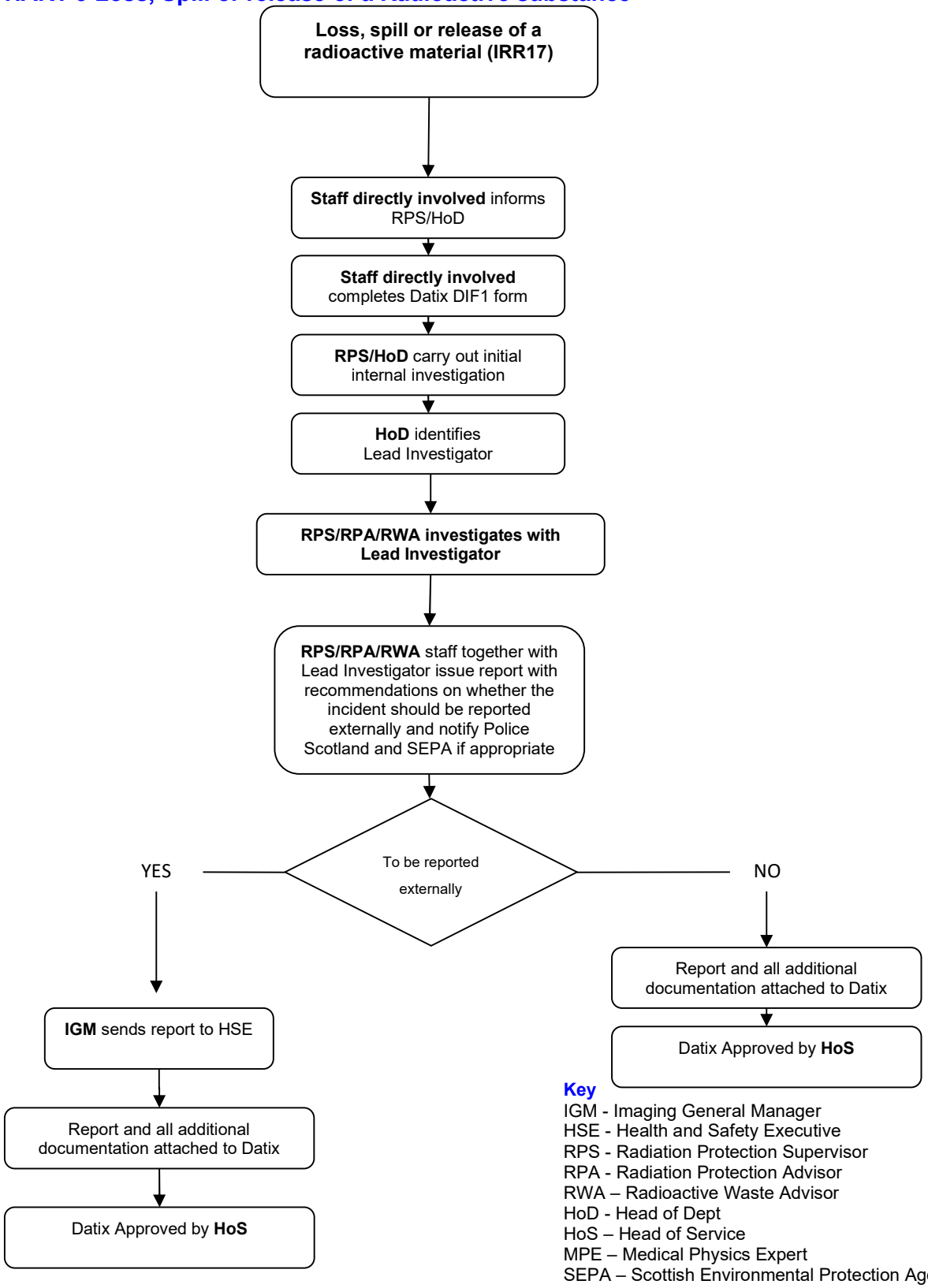
FLOWCHART 2 – Equipment Faults



Key

IGM - Imaging General Manager
SM - Scottish Ministers
SeS - Sector Superintendent
HSE - Health and Safety Executive
SiS - Site Superintendent
RPS - Radiation Protection Supervisor
RPA - Radiation Protection Advisor
HoD - Head of Dept
HoS – Head of Service
MPE – Medical Physics Expert
Lead Investigator – as shown in Datix Incident Record

FLOWCHART 3 Loss, Spill or release of a Radioactive substance



Key
IGM - Imaging General Manager
HSE - Health and Safety Executive
RPS - Radiation Protection Supervisor
RPA - Radiation Protection Advisor
RWA – Radioactive Waste Advisor
HoD - Head of Dept
HoS – Head of Service
MPE – Medical Physics Expert
SEPA – Scottish Environmental Protection Agency
Lead Investigator – as shown in Datix Incident Record