Safety Incident Management Policy

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1.0 Policy

It is the policy of the Health Service Executive (HSE) that all safety incidents are identified, reported and investigated. Incidents will be disclosed in accordance with the guidance provided in the HSE / State Claims Agency (SCA) Open Disclosure: National Guidelines (HSE / SCA, 2013)

The HSE aims to:

- Promote a just, proportionate and consistent approach to the management and investigation of safety incidents.
- Be committed to the protection and wellbeing of its service users and employees and others.
- Demonstrate compliance with legislative and regulatory requirements and HSE risk management and control assurance processes.
- Manage and investigate safety incidents in a timely and cost effective way and in a manner in which managers, employees, service users and the public can be confident.

The HSE recognises the importance of learning from safety incidents and therefore promotes an environment within which individuals and groups are encouraged to report, investigate, disseminate and implement learning from safety incidents promptly. Safety incident management occurs within the framework of the principles of open disclosure, integrated risk management, just culture and fair procedures.

The purpose of safety investigations is to collect and analyse safety data to identify the system causes of harm so that recommendations may be made to improve the safety of our health services for our service users, staff and others.

In the interest of patient safety it is the policy of the HSE that safety incident investigations should always proceed where possible. An investigation may be carried out while other internal or external investigations are ongoing or anticipated relating to a safety incident. Examples of internal HSE investigations include those undertaken for example by HR and internal audit. Examples of external investigations include inquests, civil litigation managed by the SCA, and investigations by the HSA, HIQA, the MHC, and/or An Garda Siochána.

In cases of investigations by the An Garda Siochána, commissioners of HSE investigations must confirm that it is in order for the HSE to proceed with a safety investigation by providing the terms of reference for the planned safety investigation to the Director of Public Prosecutions (DPP) and documenting the DPP decision.

It is the role of the Investigation Commissioner to ensure/facilitate considered and appropriate communications and linkages between the various investigation bodies.

2.0 Purpose

The purpose of this document is to set out the HSE's policy for managing safety incidents.

Safety incidents include staff or service user complaints which are associated with harm. Allegations of abuse are managed in accordance with the HSE's Trust in Care Policy (HSE, 2005).

3.0 Scope

This policy applies to all employees of the HSE and all agencies funded wholly by the HSE including section 38 & section 39 service arrangements.

4.0 Legislation / Other Related Policies

4.1 Legislation
- Safety, Health and Welfare at Work Act 2005 (S.I. 10 of 2005) and The Safety, Health and Welfare at Work (General Application) Regulations, 1993 SI44 Part X
- The Health Act 2004

- Data Protection Acts 1988 & 2003
- Freedom of Information (Amendment) Act, 2003

4.2 Policies that are being replaced by the HSE safety incident management policy (2014)

The HSE Safety Incident Management Policy (2014) replaces the following documents

- QCD001 HSE Risk and Incident Escalation Procedure (2010)
- QCD001a HSE Risk and Incident Escalation Form (2010)
- OQR008 HSE Toolkit of Documentation to Support Incident Management in the HSE (2009)
- HSE Serious Incident Management Policy (2008)
- HSE Serious Incident Sign Off Form (2008)
- OQR006 HSE Incident Management Policy and Procedure (2008)

Related HSE polices and guidelines

- Quality and Safety Committee(s) Guidance and Sample Terms of Reference (2013)
- Open Disclosure: National Guidelines (2013)
- Supporting Staff following an Adverse Event: The Assist Me Model (HSE/SCA, 2013).
- QPSD-GL-52-1 Guidelines for Systems Analysis Investigation of Incidents and Complaints (2012)
- Serious Incident Management Team Guideline on Conducting Look-back Reviews (Part 7) (2008)
- Integrated Risk Management Policy (2011)
- Developing and Populating a Risk Register Best Practice Guidance (2009)

5.0 Glossary of terms and definitions

Term	Definition
Accident	An unplanned, unexpected, and undesired event, usually with an adverse consequence.
Adverse Event	An incident which resulted in harm.
Contributory Factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Harm	**1. Harm to a person:** Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury **2. Harm to a thing:** Damage to a thing may include damage to facilities or systems; for example environmental, financial, data protection breach etc.
Hazard	A circumstance, agent or action with the potential to cause harm.
Incident	An event or circumstance which could have, or did lead to **unintended and/or unnecessary harm**. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complains which are associated with harm. Incidents can be clinical or non-clinical and include Incidents associated with harm to: • patients, service users, staff and visitors • the attainment of HSE objectives • ICT systems • data security e.g. data protection breaches • the environment
Integrated Risk Management	A continuous, proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective.
Investigation Commissioner	The Commissioner of an investigation differs across the health system, but it is typically the senior accountable officer in a service, division or care group that commissions an investigation of a clinical or non-clinical safety incident.
Investigator	An individual who has training and experience in conducting investigations in accordance with HSE guidelines i.e. Systems analysis investigations of incidents and complaints and

Term	Definition
	/ or Look Back Review Guidelines
Just Culture	A just culture seeks to balance the need to learn from mistakes and the need to take disciplinary action.
Key Causal Factor	Issues that arise in the process of delivering and managing health services which had an effect on the eventual adverse outcome.
Look back review	Review where a number of people have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them.
Near-miss	An incident which could have resulted in harm, but did not either by chance or timely intervention.
Open Disclosure	An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.
Risk	The chance of something happening that will have an impact on objectives
Risk Management Process	The systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk
Safety Incident Management Team	A Safety Incident Management Team is convened by the senior accountable officer in a service, division or care group, particularly for incidents of death and serious harm. The team is convened within 24 hours of the senior accountable officer being informed of the incident. The Safety Incident Management Team may be an existing appropriate management team or a subgroup of an existing appropriate management team, the Quality and Patient Safety Committee, Clinical Governance Committee or any other similar group provided that the team has a chair and appropriate membership.
Senior Accountable Officer	The senior accountable officer is the person who has ultimate accountability and responsibility for the services under his/her governance (e.g. in the case of a hospital, it is the hospital chief executive officer).
Serious Harm	Serious injury to a person, or serious damage done to a thing. • An injury which creates a substantial risk of death or which causes serious disfigurement or substantial loss or impairment of the mobility of the body as a whole or of the function of any particular bodily member or organ. • See HSE Impact table (appendix 1) for specific description of Serious harm for both clinical and non-clinical incidents.
Serious Incident	An incident that results in death or serious harm.
Service User	Members of the public who use, or potentially use, health and social care services as patients, carers, parents and guardians. This also includes organisations and communities that represent the interests of people who use health and social care services.
Systems analysis investigation of an incident (previously known as root cause analysis)	A methodical investigation of an incident which involves collection of data from the literature, records (general records in the case of non clinical incidents and healthcare records in the case of clinical incidents), interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that lead up to the incident, identifying the key causal factors that had an effect on the eventual adverse outcome, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable.

6.0 Roles and responsibilities

The roles and responsibilities of managers, employees and senior accountable officers of the HSE in relation to this policy and related guidelines and procedures are set out in sections 6.1 - 6.4 below.

6.1 Open disclosure

This policy must be read within the context of the HSE / SCA *"Open Disclosure: National Guidelines" (2013).*

6.2 Employee responsibilities

It is the role and responsibility of all employees to:

- Comply with this policy.
- Ensure that safety incidents are reported, managed and investigated in a timely manner.
- Participate in and co-operate with investigations conducted in accordance with this policy.
- Participate in the introduction of changes identified as a consequence of an investigation.

6.3 Manager responsibilities

It is the role and responsibility of all managers to:

- Ensure that they, their employees and/or persons and agencies providing services or advice are aware of and comply with the HSE Safety Incident Management Policy (2014).
- Facilitate training for employees to comply with this policy (including investigators).
- Develop and implement local processes to comply with this policy.
- Monitor and conduct regular audits of compliance with this policy and related procedures, protocols and guidelines.
- Ensure that safety incidents are reported, managed and investigated, and safety recommendations are implemented in a timely and cost effective manner.
- To follow the correct HSE processes relating to Freedom of Information requests, Data Protection access requests, Parliamentary Questions, Media Queries and Briefing documents in the management of safety incidents.

6.4 Senior accountable officer responsibilities

The senior accountable officer is the person who has ultimate accountability and responsibility for the services under his/her governance, for example, in the case of a hospital it is the hospital chief executive officer.

It is the role of the senior accountable officer (or his/her senior nominee) to:

- Ensure that they comply with this policy.
- Commission and chair Safety Incident Management Teams for a) incidents that result in death or serious harm and are rated as major or extreme harm according to the Impact Table (see Appendix 1 section 7.2.4) and b) look back reviews (see section 7.2.5.7).
- Commission system analysis investigations of incidents of death and serious harm as set out in the HSE "Guidelines for Systems Analysis Investigation of Incidents and Complaints" (HSE, 2012) or as set out in the HSE "Guideline on Conducting Look-Back Reviews" (HSE 2008) where applicable
- Ensure that aggregate analysis, investigations and look-back reviews are completed in a timely and cost effective manner.
- Have clear systems of governance in place to manage all safety incidents including incidents that result in death and serious harm.
- Be accountable for quality and safety within services under his/her governance.
- Ensure that robust systems are in place to both proactively and retrospectively enhance quality and safety systems throughout their organisation or service.
- Have clear systems of governance in place to implement the recommendations of investigation reports (see sections 7.3-7.4).

7.0 Safety incident management process

Sections 7.1 – 7.4 outline the incident management process to be undertaken to comply with this incident management policy. The incident management process has four elements including:

      7.1   Prevention and Planning

      7.2   Management and investigation of safety incidents

      7.3   Circulation of Reports and Recommendations

      7.4   National Learning

At all stages of the safety incident management process there is a requirement to capture data from service levels upwards to the national level, with appropriate data protection. The National Adverse Events Recording System (NAEMS), previously known as STARSWeb, is hosted by the SCA. It is the national system for reporting of incidents associated with clinical activities in all services funded or wholly managed by the HSE. As of March 2014, non-clinical safety incidents relating to personal injuries sustained by members of the public or employees, or incidents resulting in damage or loss to the public or employees, are also reported on the NAEMS system by wholly owned and managed HSE hospitals/services.

7.1 Prevention and planning

The HSE has to provide strong leadership and support to ensure a just and supportive safety culture is developed. This must be supported by policies and guidelines to guide the development of local processes in the areas of:

- HSE integrated risk management
- Patient safety initiatives
- Complaints management process

Prevention of safety incidents is supported by local/regional/divisional/national learning from the causes of such incidents. The learning from every safety incident must be applied in the location and service where the safety incident occurred, and disseminated across other services/divisions as applicable. From a national perspective, the overall analysis and dissemination of information will be centralised in a national learning system with appropriate assurance processes (See Section 7.4).

Planning for the management of safety incidents is facilitated and supported by:

- The development and implementation of local processes to meet the requirements detailed in this policy.
- Ongoing training and education of staff on how to prevent, report, manage and investigate safety incidents.
- Regular monitoring and auditing of the above.

7.2 Management and investigation of safety incidents

The steps in managing and investigating a safety incident that has occurred are as follows. Note: the process generally refers to individual incidents, but some elements apply to multiple incidents where aggregate analyses and look back reviews are covered:

      7.2.1.   Identification of a safety incident

      7.2.2   Reporting of a safety incident

      7.2.3.   Assessment of a safety incident

      7.2.4.   Convening a Safety Incident Management Team

      7.2.5.   Investigation of the safety incident

      7.2.6.   Safety improvement

Diagram 1 Overview of the safety incident management process.

Overview of Incident Management process

Identification & immediate management

- Audit output
- Staff become aware that an incident has occurred and report it
- Colleagues express concerns
- Complaint (internal or external) that is deemed to be an incident

Immediate action to:
- Provide care
- Prevent more harm
- Ensure service continuity
- Open Disclosure per HSE Policy

Reporting

Input to NAEMS ← Reporting and communication of an incident

Assessment

Reassessment required

Analysis of data for aggregate review ← Review decisions at Quality and Safety Committee ← Record decision & document ← No — Assessment to determine if investigation Required and type of investigation

Yes

Investigation

Incident Management team

Look Back review

Systems Analysis investigation

Aggregate analysis
Incidents resulting in no harm, negligible harm, minor, or moderate harm according the HSE's impact table

Look back review (per HSE policy)
Incidents where it appears a number of people have been exposed to a specific hazard

Systems analysis investigation

Yes — Determine if look back review required

Yes — Determine if look back review triggers systems analysis investigation of an incident

Safety Improvement

Report to commissioner of the investigation;
Report contains:
Key causal factors
Contributory factors
Incidental findings
Recommendations

Data Capture, Reporting, Analysis, and Dissemination of Learning

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7.2.1 Identification of a safety incident

All employees and those who supply services to the HSE should be aware of what constitutes a safety incident so that they are in a position to detect, disclose and report such incidents when they occur.

A safety incident may be identified by:

- An **employee** when a safety incident occurs or an unexpected outcome is detected.
- A **patient, patient advocate**, **service user, carer, or visitor** who expresses concern or complaint about a service, at the time of the safety incident or at a later time.
- **Incident identification processes** such as staff incident reporting, medical records review, surveillance or retrospective review/audit.
- Issues/concerns identified as part of the **transfer/referral/discharge processes** within and across services or identified at interfaces between services.

All employees must ensure that they manage immediate safety concerns following the identification of a safety incident and disclose and report incidents in line with this policy, local processes and the HSE/SCA Open Disclosure: National Guidelines (2013).

7.2.1.1 Management of immediate safety concerns

The following is a list of essential steps to manage immediate safety concerns following the identification of any safety incident.

- When a safety incident is identified, the first responsibility is to ensure that the safety, health and welfare of the person(s) affected are protected.
- Any care that is required as a consequence of the safety incident must be provided without delay and circumstances reported to the treating clinician or, in the case of a non-clinical incident, to the appropriate manager.
- Any threat to the future safety, health and welfare of service users, employees or others must be removed or minimised as far as is reasonably practicable.
- Relevant materials, equipment or supplies that may have contributed to the safety incident must be preserved and retained. Healthcare records must be preserved and retained in line with HSE Standards and Recommended Practices for Healthcare Records Management *QPSD-D-006-3 V3 (2011).*
- Where there is a requirement to photograph a person for investigation purposes, HSE guidelines for data protection and consent should be complied with when creating, preserving or retaining such photographs.
- Maintain or resume normal services as soon as it is practicable and safe to do so.
- Employee(s) may be stepped down to ensure that they receive appropriate care and support following a safety incident. For more guidance please see the HSE/SCA guidance document "Supporting Staff following an Adverse Event: The Assist Me Model" (2013).
- Determine if any individual's actions presents an immediate safety concern. There may be a need for immediate precautionary action (e.g. step-down from duty). Please refer to the incident decision tree and related guidance (see Appendix 2a & Appendix 2b).
- Ensure that counselling and support is provided to employees as soon as possible. (See Appendix 3 for details on the HSE Employee Assistance Programme).
- Ensure that appropriate counselling and support details are provided to patients and their families as soon as possible.
- Ensure appropriate communication with the patient / family. See Appendix 4 for Guidelines for Consideration When Communicating with a Patient or Family in relation to an incident.

7.2.2 Reporting safety incidents & serious reportable events

All safety incidents must be reported to a line manager. As noted previously, NAEMS is the national system to electronically record all reported incidents. Mandatory fields on NAEMS should be completed to ensure standard reporting and data capture. NAEMS enables all incidents, including incidents that might be classified as *"sentinel events"; "serious reportable events"* or *"never events"* to be reported, classified and analysed, to inform local and national safety improvements. It is the policy of the HSE to use the term *"serious reportable events".* A governance group will oversee the list of "serious reportable events" and associated guidance for implementation. The list of *"serious reportable events"* will be reviewed annually. The list of *"serious reportable events"* is included within Appendix 5.

7.2.2.1 Responsibilities of the person who identified or observed the safety incident

Following the identification of a safety incident, the following steps are the responsibility of the person who identified or observed the incident*:*

- Immediately manage, or have someone manage, any immediate safety concerns (including communication and caring for those affected see Section 7.2.1).
- Report the safety incident to their line manager using agreed local processes.
- An incident report form should be completed by an employee involved in or who observed a safety incident as soon as practicable and at least prior to going off duty (see Appendix 6 for requirements of an incident reporting form). Where an employee is not in a position to do this, the form should be completed by another employee who observed the incident, or by the line manager.
- All completed incident report forms are sent to the designated local manager.

7.2.2.2 Reporting of death and serious harm incidents

In addition to the steps outlined in the section above, all safety incidents which result in death or serious harm must be reported to the senior accountable officer **within 24 hours**. These include incidents categorised as 'major' and 'extreme' on the Impact Table (See Appendix 1).

7.2.2.3 Actions taken by managers on receipt of an incident report form

It is the responsibility of each manager to assess and manage minor incidents locally and inform their line manager as required. The following actions must be taken by managers on receipt of an Incident Report Form in as timely a manner as is possible:

- Review the Incident Report Form.
- Seek assurance that any actions required to ensure that immediate safety concerns have been addressed (including communication and caring for those affected see section 7.2.1).
- Conduct a preliminary assessment to determine the level and type of investigation required (see section 7.2.3).
- Communicate / escalate incidents of death and serious harm to the level of management determined by local/national division processes (see incident communication / escalation form Appendix 8 and sections 7.2.2.4 and 7.2.2.5).
- Consider if it is necessary to report factual information to external agencies/authorities as per HSE reporting requirements (See Appendix 7).
- Ensure all necessary people are informed e.g. senior managers, counselling and support services, and communications personnel. It is essential to involve communications personnel with the management of incidents, particularly with regard to incidents of death and serious harm. Communications personnel assist in the preparation of draft press statements and assist with responses to media queries at local, regional and national level.
- All Incident Report Forms once complete will be sent to the designated local manager and be communicated, if required as per local processes.
- Ensure that all elements of the safety incident management process are followed.

Reporting of a minimum data set of information on all safety incidents and investigations will be provided to the national learning system (via NAEMS) to facilitate quality assurance of the data and analyses and dissemination of the information to inform national learning. (See section 7.4).

In most cases a safety incident can be managed locally. There are situations where it is appropriate to escalate/communicate the safety incident to the next level of management; the considerations for this are in the next section.

7.2.2.4 Determining if incidents must be <u>communicated</u> to the next level of management.

In the context of this policy initial communication by the local manager within the service or department where the safety incident occurred to the next level of management refers to providing information about the incident so that the higher level of management is aware of the incident. There is no transfer of responsibility for the management of the incident to the next or any higher level of management.

All cases of death or serious harm and other categories of incidents (locally defined) must be communicated to the level of management determined by local/division or directorate processes.

On completion of the investigation into the safety incident, the key causal factors, contributory factors, and any recommendations must be communicated to the relevant National Director if the recommendations have a national implication. This is to ensure that they are considered locally and nationally to inform appropriate safety interventions.

7.2.2.5 Determining if incidents must be <u>escalated</u> to the next level of management

In the context of this policy, escalation refers to the process whereby the local manager reports on the safety incident to the management level above them and onward to hospital group / primary care area / administrative area and National Director level as required. An incident is escalated when the local manager determines that additional support is required for managing and investigating the incident.

The following considerations influence the decision to escalate a safety incident for additional support:
- The safety incident involves more than one division, care group or hospital group which makes the incident management or investigation problematic for the local service.
- The local area has issues with capacity or capability to manage and investigate the safety incident according to HSE Safety Incident Management Policy (2014) and related guidelines.
- The HSE Investigator(s) deem that external input to the investigation is required.
- Where the assessment of a safety incident indicates that a look back review is required.
- If there is a significant risk to public confidence in services.
- Where there is another investigation being conducted by an external agency for example investigations by professional or other regulators such as the Mental Health Commission (MHC), the Health Information and Quality Authority (HIQA), the Health and Safety Authority (HSA) or An Garda Siochána.

The level to which any safety incident is escalated will be determined by local or division processes taking the above considerations into account. The risk of litigation in itself is not a criteria for escalation (see additional information in section 7.2.5.4).

See appendix 8 for a copy of the safety incident communication / escalation form.

7.2.3 Assessment to determine type of investigation required

Following the management of immediate safety concerns, line managers must make an assessment of the safety incident to determine the level of investigation required. This assessment must be conducted in as timely a manner as is possible. In the case of **incidents resulting in death or serious harm rated as major or extreme harm according to the Impact Table (Appendix 1) the assessment must occur within 24 hours after the incident occurred.** This assessment may be informed by the impact of the incident according to the Impact Table (Appendix 1), relevant literature or may be related to whether a look back review is indicated.

The assessment of safety incidents will:

- Establish the context of the safety incident (where an incident occurred and what occurred).
- Assess the impact of an incident according to the Impact Table (Appendix 1).
- Decide the appropriate type of investigation required, reporting requirements, ongoing management plan and whether onward communication or escalation is required.

The local manager may decide that no further investigation is required. This occurs in cases where an adverse outcome has arisen but where it is immediately evident that there were no key causal factors that contributed to the actual adverse outcome (the incident). Please see Appendix 9 for an example of same).

For safety incidents where no further investigation is required, managers must ensure that:

- The data from the Incident Report Form is captured (as per local arrangements) for aggregate review.
- The local manager's decision not to investigate further and the reasoning/factors influencing this decision are noted clearly in documentation and conveyed to all involved, including staff / patients involved in the incident and the local quality and safety committee or equivalent, in a manner that respects the rights of all to privacy and confidentiality.
- A local quality and safety committee (or an equivalent) should seek assurance through documentation that a decision not to investigate further is appropriate.
- There is appropriate communication with the patient / family.

If there is any doubt about whether a safety incident was unforeseeable / unavoidable, the first three steps of a systems analysis investigation of an incident should be undertaken (HSE, 2012). If the event was unforeseeable / unavoidable, no key causal factors will be identifiable upon analysis of the chronology and it can be confirmed that, while it is regrettable that harm occurred, it is not an incident of harm caused by some act or omission on the part of the HSE.

7.2.4 Convening a safety incident management team

All safety incidents that require investigation will be managed by a Safety Incident Management Team. A Safety Incident Management Team is convened by the senior accountable officer in a service, division or care group and must be convened for incidents of death and serious harm and rated as **major or extreme** harm according to the Impact Table (Appendix 1)

A Safety incident Management Team is convened within 24 hours of the senior accountable officer being informed of the incident. The team may be an existing appropriate management team or a subgroup of an existing appropriate management team, the Quality and Patient Safety Committee, Clinical Governance Committee or any other similar group provided that the team has a chair and appropriate membership.

Members of a Safety Incident Management Team should not include individuals involved in the incident. Safety Incident Management Teams can be internal to the hospital/primary care area/management unit where the incident occurred.

See Appendix 10 for a suite of documentation to support Safety Incident Management Teams including proposed membership, sample terms of reference and a sample agenda for team meetings.

7.2.5 Investigation of the safety incident

7.2.5.1 Consent to access healthcare records

It is the policy of the HSE that all reasonable efforts should be made to seek consent to access relevant sections of healthcare records for the purposes of individual systems analysis investigations of safety incidents. Signed consent forms and/or documentation of conversations and/or efforts to seek and gain consent must be retained locally. Managers should also consider implicit consent (e.g. calls to a helpline) that include a request for a file to be reviewed. A copy of a sample patient information leaflet and consent form is included in Appendix 11A and 11B of this policy document.

Where consent is not provided or consent is withdrawn managers must make a determination whether or not to proceed with an investigation with regard to the greater safety imperative in the interest of patient safety. Any instance where consent has not been provided must be assessed on a case to case basis weighing up the wishes of the person withholding consent verses any risk to broader patient safety if an investigation is not carried out. Factors impacting on each case where consent is not provided must be taken into account.

Principles for managers to take into account when determining the appropriate action where no consent has been given are:

➢ Only those parts of the healthcare record that are relevant to the incident investigation will be accessed

➢ Consideration if the incident investigation may have wider safety application to the service or broader health services / public good.

Where consent is not provided and a decision is made to proceed with the investigation, the rationale for this decision must be clearly documented.

7.2.5.2 Communication of safety concerns by the investigation team to the investigation commissioner

In all safety investigations there must be communication and management of safety concerns to the investigation commissioner as soon as they are identified. The investigation commissioner is typically the senior accountable officer in a service, division or care group. Section 7.2.1 outlines the management of immediate safety concerns following the identification of an incident.

A safety incident investigation may identify contributory factors/hazards that exist at the site where the safety incident occurred or at other similar HSE sites.

In these instances, the Safety Investigators must immediately convey such safety concerns to the Investigation Commissioner who must ensure that the details of the contributory factors/hazards identified and the associated recommendations are urgently communicated within the service/site and/or the other relevant parts of the HSE for learning and quality and safety improvement purposes as soon as they are identified even if this is before an investigation is finalised.

7.2.5.3 Legal protections and information collected through safety incident reporting, management and investigation processes

The Commission on Patient Safety and Quality Assurance recommended under recommendation R7.32 (Department of Health, 2008) that "information collected under the [recommended] reporting system (both mandatory and voluntary) must be strictly confidential, protected from legal discovery and exempted from Freedom of Information legislation."

The HSE recognises the importance of high rates of incident reporting and high quality participation by employees in incident investigations for safety. The HSE also recognises that employee participation in incident reporting and investigation improves when these are conducted in a safe and confidential environment.

There is currently no legal protection in Ireland protecting information received as part of safety incident investigations. No guarantee can be given by the HSE that information received as part of an incident investigation will be fully protected from legal discovery and / or disclosure.

Please see appendix 7 for a list of agencies to whom the Health Sector reports factual information.

7.2.5.4 Aggregate analysis of incidents that resulted in negligible, minor or moderate harm

It is the policy of the HSE that at a minimum there will be aggregate analysis of the causes of low impact safety incidents according to incident type (e.g. falls). Aggregate analysis includes analysis of near miss incidents and incidents that resulted in *"negligible"*, *"minor" or "moderate"* harm according to the Impact Table (see Appendix 1). Aggregate analyses will be overseen by the local quality and safety committee or equivalent, who must have access to appropriate expertise to conduct these aggregate analyses.

The following must be summarised in a brief report to the local quality and risk committee or equivalent:

- The identification of key causal factors contributing to the safety incidents by type
- The identification of contributory factors for each key causal factor (See Appendix 15 for Contributory Factors Framework).
- The identification of control measures and quality improvement plans to address the contributory factors identified (See Appendix 16).

In any service a high volume of low impact incidents is expected. Aggregate analysis of high frequency incidents are particularly important and should be informed by subject experts and the relevant department/service leads. An example of an aggregate review of incidents is presented in Appendix 12.

Data produced will be used for local and national analysis, which may trigger a look-back review if necessary (See section 7.2.5.4).

Contributory factors or hazards identified should be managed and communicated via the local risk register, according to risk management policy and procedures.

7.2.5.5 Systems analysis of incidents with major to extreme impact

All safety incidents that result in death or serious harm and as such are rated as resulting in major or extreme harm according the Impact Table (Appendix 1) must be investigated to determine any key causal factors and contributory factors according to the guidance set out in the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE 2012).

Incidents of death and serious harm must be overseen by a **Safety Incident Management Team** (see section 7.2.4), to be convened by the Senior Accountable Officer within one working day following notification of the incident. The Safety Incident Management Team must be chaired by the Senior Accountable Office or his/her delegate.

The Senior Accountable Officer must commission an **Investigation Team** within two working days following notification of the incident. This Team must be chaired by an individual with training and experience in conducting systems analysis investigations according to HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE 2012).

The Senior Accountable Officer must ensure the following in relation to the systems analysis investigation of the safety incident.

- Members of the investigation team should not include individuals directly involved in an incident or managers of the service/department where an incident occurred.

- Investigation teams should consist of the smallest number of members necessary to achieve the objectives of the investigation (minimum: two). In most circumstances, it is appropriate to have one trained and experienced Investigator and one person to take notes.

- Investigation team chairpersons should be trained and experienced in conducting investigations according to Guidelines for Systems Analysis Investigations of Incidents and Complaints (HSE 2012).

- If external/expert input is required to the investigation team, trained and experienced HSE Investigators should be able to identify this need and should request such input through the Investigation Commissioner. The need for external expert input and the type of expert input required will usually become apparent as the investigation progresses.

- Members of the investigation team should not be members of the Safety Incident Management Team. The investigation team should update the Safety Incident Management Team and/or Investigation Commissioner on the progress of the investigation and any emerging safety issues. The Safety Incident Management Team addresses any emerging safety issues and obstacles that arise in relation to completing the investigation within an appropriate timeframe.

- The investigation team must conduct the investigation and deliver the investigation report to the Investigation Commissioner in as timely a manner as possible. The target for completion of an investigation report is four months ,or less, from the date the investigation team is established. All immediate safety concerns must be communicated to the senior accountable officer as soon as they are identified.

- The systems analysis investigation of an incident is conducted as described in the Guidelines for Systems Analysis Investigations of Incidents and Complaints (HSE 2012)

- Investigation reports are quality assured by an individual who was not involved in the incident and is not a member of the incident management or investigation team.

This investigation may trigger a look back review, if necessary (See section 7.2.5.7).

Contributory factors or hazards identified should be managed and communicated via the local risk register and according to risk management policies and procedures.

7.2.5.6 Look-back review

A look-back review is conducted as a matter of urgency when a **number of people have been exposed to a specific hazard** in order to identify if any of those exposed have been harmed and how to take care those harmed. Examples of hazards that should require a look-back review include but are not limited to the following:

- Audits showing that the results delivered by either a service or an individual may not be up to best practice standards.

- Identification of a faulty batch of vaccines.

- Equipment found to be faulty or contaminated in a manner that puts people at risk of harm.

- Concern about the level of injury in a care setting.

The HSE Guideline on look-back reviews(2008) must be followed and the process must be overseen by a Safety Incident Management Team.

The look-back review team must conduct its investigation and deliver its completed report to the Investigation Commissioner in as timely a manner as is possible.

Any incidents of major, extreme harm, death or serious harm identified by a look-back review which were not identified previously should be investigated further as per section 7.2.5.6 above and using the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (2012).

The potential that a look-back review may take place should always be notified to the management level above prior to commencement.

7.2.6 Safety improvement

Making recommendations to improve the quality and safety of services is one of the most important elements of an investigation report. The following are important in making recommendations to enhance safety:

- Recommendations must be linked to the factors that contributed to the incident i.e. contributory factors.
- Recommendations should be written in a way that ensures they are Specific, Measurable, Achievable, Realistic (implementable) and state a Timeframe for completion (SMART).
- Recommendations should be developed using the hierarchy of preferred control measures (see Appendix 16) to ensure recommendations:
  o Address local incident causes/contributory factors.
  o Address incident causes/contributory factors that exist at other HSE sites/hospitals/centres.
  o Are easy to follow and implement, and are cost--effective.
  o Are made with input from those directly involved in the incident; the Safety Incident Management Team (where applicable); and national experts (where applicable).
- Recommendations should reference existing safety initiatives including national and / or local standards and guidelines.
- All recommendations should be assigned to person(s) who are accountable and responsible for their implementation, with a designated timeframe for completion.

7.3 Circulation of reports and recommendations

Once the investigators submit a report to the Investigation Commissioner or Quality and Safety Committee, the Investigation Commissioner or Committee is responsible for ensuring the assessment, circulation, monitoring and implementation of the recommendations and sharing of the learning both locally and nationally, as appropriate.

It is the policy of the HSE that all final investigation reports are anonymised in terms of location and identifiable persons. They should be provided to the patient or his/her family member or advocate, unless they have expressed a wish not to receive the final report. Occasionally there may be exceptional circumstances where an investigation report cannot be provided to the patient or his / her family member or advocate; any exceptional circumstances must be documented. Reports are considered final versions when:

- Fair procedure processes are complete. This means that investigators can assure commissioners that the report is factually accurate and that all submissions and comments have been received and considered. In particular, where sections of the draft report may reflect adversely on certain individuals, the individuals have been afforded an opportunity to review and input into those sections and the conclusions of the draft report to ensure it is factually accurate before a report is provided to third parties.
- The investigation methods comply with those set out in the document 'HSE Guidelines on Systems Analysis Investigation of Incidents and Complaints' (2012) and / or the HSE Guidelines for conducting look back reviews (2008).
- Rights to personal data protection, privacy and confidentiality have been complied with. For clinical incident investigations, personal and confidential medical information should only be referred to within a report if inclusion of the information is necessary to achieve the objectives of the investigation.

Anonymised final investigation reports relating to patient safety incidents will be provided to third parties provided there is no service user safety and wellbeing reason not to do so. Examples of third parties (other than a patient or his / her family) who may receive final anonymised versions of investigation reports and recommendations include:

- Health services managers who have responsibility for making decisions, allocating resources, planning for and implementing related recommendations.

- Health stakeholders including the Department of Health, the HSA, the MHC, HIQA, the Forum of Irish Postgraduate Training Bodies, the SCA, Clinical Programmes and their equivalent in response to a specific request or as part of activities to contribute to improvements to patient safety.

Final investigation reports may also be communicated to relevant employees to create safety awareness and may be used as learning resources for safety incident management training purposes.

7.3.1 Monitoring the implementation of recommendations

Services must have in place adequate mechanisms for monitoring the implementation of recommendations, reporting on performance through the local Quality and Patient Safety Committee or equivalent, and onto the Executive Management Team and Board. Appropriate monitoring tools include the development of an action plan and periodic review and monitoring of action plans up to implementation of all recommendations.

Responsibility for the implementation of recommendations depends on the governance level to which the recommendation is addressed e.g. local management is responsible for implementation of local recommendations, and National Directors are responsible for the implementation of national recommendations. It is the responsibility of local managers to communicate nationally applicable recommendations to the appropriate National Director. In all cases, recommendations must be communicated and implemented within the shortest timeframe possible.

If funding is required for the implementation of recommendations, issues will be prioritised for funding, including prioritising in the service planning process where applicable.

7.4 National learning

In order to ensure that there is aggregate collation and analysis of data on incidents at all levels of the HSE, a national data collection system will be developed and form the basis of mandatory reporting. Local managers must ensure that the appropriate data capture takes place to feed into this national data collection. The data will include, from sources both external and internal:

- Incident type and impact.
- Service/provider/location of incident.
- Key causal factors and contributory factors.
- Factors that influence whether investigations occur, the level and type of investigations that occur, and any legal implications of investigations.
- The quality of investigations including the cost of investigations; the timeliness of investigations; the confidence and satisfaction of stakeholders in investigations; and the validity, reliability and generalisability of investigations.
- Recommendations from investigation reports and the impact of implementing recommendations.

This information will be supplemented by access to similar information in other jurisdictions to benchmark performance and learn from international experience. Systems will be put in place at all levels of the organisation to ensure that the learning from incidents is applied to the services and that avoidable incidents are not repeated as far as is reasonably practicable. Learning will be shared using appropriate formats and media; and it will support the services in identifying priorities for safety locally and nationally.

8.0 Implementation plan

The following table outlines the plan for implementing this Safety Incident Management Policy:

Task	Process steps	Deliverables	Date	Responsible
National Policy	National policy for incident management	Revised national Policy signed off. Policy will include revised escalation criteria and policy, and communication of local/national recommendations and causes of incidents.	May 2014	NIMT/QPS
	Serious Reportable Events (SRE)/	Pending full development of a 'revised national process for local/national learning provide interim capability on NAEMS to classify SRE incidents for reporting purposes.	May 2014	NIMT/QPS
	National investigation processes	Revised national process signed off (Include template for data capture for local/national learning).	Oct 2014	NIMT
	National policy on QPS access to data.	Mandate with QPS to get specified anonymous data for learning purposes from HSE services, CIS, funded services, etc.	De 2014	QPS
Implementation	Training	Incident Management Training for Senior Managers including Clinical Directors	Commenced June 2013 and ongoing	NIMT
		System analysis training for incident investigators to level necessary to undertake serious incident investigations.	Commenced June 2013 and ongoing	NIMT
		Train Division Investigation Supporters to support local investigations, and to deliver incident management and awareness investigation to all staff within each division	May –July 2014	NIMT
	Transfer appropriate cases from NIMT to regions/ divisions	Identify all cases for de-escalation to regional/divisions management which are currently on NIMT log.	March 2013 and ongoing	NIMT
		Case by case plan for de-escalation	April 2014 and ongoing	NIMT/region
		Transfer to regional/divisional ownership	April/May 2014 and ongoing	NIMT/region
New NIMT role	Set up new role for NIMT	Develop process to capture data from investigation templates into national learning centre	May 2014	NIMT/region
		Strategy and procedure on disseminating learning from incident management	May 2014	NIMT/region
	Begin delivering on learning	Initial data capture and analysis	July/Aug 2014	NIMT
		First NIMT learning publication	Oct 2014	NIMT
		First NIMT learning event	Oct 2014	NIMT

9.0 Revision and audit

To facilitate regular review and audit of the policy, all training and education on the HSE Safety Incident Management Policy (2014) will include a requirement to provide any feedback on the policy for the attention of the National Quality and Patient Safety Division to inform future revisions.

The Quality and Patient Safety Division will undertake audits of compliance with the HSE Safety Incident Management Policy (2014) through specific audit requests to the HSE Director of Quality and Patient Audit Services.

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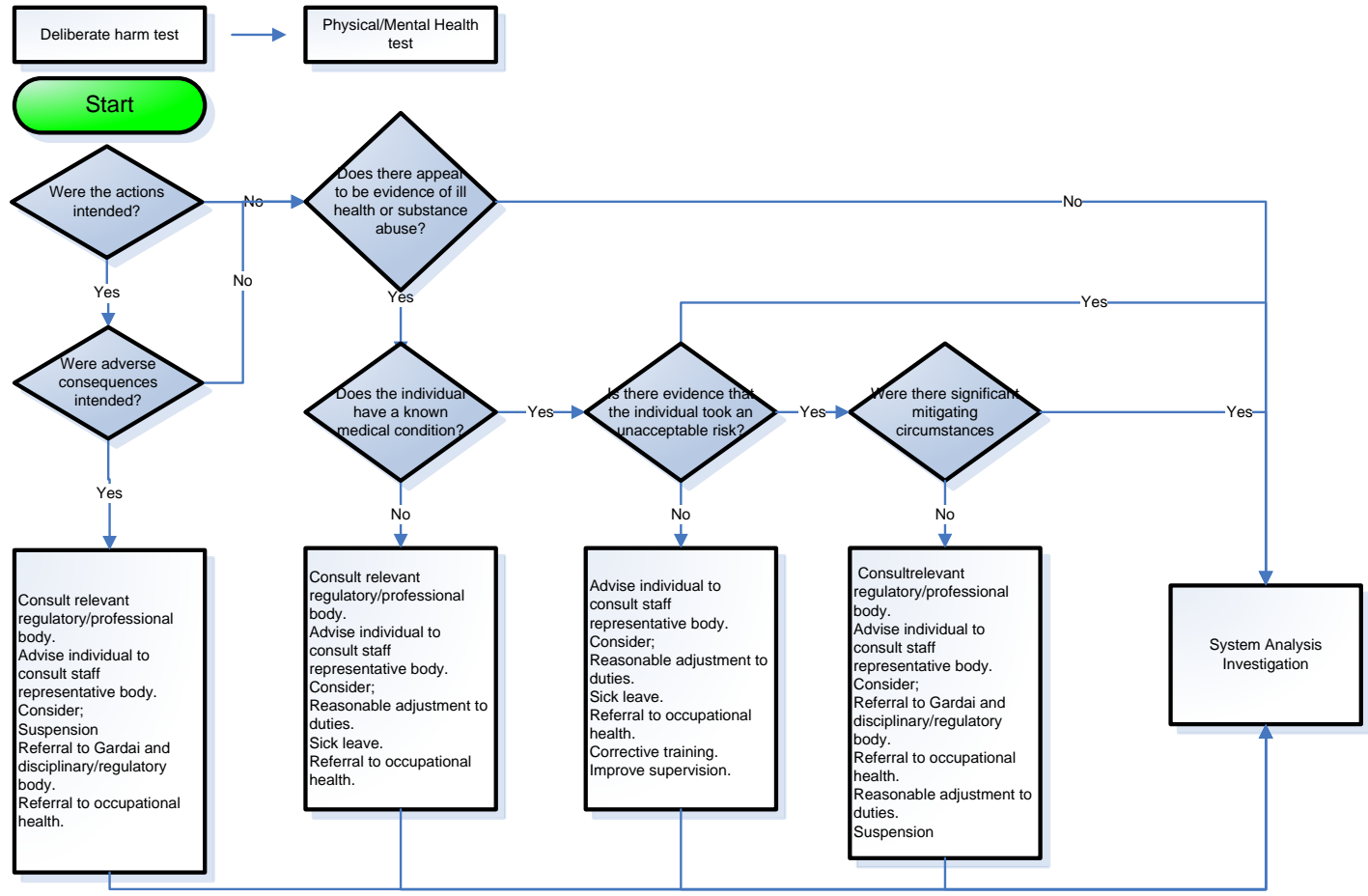
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Appendix 1: Impact Table (Clinical and Non-Clinical Incidents)

	Negligible	Minor	Moderate	Major	Extreme
Injury	Adverse event leading to minor injury not requiring first aid. No impaired Psychosocial functioning	Minor injury or illness, first aid treatment required <3 days absence < 3 days extended hospital stay Impaired psychosocial functioning greater than 3 days less than one month	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence 3-8 Days extended hospital Stay Impaired psychosocial functioning greater than one month less than six months	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling Impaired psychosocial functioning greater than six months	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public Permanent psychosocial functioning incapacity.
Service User Experience	Reduced quality of service user experience related to inadequate provision of information	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being to talked to & treated as an equal; or not being treated with honesty, dignity & respect - readily resolvable	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week)	Unsatisfactory service user experience related to poor treatment resulting in long term effects	Totally unsatisfactory service user outcome resulting in long term effects, or extremely poor experience of care provision
Compliance with Standards (Statutory, Clinical, Professional & Management)	Minor non compliance with internal standards. Small number of minor issues requiring improvement	Single failure to meet internal standards or follow protocol. Minor recommendations which can be easily addressed by local management	Repeated failure to meet internal standards or follow protocols. Important recommendations that can be addressed with an appropriate management action plan.	Repeated failure to meet external standards. Failure to meet national norms and standards / Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/or lack of adherence to regulations.	Gross failure to meet external standards Repeated failure to meet national norms and standards / regulations. Severely critical report with possible major reputational or financial implications.
Objectives/Projects	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over – run.	Inability to meet project objectives. Reputation of the organisation seriously damaged.
Business Continuity	Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.	Short term disruption to service with minor impact on service user care.	Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service	Sustained loss of service which has serious impact on delivery of service user care or service resulting in major contingency plans being involved	Permanent loss of core service or facility. Disruption to facility leading to significant 'knock on' effect
Adverse publicity/ Reputation	Rumours, no media coverage. No public concerns voiced. Little effect on staff morale. No review/investigation necessary.	Local media coverage – short term. Some public concern. Minor effect on staff morale / public attitudes. Internal review necessary.	Local media – adverse publicity. Significant effect on staff morale & public perception of the organisation. Public calls (at local level) for specific remedial actions. Comprehensive review/investigation necessary.	National media/ adverse publicity, less than 3 days. News stories & features in national papers. Local media – long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in Dail. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation	National/International media/ adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined. HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach/Minister forced to comment or intervene. Questions in the Dail. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.
Financial Loss (per local Contact)	<€1k	€1k – €10k	€10k – €100k	€100k – €1m	>€1m
Environment	Nuisance Release.	On site release contained by organisation.	On site release contained by organisation.	Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc.)	Toxic release affecting off-site with detrimental effect requiring outside assistance.

Appendix 2a: Incident Decision Tree & Guidance Notes

Incident Decision Tree*   Note: Work through the tree fully from left to right and separately for each individual

Deliberate harm test → Physical/Mental Health test

Start

Were the actions intended?

— No → Does there appear to be evidence of ill health or substance abuse? — No →

Yes ↓

No ↓

Yes ↓

Were adverse consequences intended?

Does the individual have a known medical condition? — Yes → Is there evidence that the individual took an unacceptable risk? — Yes → Were there significant mitigating circumstances — Yes →

Yes ↓

No ↓

No ↓

No ↓

Consult relevant regulatory/professional body.
Advise individual to consult staff representative body.
Consider;
Suspension
Referral to Gardai and disciplinary/regulatory body.
Referral to occupational health.

Consult relevant regulatory/professional body.
Advise individual to consult staff representative body.
Consider;
Reasonable adjustment to duties.
Sick leave.
Referral to occupational health.

Advise individual to consult staff representative body.
Consider;
Reasonable adjustment to duties.
Sick leave.
Referral to occupational health.
Corrective training.
Improve supervision.

Consult relevant regulatory/professional body.
Advise individual to consult staff representative body.
Consider;
Referral to Gardai and disciplinary/regulatory body.
Referral to occupational health.
Reasonable adjustment to duties.
Suspension

System Analysis Investigation

* Based on James Reason's culpability model
** HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2012)

Appendix 2B: Incident Decision Tree Guidance Notes

(Please use in conjunction with section 7.2.1 Identification of a Safety Incident within the HSE Safety Incident Management Policy, 2014).

System causes verses individual responsibility for an incident

It is essential that the facts (including contributory system factors) surrounding a safety incident are established and analysed in a fair, impartial and objective manner. This is especially true if management is considering precautionary suspension of an employee.

Managers should consider the overall performance of an individual within the context of an employees documented performance appraisals under the HSE Performance Management Framework (2012) and not limit their assessment of an individual based on one incident. The results of a systems analysis investigation may show that another individual coming from the same professional group, possessing comparable qualifications and experience may have behaved a similar way in similar circumstances, e.g. there may have been broader system deficiencies in training, supervision or policies, procedures or guidelines.

Employees may be referred to HSE disciplinary procedures in the following circumstances:
- Non-participation in the HSE safety investigation
- Where an individual deliberately concealed an incident
- Where an employee acted criminally, or in a deliberately malicious manner

How the Incident Decision Tree works with regard to the management of <u>Immediate Safety Concerns</u>

The Incident Decision Tree is based on a flowchart, and takes you through a series of structured questions about the individual's actions, motives and behaviour at the time of the incident. In the majority of cases following the completion of a systems analysis investigation of a safety incident a system failure may turn out to be the cause of the incident.

The Deliberate Harm Test

In the vast majority of safety incidents the individual had the service objectives at heart. There may be extremely rare occasions when the intent was to cause harm, physical, emotional, fraud etc. The Deliberate Harm Test asks questions to help identify or eliminate this possibility at the earliest possible stage and determine if it is appropriate to report the case to the Gardaí and / or the relevant regulatory/professional body.

The Physical/Mental Health Test

If intent to deliberately cause harm has been discounted, the Physical/Mental Health Test helps to identify whether an employee's ill health or substance abuse caused or contributed to the safety incident.

Systems Analysis Investigation of Incidents and Complaints
If physical and mental health issues have been discounted managers must arrange for a systems analysis investigation to be conducted as soon as possible to determine if there were mitigating circumstances, e.g. was it likely that another individual coming from the same professional group, possessing comparable qualifications and experience, working in a similar environment may have behaved a similar way in similar circumstances. A systems analysis investigation identifies broader system deficiencies in training, supervision or policies, procedures or guidelines specific to an incident. For guidance on conducting a systems analysis of investigation of incidents and complaints, please see "Guidelines for Systems Analysis Investigation of Incidents and Complaints" (HSE, 2012).

After you have worked through the questions

The individual's employee group may affect the processes you need to follow and although some processes vary from employee group to employee group. The HSE promotes comparable treatment for individuals of all professional backgrounds.

Once you have made your selection, you will be led to the appropriate outcome box.

Outcome box.

The outcome box will suggest a range of actions to consider taking in the circumstances.

Note: Discussion is underway with HSE HR and professional/regulatory and training bodies regarding clinical proficiency/competency and professionalism. Once decisions have been made regarding this, this will be added to the documents supporting the HSE Safety Incident Management Policy (2014).

Appendix 3: Employee Assistance Programme (EAP)

Employee Assistance Programme (EAP) provides a confidential counselling support and referral service for all staff with personal or work related difficulties.

Advice and guidance is available to managers in dealing with staff welfare issues. The Employee Assistance Programme also provides formal structured support to groups of staff who have experienced stress reactions as a result of a critical incident in the work place.

The Employee Assistance Programme is a confidential service, and is free of charge to all HSE employees. The service is provided by trained and experienced counsellors who are professionally qualified and bound by the codes of conduct of the professional bodies to which they belong and is available to all employees for support with both personal and work-related concerns.

A wide range of issues are dealt with by EAP, including:
- Stress at work
- Difficult relationships in work (including bullying)
- Traumatic events (e.g. assault, suicide)
- Addictions
- Personal issues outside of work (e.g. bereavement, relationships)

The service provides, on a confidential basis:
- Professional assessment
- Personal support
- Counselling
- Referral onwards to other professional resources where appropriate
- Trauma support

Managers may contact the service for advice and guidance on issues relating to Employee Wellbeing. The service participates in the provision of lectures/training as required, in areas where the Employee Assistance Professional has relevant expertise, e.g. stress management, post trauma support, team building and management training.

The service provides feedback to the organisation regarding broad issues which may enhance Employee Wellbeing and the organisation's effectiveness.

If you wish to access the service for information or an appointment, you can contact your local HSE EAP Managers. The Occupational Health Service can also refer clients with their consent.

For additional information on supporting staff, please see the HSE/State Claims agency guidance document "Supporting Staff following an Adverse Event: The Assist Me Model" (2013) is available to view at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/booklet SuppStaffadverseevent.pdf

Contact Details of your local HSE Employee Assistance Programme are available at: http://hsenet.hse.ie/Human_Resources/staffhealthsafety/supporteap

Appendix 4: Guidelines for Consideration When Communicating with a Patient or Family in relation to an incident

Source: Institute for Healthcare Improvement (2011) "Respectful Management of Serious Clinical Adverse Events"

The following elements are offered for organisations to consider to achieve the goal of never losing sight of the patient and family when responding to a patient safety incident:

- Focus first and foremost on the patient's immediate clinical needs while assembling the facts.
- When communicating about the harm that the patient experienced, state what happened, why it happened, and what's being done to prevent it from happening again.
- Appoint an appropriate (determined case by case) staff member as a patient and family point of contact that is available 24 hours a day, 7 days a week.
- As soon as the organisation has new information about the event, inform the patient and family.
- For incidents resulting in death and serious harm and rated as major or extreme on the Impact Table arrange for consent to access healthcare records to be sought as soon as possible and provide assurance that this will enable the organisation to investigate fully as soon as possible.
- Engage with those members of the patient's extended care team who may not be directly engaged already, including the patient's primary care physician.
- Never let the patient and family encounter excuses, a dead end, emotional distance, or inappropriate body language.
- Ensure that all communications are culturally and linguistically appropriate.
- **Address any concerns the patient and family have as soon as possible.**

Appendix 5: List of Serious Reportable Events (SRE)

1	Surgical Events
A	Surgery performed on the wrong body part by a healthcare provider.
B	Surgery performed on the wrong patient by a healthcare provider.
C	Wrong surgical procedure performed on patient by a healthcare provider.
D	Unintended retention of a foreign object in a patient after surgery or other procedure performed by a healthcare provider.
E	Intra – operative or immediately post operative death of a normal health patient with no known medical problems after surgery or other procedure performed by a healthcare provider.
2	**Product or Device events**
A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by a healthcare provider.
B	Patient death or serious disability associated with the use or function of a device in patient care provided by the healthcare provider in which the device is used or functions other than as intended or anticipated.
C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by a healthcare provider but excluding death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
3	**Patient protection Events**
A	Child or other dependent person discharged to the wrong person by a healthcare provider
B	Patient death or serious disability associated with patient absconding from a healthcare facility whilst under medical supervision but excluding where the patient advises the healthcare provider that he or she is leaving against medical advice.
C	Patient suicide, or attempted suicide, resulting in serious injury or disability while receiving health services from a healthcare provider.
4	**Care Management Events**
A	Patient death or serious disability associated with a medication error by the healthcare provider but excluding reasonable differences in clinical judgement involving drug selection and dose.
B	Wrong route administration of chemotherapy by a health care provider.
C	Intravenous administration of mis–selected concentrated potassium chloride by a healthcare provider.
D	Patient death or serious disability associated with a haemolytic reaction due to the administration of incompatible blood or blood products by a healthcare provider.
E	Maternal death or serious disability, occurring within 42 days post delivery, associated with labour or delivery in any pregnancy while being cared for by a healthcare provider.
F	Death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy.
G	Patient death or serious disability associated with hypoglycaemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
H	Death or serious disability (kernicterus) associated with failure by a healthcare provider to identify and treat hyperbilirubinermia in infants within the first 28 days of life.
I	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility but excluding progression from stage 2 to stage 3, if stage 2 was recognised upon admission.
J	Patient death or serious disability due to spinal manipulative therapy by a healthcare provider
K	Artificial Insemination with the wrong donor sperm or wrong egg by a healthcare provider.

5	Environmental events
A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility but excluding events involving planned treatment such as electric countershock or elective cardioversion.
B	An incident in which a line designated for oxygen or other gas to be delivered to a patient while being cared for by a healthcare provider contains the wrong gas or is contaminated by toxic substances.
C	Patient death or serious disability associated with a burn incurred within a healthcare facility.
D	Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
E	Patient death or serious disability associated with the use of physical restraints or bedrails while being cared for in a healthcare facility.
6	Criminal Events
A	Any instance of care ordered by someone impersonating a healthcare professional.
B	Abduction of a patient of any age while being cared for in a healthcare facility.
C	Sexual assault on a patient within or on the grounds of a healthcare facility.
D	Death or serious harm of a patient or other person resulting from a physical assault that occurs within or on the grounds of a healthcare facility.
E	Patient death or serious disability associated with physical assault while being cared for in a health care facility.

Please see the Quality and Patient Safety Section of the HSE Website for any updates in relation to Serious Reportable Events (SRE).

Appendix 6: Requirements of an Incident Reporting Form

All incidents must be recorded using an Incident Report Form. It is recommended that a single form be used to record all incidents. This simplifies the reporting process for employees and ensures that Incident reporting systems across all areas are comparable for purposes of analysis, trending and tracking the impact of interventions/control measures on the quality and safety of the services for service users and employees.

Incident Report Forms must be available in all wards/departments/sections/areas. All incidents including near miss incidents must be reported so that action can be taken to investigate and to address contributory factors to prevent future harm arising from them and where this is not possible to reduce the risk of harm as far as is reasonably practicable.

Detailed guidance in relation to completion of the Incident Report Form must be made available to all employees in conjunction with the report forms.

Guidance should include:

- All incidents should be reported verbally to the line manager as soon as possible. Outside of normal working hours, where the line manager is not on duty, the incident should be reported to the relevant senior manager on duty.
- The Incident Report Form should be completed by the employee/employees involved in or is witness to the incident. Where an employee is not in a position to do so (they are injured as a result of the event physically or psychologically) then the Incident Report Form should be completed by the next appropriate person. This will be another employee who has witnessed the incident or the Line Manager.
- If an incident has not been observed by an employee then this must be made clear i.e. *The service user/visitor states…..*
- Commence the documentation of the incident as soon as possible after occurrence and ensure that all subsequent actions are recorded in chronological order.
- Document the immediate actions taken to manage the incident.
- Where there is more than one person affected by the incident, supplementary forms can be attached to provide details of the injured parties involved. Incident Report Forms must be capable of capturing data to indicate that multiple individuals have been affected, and Incident Report Forms of multiple individuals involved in a single incident must be easily linkable.
- Details on the form must be accurate and factual and must not contain opinions or apportion blame.
- Use black indelible ink and write legibly in block capitals.
- Recognisable signatures are essential. Print your name adjacent to your signature.
- Abbreviations should not be used unless they are specific abbreviations that have been approved by the organisation.
- Correction fluid must not be used. Correct any errors by putting a line through them and attaching your signature. An incorrect entry must not be made difficult to read.
- Ensure additions to existing entries are individually dated, timed and signed.
- The 24 hour clock must be used when documenting events.
- If the incident has been notified to an external body the details of this must be noted on the Incident Report Form.

Minimum Data set required on an Incident Report Form

Indicate whether:

- Incident, near miss or complaint.
- Clinical or non-clinical incident.

Personal Details of the Affected Person

- Surname, first name, gender, date of birth, address and contact number, Medical Record or PPS number (*This information must be treated as sensitive, private and confidential and managed in a*

manner that complies with data protection requirements; and good practice for the management of confidential and sensitive information.)

- State whether service user, visitor or employee.

Report details

- Date the incident was reported.
- Who reported the incident; name, job title, staff category and contact details.
- Who the incident was reported to; name and job title.

Impact Details

- Record impact of incident, i.e. negligible, minor, moderate, major and extreme (as per HSE Impact Assessment Tool).

Event details

- Specify where (e.g. Service Area, Location & Department) the incident took place, the date and time (use 24 hr clock) the incident took place.
- Give a brief description of what happened and the immediate management. Only record facts, do not record opinions.
- Indicate what type of injury was sustained for both clinical and non-clinical incidents.
- Specify the speciality and sub-speciality involved.
- For clinical incidents specify the general incident type and specific incident type.
- For non-clinical incidents specify the primary cause of injury and specific cause of injury.

Observers of Incident/Other Persons Involved

- Record any details of any individuals who observed the incident or other persons involved in the incident.
- Record their name, address and contact details.

Follow Up

- What immediate attention did the person(s) affected receive?
- Have they been informed of the incident?
- Have their relatives been informed?
- If person involved is a patient/service user has their consultant/GP or other healthcare professional been notified?

Department Manager

- Department manager should document actions taken or planned to prevent/mitigate recurrence.
- Did the incident result in absence from work and the period of time. If absent for more than 3 days has a HSA, IR1 form been completed and forwarded to the Health and Safety Authority?
- Specify any further action that was taken. This must be signed and dated by the Manager.

External Agencies

- Many external agencies require the HSE to report incidents to them e.g. Mental Health Commission, Indemnifiers, Health and Safety Authority. These requirements must be included in the minimum data set of information required. (See Appendix 3 on reporting to external agencies, regulators and professional regulators.)

Database Input

- If the information on the form is being entered on a database then this should be indicated.
- Name and signature of the person who entered the information on the database and the date of input must be recorded.
- Document on the Incident Report Form the STARSWeb /NAEMS number and any number generated by any other incident information management system (e.g. IIMS) in use for the management of incidents.

Appendix 7: Agencies to whom the Health Service reports*

*The 'responsible person' may vary across services. It is important that local processes are developed for reporting to agencies to whom the health service reports.

Name of External Body	What to report	How to Report	Responsible Person
Clinical Indemnity Scheme. (CIS)	Any incident directly related to service user treatment or care which, did or could have resulted in an adverse outcome. (e.g. treatment error, medical equipment failure, etc.)	Via STARSWeb	Local Risk Manager in whose area the incident occurs.
Coroners office	There are a total of 32 instances in which deaths must be reported to the coroner.	The list of instances can be found on www.coroners.ie choose the deaths which must be reported tab. Contact is made directly to the relevant local Coroner. This is usually done by phone, and anote of the time and date of contact should be made in the patient's clinical notes.	The Registered Medical Practitioners in whose care the patient is will report the majority of cases but reports can be received from other clinical staff.
Data Protection Commissioner via Consumer Affairs	All information/data breaches	All information/data breaches must be reported to the Consumer Affairs or ICT Division immediately. Members of staff and their line manager must complete a Data Breach Incident Report and forward (via fax or email a scanned copy) this to their local Consumer Affairs Officer for breaches involving manual (paper based) information/data or the their local ICT call centre/helpdesk for breaches involving electronic data. The Data Protection Breach Management Policy is available to view at: http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Data_Protection_Breach_Management_Policy.pdf	
Health & Safety Authority	Incidents in respect of Accidents to employees "where any Accident occurs at a place of work as a result of which any person carrying out work at that place of work dies or is prevented from performing his normal work for more than three consecutive days , excluding the day of the Accident but including all other days which would have been working days".	IR1 form. On-line reporting available at www.hsa.ie	Senior Site/Service Manager
Health & Safety Authority	Incidents in respect of Accidents to non-employees "where any person who is not at ork but who as a result of an Accident related to a place of work or a work activity dies or suffers any injury or condition as a result of an Accident which results in the person requiring treatment from a registered medical practitioner or treatment in a hospital as an in-patient or out-patient".	IR1 form. On -line reporting available at www.hsa.ie	Senior Site/Service manager
Health & Safety Authority	Incidents in respect of events which are categorised as dangerous occurrences are outlined in the Health & Safety Authority IR 3 form.	IR3 form. On-line reporting available at www.hse.ie.	Senior/Site service manager
Health	Residential Services for Older Persons	Forms are available on line at http://www.hiqa.ie. (choose the social services	Registered provider

Name of External Body	What to report	How to Report	Responsible Person
Information and Quality Authority (HIQA)	Those in charge of a designated centre must ensure that the Authority is formally notified when certain events or incidents take place – these are known as "notifiable events". Provider information in relation to events that are notifiable is available on line at http//:www.hiqa.ie/media/pdfs/notifiable_Events.pdf	inspectorate tab on the home page and click on information for Nursing Home Providers at the top of this page)	in whose facility the incident occurred.
Health Information and Quality Authority (HIQA)	<u>Children in Childcare.</u> The following deaths should be reported to the SSI within 48 hours of the death occurring ; • All deaths of children in care. • All deaths of children known to the HSE child protection system. • All death of young adults (up to 21yrs of age) who were in the care of the HSE in the period immediately prior to their 18th birthday or were in receipt of aftercare services under section 45 of the Child Care Act 1991. • When a case of suspected or confirmed abuse involves the death of a child known to the HSE or a HSE funded service. SSI should also be informed within 48 hours of serious incidents relating to the following children • Children in care • Children known to the HSE child protection system • When a case of suspected or confirmed abuse involves a serious incident to a child known to the HSE or a HSE funded service. A serious incident is defined as; "A death or a potentially life-threatening injury or serious and permanent impairment of health, wellbeing or development."	Form is available in HIQA Guidance for the HSE for the Review of Serious Incidents including Death of Children in Care.(for a copy of this guidance, on the HIQA homepage choose the Social Services Inspectorate tab and click on social care guidance at the top of the page.)	AM to submit the Child Death/SI form to the RDO. The RDO to forward to the National C& FSS.
Health Protection Surveillance Centre	Diseases that are identified by the HPSC as reportable.	Notifications are made to the relevant Medical Officer for Health using the relevant form. (these are downloadable from HPSC website http://www.ndsc.ie/hpsc/ & choosing the notifiable diseases tab on the home page)	Medical Practitioners and Clinical Directors of Laboratories.
HSE 's Indemnifiers	All non – clinical incidents deemed as having potential to result in a claim e.g. Public/Employee liability.	Via relevant indemnifiers reporting procedure.	Local Risk Manager in whose area the incident occurs.
Irish Medicines Board	• **Any malfunction of or deterioration in the characteristics and performance of a device,** as well as inaccuracies in the instruction leaflet, which might lead to or might have led to the death of a service user or to deterioration in health. • Any technical or medical reason due to a risk of serious injury or death resulting in the recall of a device from the market by a manufacturer or the issue of an advisory notice.	Form available on line at http://www.imb.ie (choose the safety and quality tab on the home page to access the form)	Line Manager in whose area the incident occurred.
Irish Medicines Board	**Incidents involving adverse drug reactions.** Health care professionals (defined as doctors, dentists, pharmacists, and nurses) are requested to report all suspected adverse reactions to IMB. Of particular importance to report are; • All suspected adverse reactions to the new medicinal	Form available online at http://www.imb.ie (choose the safety and quality tab on the home page to access the form.)	Reporting clinician in association with the Chief Pharmacist.

Name of External Body	What to report	How to Report	Responsible Person
	products. • Serious suspected reactions to established medicines. • Any suspected increase in the frequency of minor reactions. • Any suspected teratogenic effects. • Any suspected reactions associated with the use of vaccines or medicines used in pregnancy.		
Irish Medicines Board	**Serious adverse reactions (SARs) and serious adverse events (SAEs) related to the collection and transfusion / application of blood and tissues and cells.**	Form available online at http://www.imb.ie (choose the safety and quality tab on the home page to access the form.)	Line Manager in whose area the incident occurred.
Maternal Death Enquiry (MDE)	1. Maternal Deaths* which are defined as: "Deaths of women while pregnant or within 42 days of the end of the pregnancy* from any cause related to or aggravated by the pregnancy of its management, but not from accidental or incidental causes" 2. Direct Maternal Deaths which are defined as: "Deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above". 3. Indirect Maternal Deaths which are defined as: "Deaths resulting from previous existing disease, or disease that developed during pregnancy and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy". 4. Coincidental (Fortuitous) Maternal Deaths which are defined as: "Deaths from unrelated causes which happen to occur in pregnancy or the puerperium". 5. Late Maternal Deaths which are defined as: "Deaths occurring between 42 days and 1 year after abortion, miscarriage or delivery that are the result of Direct or Indirect maternal causes". * This term includes delivery, ectopic pregnancy, miscarriage or termination of pregnancy.	Maternal Death Notification form available from: Maternal Death Enquiry office: 5th floor, Cork University Maternity Hospital Wilton, Cork Tel: 021 4205042 E-mail: mdeireland@ucc.ie	Identified MDE hospital co-ordinators.
Medical Exposure Radiation Unit	Radiation incidents to patients. Incidents above a threshold level where the wrong patient received a radiation dose or received a dose much greater than intended. Contact Medical Exposure Radiation Unit for guidance.	Contact the Medical Exposure Radiation Unit at 045,882570 email Rachel.brennan1@hse.ie	Radiologist in charge / Radiation Protection Advisor / Radiation Safety Committee
Mental Health Commission	Death occurring in approved centres within 48 hours of the death. All sudden, unexplained deaths of persons attending a day hospital, day centre or currently living in a 24 hour staffed community residence within 7 days of the death. Incident summary reports are required on a 6 monthly basis.	Via the MHC's Death and Notification Form (DNF) or approved centres may use their own existing notification form where such a form contains all the fields specified in the MHC's DNF. Day Hospitals, Day Centres and 24 hour staffed Community Residences to report using MHC's DNF. The DNF is available in the code of Practice for MHS's Notification on Deaths and Incident Reporting. (this is available on the MHS website by choosing from the pick list accessed from the Mental Health Legislation, 2001 tab on the home page.)	Resident Medical Superintendent/Director/Chief Psychiatrist.
National Perinatal Epidemiology Centre (NPEC)	1. Still births which are defined as: "Baby delivered without signs of life from 24 weeks gestation or with a birth weight ≥500g". 2. Early Neonatal Deaths which are defined as: "Death of a live born baby occurring within 7 completed days of birth".* 3. Late Neonatal Deaths which are defined as "Death of a live born	Perinatal Death Notification Form available on the NPEC website: http://www.ucc.ie/en/npec/projects/	Identified NPEC hospital co-ordinator

Name of External Body	What to report	How to Report	Responsible Person
	baby occurring after the 7th day and within 28 completed days of birth".* *Live born refers to any baby showing signs of life at birth regardless of gestational age or weight		
National Haemovigilance Office	Incidents relating to severe adverse reactions and events relating to blood component administration.	Notifiable to the NHO as soon as possible using the Initial Report Form (IF) (this is available on the NHO webpage accessed through www.giveblood.ie clicking on clinical services tab and choosing Haemovigilance. The NHO also has a Rapid Alert Notification System to be used in rare circumstances to initiate a recall of blood components, or to prevent the issue of blood components from a donor which may remain in stock. In this case notification is initially made by phone, followed by the completion of an IF.	Transfusion Surveillance Officer (TSO)
Radiation Protection Institute of Ireland	Radiation incidents to staff or members of the public. • Any incident involving the unintended exposure of a person arising from a design flaw, incorrect calibration or malfunction of a licensed item. • Any incident arising from a diagnostic or therapeutic procedure in which a wrong patient* receives a dose exceeding the dose limits of a member of the public. • Any incident in which a foetus receives a dose in excess of 1 mSv as a consequence of the licensee either failing to establish or adhere to appropriate procedures in relation to the determination of possible pregnancy of a patient undergoing either a diagnostic or therapeutic procedure.	Contact the RPII, www.rpii.ie tel.01.2697766.	Radiologists in Charge, Radiation Safety Committee and/or relevant local processes.

Appendix 8: Safety Incident Management Communication / Escalation Form

HSE Safety Incident Management (SIM) Policy
Communication / Escalation Form
(Please ensure this form is as complete as possible & and refer to the Safety Incident Management Policy 2014 for guidance)

NAEMS (SCA) Reference	*(State Claims Agency)*
IIMS Reference Number	*(QPS)*
	(Other)

Date incident occurred:
D D M M Y Y Y Y

Date incident report form completed:
D D M M Y Y Y Y

Date incident inputted/reported on NAEMS (State Claims Agency) :
D D M M Y Y Y Y

Date incident inputted/reported on IIMS :
D D M M Y Y Y Y

The Form is Being Notified to the Next Level of Management to: *(see section 7.2 of SIM policy)*
Communicate ☐ **Escalate** ☐ **details of the management of the safety incident (with no transfer of responsibility for management)**

1. Impact assessment of incident according to the Impact Table *(see appendix 1 of SIM policy)*

Negligible ☐ Minor ☐ Moderate ☐ Major ☐ Extreme ☐ (please choose one)

2. Is this incident a Serious Reportable Event (SRE) No ☐ Yes ☐ *(if yes, see below & refer to appendix 5)*

If yes, please write event type (care management etc.)	
If yes, please write the event sub-category (A, B etc.)	

3. Briefly Describe the Safety Incident What (unintended / unnecessary) harm has occurred; include numbers of service users / staff involved?
(do _not_ include details that could identify a patient or person).

4. Location & Contact Details
Name of Service:	
Service location (Hospital Group/PCCC area):	
Section/Ward/Department/Service:	

5. Named Senior Accountable officer (or their delegate) with responsibility / accountability for managing this incident / service.
Name / Title	
Email:	
Landline	
Mobile	0 8

6. Is there a requirement to report this Safety Incident to any external regulators / agencies / insurers (other than State Claims Agency)?
☐ No ☐ Yes (If yes, *see below*) *(see Appendix 7 HSE Safety Incident Management Policy)*

If *Yes*: **Name** regulator(s)/agency (ies) reported / notified to:	**Date(s)** of notification to regulator(s)/agency(ies)
1	D D M M Y Y Y Y
2	D D M M Y Y Y Y
3	D D M M Y Y Y Y

7. Has a complaint been made under Your Service Your Say? No ☐ Yes ☐ (If yes, complete contact details below).

The complaints officer handing this complaint is [**insert name / title**]	The complaints officer Phone Number is [**insert phone number**]

8. Has this incident been assessed to determine the type of investigation required ☐ No ☐ Yes

Outcome of Assessment	No	Yes	
Decision to conduct a systems analysis investigation in line with HSE Guidance.			*If yes, please fill in section 9.*
Decision to analyse data for aggregate analysis			*If yes, aggregate should be reviewed by local quality &safety committee (or an equivalent)*
No further investigation required past assessment. (Assessment identified that no key causal factors contributed to the adverse outcome).			*If yes, this decision should be reviewed by local quality &safety committee (or an equivalent)*
Decision to conduct a look-back review			*If yes, decision communicated to the relevant national director.*
Incident Management team established			*If yes, please fill in section X*

9. Systems Analysis Investigation Details	No	Yes	
Have investigator(s) been assigned?			*If yes, complete names below.*
Have terms of reference (TOR) been prepared in line with HSE Guidance			*If yes, please attach TOR.*
Were the investigator(s) directly involved in this incident or the management of the service / department *(please note HSE guidance specifies that investigators should **not** be)*			*If yes, please refer to HSE guidance.*

Name(s) of the Investigators	**Date(s)** investigator(s) assigned
1	D D M M Y Y Y Y
2	D D M M Y Y Y Y

Anticipated completion date of the systems analysis investigation	D D M M Y Y Y Y

10. Safety Incident Management Team Details
Name / Title of Chairperson of the Safety Incident Management Team
Email:
Landline
Mobile   0   8
Date Established

11. Is this incident being escalated to the next level of management for additional support? ☐ No ☐ Yes *(if yes, see below)*

	Please chose from the following (you may chose more than one)	Yes	No
1	The incident involves more than one division / care group / hospital group.		
2	The local area has issues with capacity or capability to manage and investigate this incident.		
3	The HSE investigator(s) deem that external input to the investigation is required.		
4	The assessment of this incident has indicated that a look-back review is required.		
5	There is a significant risk to public confidence in services.		
6	An external investigation is being conducted (e.g. by Mental Health Commission, HIQA, HSA, Gardaí.		
7	The incident is a serious reportable event		
8	Other, please write.		

12 . Has a draft media statement / communications plan been prepared with press office / communications manager? ☐ Yes ☐ No

13 Describe any service user / carer / public / staff other key holder needs & arrangements put in place to address these

14. Describe any public or staff confidence issues identified and actions taken including communication undertaken and planned / support provided / further support planned.

15 Record of Communication / Escalation	
	Form completed by *(name, title, date)*	Form escalated / communicated to *(name, title, date)*
1		
2		
3		

Appendix 9: Guidance / Example of a Safety Incident Assessment that may in Result in a Decision that No Further Investigation is Required

Guidance

Local managers may consider and decide that there is no need to investigate further because they believe that the harm resulted from a known complication.[1]. It is important to understand that with advances in care some complications will, over time, become preventable and, therefore, classified as safety incidents requiring further investigation. Without conducting an incident investigation, opportunities for learning and improvement may be lost. These incidents must at least be the subject of aggregate review.

Similarly, a decision may be taken that there is no need to investigate further because technological limitations meant that it was not possible to predict/prevent harm. However, advances with technology may mean that conditions that were formerly unpredictable and unpreventable may become predictable and preventable in the future. Furthermore, it is important to analyse safety incidents where technological limitations arise as this may inform the need for targeted emphasis on specific aspects of healthcare technology development in the interest of healthcare safety.

Example

A family complained to the local hospital in relation to their 71 year old father who passed away due to lung cancer in January 2011. The gentleman had been referred to the local hospital by his General Practitioner complaining of nagging right lower rib pain and right upper quadrant abdominal pain in August 2010. The patient was subsequently seen at the Hospital on a number of occasions during August and September 2010 and underwent a number of examinations and diagnostic tests while under the care of the medical and surgical teams at the hospital, all which appeared normal. A CT scan of the thorax, abdomen and pelvis was scheduled for October 2010.

The gentleman moved to live with his daughter in another area in October 2010 when a CT scan at another hospital at that time identified that the patient had lung cancer. The patient died in January 2011.

The Clinical Director and the Hospital Manager at the local hospital arranged for a review of the patient's chart and radiological films. This review found that appropriate blood tests were ordered on all occasions and all were within normal limits. There were no indicators that the patient had cancer at that time. A retrospective review of the radiological films and the MR images undertaken in August and September 2010 did identify a small (approximately 2 x 2 cm) nodule in the lower lobe of the patient's right lung which had not been identified in the x-ray's and images in August and September 2010. This nodule was tucked in below the hilum and against the spine.

The Clinical Director and the Hospital Manager discussed the case with the clinicians involved in the gentleman's care, and with the clinical director of Radiology Services. They deliberated on the literature which indicates that lesions located in this anatomical position in the chest are very difficult to identify. They reviewed articles on the subject in peer-reviewed journals, which indicated that failure to identify lung cancer on chest x ray has become one of the most frequent causes of missed diagnosis in radiology; 65% of the lung cancers arising in the hilum were missed as part of a screening programme; and that the most overlooked lung cancers on chest x rays are solitary pulmonary nodules.

They requested an urgent local discrepancy meeting which considered this case on the same day in the context of the Faculty of Radiology Guidelines for the Implementation of a National Quality Assurance Programme in Radiology (Faculty of Radiology 2010[2]). Using guidelines in relation to RADPEER Scoring language, this was considered a level 2 discrepancy (i.e. the

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[1] Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton, AB: Canadian Patient Safety Institute; 2012. http://www.patientsafetyinstitute.ca/English/Pages/default.aspx
[2] Faculty of Radiology 2010, Guidelines for the Implementation of a National Quality Assurance Programme in Radiology

diagnosis would not ordinarily be expected to be made based on these films and images) and, therefore, this was an understandable miss. While it was possible to see the nodule now with the benefit of hindsight and with the information that the patient had lung cancer, all agreed that this was a lesion that was difficult to see prospectively when there was no other clinical information indicating that the patient had lung cancer.

The Clinical Director and Hospital Manager documented their decision not to investigate further and the reasoning/factors influencing this decision, and conveyed this to the quality and safety executive committee as well as to the complainants to whom they offered their sympathy. They also offered to meet the complainants in relation to this matter.

The Clinical Director and the Hospital Manager also ensured that the Incident Report Form was completed (as per local arrangements) for aggregate review and reporting both locally and nationally. Specifically in this case, the Clinical Director and the Hospital Manager were aware that this information would be helpful for local, regional and national analysis in relation to the limitations of the radiological technology to produce films and images that would make lesions more easily identifiable.

Appendix 10: Local Safety Incident Management Team Sample Membership, Terms of Reference, and Meeting Agenda

A: Proposed Membership of a Safety Incident Management Team and Roles of Members

- **Senior Accountable Officer e.g. ISA Manager/Voluntary Hospital CEO/Area Manager:** Chairs Incident Management Team. Ensures that all members of the Incident Management Team fulfil their role to achieve the terms or reference of the Incident Management Team

- **Communications Manager:** Deals with communications issues including communications with those affected, staff, service users, the public and the media if required. Links with national communications as necessary

- **Relevant senior clinician (Clinical/Executive Clinical Director) in the case of a clinical incident and relevant senior manager in the case of a non-clinical incident:** Manages clinical issues as they arise during the course of managing and investigating the incident. Supports staff involved with management and investigating the incident

- **Healthcare risk manager/advisor, clinical risk manager/advisor, quality and safety/coordinator/advisor:** Advises on relevant quality and patient safety policy/process

- **Finance Manager (If it is a finance related incident or if there are finance implications):** Deals with finance related issues

- **Human Resources Manager (If it is a HR related incident or if there are HR implications):** Deals with HR issues

- **Complaints Officer/Consumer Affairs Manager/Area Officer:** May lead the systems analysis investigation if the incident came through the complaints process and if so submits incident investigation report to the chair of the incident management team or may liaise with the risk advisor/manager who leads the investigation. Incidents identified through a complaint under Part 9, Health Act 2004 should be managed in accordance with HSE Incident Management Guidelines (2012).

- **Service User Representative**

- **Any specialists relevant to the incident.**

NOTE: Members of the investigation team should not be members of the Safety Incident Management Team. A trained/experienced HSE Investigator leads the systems analysis investigation/look-back review and submits an incident investigation report to the chair of the Safety Incident Management Team. In a non-member role, the Investigation Chairperson should update the Incident Management Team and/or Investigation Commissioner on the progress of the investigation and any emerging safety issues. The Safety Incident Management Team address safety issues and obstacles that arise in relation to completing the investigation within an appropriate timeframe.

B: Sample Safety Incident Management Team Terms of Reference

The terms of reference of the Safety Incident Management Team is to:

1. Oversee the management of the incident including caring for those harmed, ensuring that the source of harm is addressed so the risk of further harm arising is eliminated or reduced as far as is reasonably practicable and contingency plans for service continuity if required

2. Ensure an appropriate investigation of the incident is conducted as per HSE Incident Management Policies and Guidelines

3. Facilitate sourcing of external independent experts to the investigation team if the Investigators deem this necessary as per HSE Incident Management Guidelines.

4. Managing communications with services users, staff, the public, and external agencies as required linking with the National Communications representatives on the National Incident Management Team if necessary

5. Inform the recommendations arising out of investigations

6. Arrange for expeditious implementation of recommendations of investigations as part of the organisations risk management work, including entering, managing and communicating "Contributory Factors" on the risk register.

C: Sample Safety Incident Management Team Agenda

1. Managing immediate safety issues
2. Caring for those harmed/affected including service users, the public and staff
3. Contingency planning for service continuity
4. Update on incident investigation from incident Investigators
5. Communications to those harmed affected, services users, the public, staff, the public and external agencies (if necessary)

Management and communication of identified "Contributory Factors" including entering, communicating and monitoring on the risk register and Implementation of recommendations arising from investigation, as per HSE Guidance on Populating a Risk Register (2011).

Appendix 11A: Patient Information Leaflet (Consent Form)

Why am I receiving this leaflet?

- The HSE always tries to provide a high standard of care and attention, however, sometimes we do not meet our goals or the expectations of our patients and service users.
- When we receive a report of an incident it is important for us to investigate it fully. It is our opportunity to find out what may have gone wrong and what we can do to improve the safety of our services.

Who will have access to my records?

- Investigators need to access all of the records that would help them to get a full picture of what happened and need your consent to access the confidential records for this purpose.
- Fair procedures may require for representatives of employees that are involved in a safety incident investigation to have access to the relevant healthcare records.
- Anyone who would have access to confidential healthcare records would be obliged to treat them confidentially

What will the investigators produce?

- The investigators will draft and finalise a safety incident investigation report.
- You will not be identified in any investigation report that is prepared. Furthermore, you will have an opportunity to see, and to give input into the parts of the draft investigation report that relate to your recollections / experience of the incident before the report is finalised.

HS E

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Information leaflet

Consent Form for Access to Healthcare Records for the Purposes of a Safety Incident Investigation

Tús Áite do
Shábháilteacht Othar
Patient Safety First

![HSE logo]

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Consent Form for Patients / Service Users

Please read the statements below and tick the relevant box. When you have answered each question, please sign and date the form and return it to the address below.

	Yes	No
I confirm that I have read and understand the leaflet called "Information leaflet for Patients and Services Users on Consent to Access Confidential Records for the purposes of a safety incident investigation".	O	O
Access to Confidential Records for the Investigation I grant permission for my personal patient confidential information / patient confidential information of my next of kin to be accessed for the purpose of investigating my incident / complaint.	Yes O	No O

Signature: _____   Date: | D | D | M | M | Y | Y |

Please PRINT your name: _____   Phone: | | | | | | | | | | |

Postal Address _____

_____

If you would like further information please contact

Appendix 12:

Example of an Aggregate Review of Incidents

A hospital, a number of care of the elderly sites in the same area, and a community care area are aware from their incident reporting system that there is a very high rate of fall incidents reported. An evidence based falls prevention strategy had been in place for two years, so they decide to undertake a review of the status of the implementation of the strategy along with an aggregate review of incidents of falls involving the service users in the hospital, the care of the elderly sites and in the community care area.

This aggregate review of falls was overseen by the local quality and safety executive committees from the hospital, the care of the elderly sites, and the community care area which included experienced systems analysis investigators, and other individual's with expertise in the areas of falls and falls prevention such as occupational therapists and physiotherapists. There was also a researcher on the overseeing committee.

The overseeing committee identified that 57 service user falls had occurred within the hospital, the care of the elderly sites and the related community care area within the past year. The committee identified that systems analysis investigations were conducted in relation to 24 of these incidents of falls. These investigations considered the status of the implementation of falls preventions strategy and whether issues with implementing this strategy had contributed to patient falls. The committee arranged for these completed investigations to be reviewed on an aggregate basis. The committee also reviewed the incident report forms for the incidents that were not investigated.

The above were considered along with the current literature in relation to best practice in falls prevention, and the data in relation to the implementation of the falls prevention strategy. The following were the findings of the aggregate review:

- Problems with flooring such as spillages; trip hazards were the most commonly identified contributory factor occurring in 79% of cases.

- The next most common contributory factor was the lack of supervision/support for the patient. i.e. the patient was mobilising outside of their ability as they did not have a family member or a care worker to assist them with some tasks. This occurred in 61% of cases.

- In 45% of cases, the fact that the patient made a decision to mobilise when conditions were risky (i.e. during snowy/icy conditions etc) was a contributory Factor.

- In 41% of cases, prescription medicines contributed to patients being unsteady, loosing their balance and falling

The committee decided to re-launch the falls prevention strategy prioritising actions in relation to the following issues to address the most common contributory factors identified on the aggregate review:

- Immediate identification and removal of all slip/trip hazards, and monitoring to ensure slip/trip hazards are not re-introduced

- Ensure optimum support and supervision for patients so the risk of them mobilising outside of their capability is reduced as far as is reasonably practicable

- Activate interventions for behavioural change in patients in relation to risk taking, multitasking and rushing

- Review patients' prescription medication to determine if this can be altered to enhance mobility

The data produced from this aggregate review was shared with the office of the National Director of Operations, and the national falls prevention strategy team so that they might use it to inform the national falls prevention strategy.

The implementation of the recommendations to address the contributory factors/hazards identified by this aggregate review was managed and monitored on the local risk registers.

Appendix 13: Published Examples of Systems Analysis Investigations of Incidents that Result in Moderate, Major or Extreme Harm

Published examples of systems analysis investigations of incidents that resulted in death and serious harm include the following:

- Investigation of an incident related to the transfer of a young patient to Kings College Hospital London for transplantation surgery (HSE 2011) [3]
- Investigation of NIMT Case 50278 (HSE 2013) [4]
- Investigation of the Middleton Ambulance On Call Investigation Report (HSE 2013)[5]

Appendix 14: Published Examples of Look Back Reviews

The North East Radiology Review (HSE 2008)[6] and the Miscarriage Misdiagnosis Review (HSE 2011)[7] are examples of look back reviews.

The miscarriage misdiagnosis review is an example of a case where the look back review was conducted in the first instance to identify the number of miscarriage misdiagnoses that occurred. 24 cases of miscarriage misdiagnosis were identified. Each of these cases was the subject of a systems analysis incident investigation at the hospital where the woman had been cared for. The findings of these individual systems analysis investigations of the individual incidents of miscarriage misdiagnosis were the subject of aggregate analysis and review and the methods and findings of this analysis are outlined in the National Miscarriage Misdiagnosis Review Report which was published by the HSE in 2011.

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[3] Investigation of an Incident related to the transfer of a young patient to Kings College Hospital London for transplantation surgery, HSE 2011.
http://www.hse.ie/eng/services/Publications/corporate/patient%20transfer%20report.pdf
[4] Final Report of the Investigation of Incident 50278, from the time of the patient's self referral to hospital on the 21st of October 2012, to the patient's death on the 28th of October, 2012.
http://www.hse.ie/eng/services/news/nimtreport50278.pdf
[5] Final Report of the Investigation of Incident 50379, from receipt of the 112/999 call at 14:00 hrs on the 6th of May 2013 to the patient's arrival at the Emergency Department.
http://www.hse.ie/portal/eng/services/Publications/corporate/midletonreport.pdf
[6] Review of Chest X-Rays and CT Scans Reported by a Locum Consultant Radiologist at Louth Meath Hospitals from August 2006 to August 2007. http://www.hse.ie/eng/services/Publications/services/Hospitals/NERadiologyReview.pdf
[7] Miscarriage Misdiagnosis Review, HSE 2011.
http://www.hse.ie/eng/services/Publications/services/Hospitals/miscarriagemisdiagnosis.pdf

Appendix 15: Framework of Contributory Factors & Fishbone Diagram

Framework of Contributory Factors Table

Factor Types	Contributory Factor (i.e. potential causes related to each key causal factor and incidental finding identified in Step 3)
Individual affected/harmed	Condition (complexity & seriousness) Language and communication Personality and social factors Psychological, existing mental health condition, stress
Task and Technology Factors	Task design and clarity of structure Availability and use of protocols, policies, standards Policies etc. relevant, unambiguous, correct and realistic Availability and accuracy of test results Decision-making aids
Individual (Staff) Factors	Knowledge and skills Competence – education, training, supervision Physical, psychological and mental health illness.
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (leadership, congruence, consistency etc.)
Work Environmental Factors	Staffing levels and skills mix Workload and shift patterns Administrative and managerial support Environment - Physical and cognitive. Design, availability and maintenance of equipment
Organisational & Management Factors	Organisational structure Financial resources and constraints Policy, standards and goals Quality & Safety culture and priorities
Institutional Context Factors	Economic and regulatory context National health service executive Links with external organisations

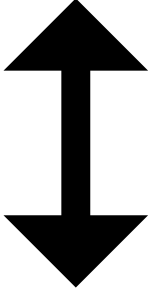**Framework of Contributory Factors Fishbone diagram**
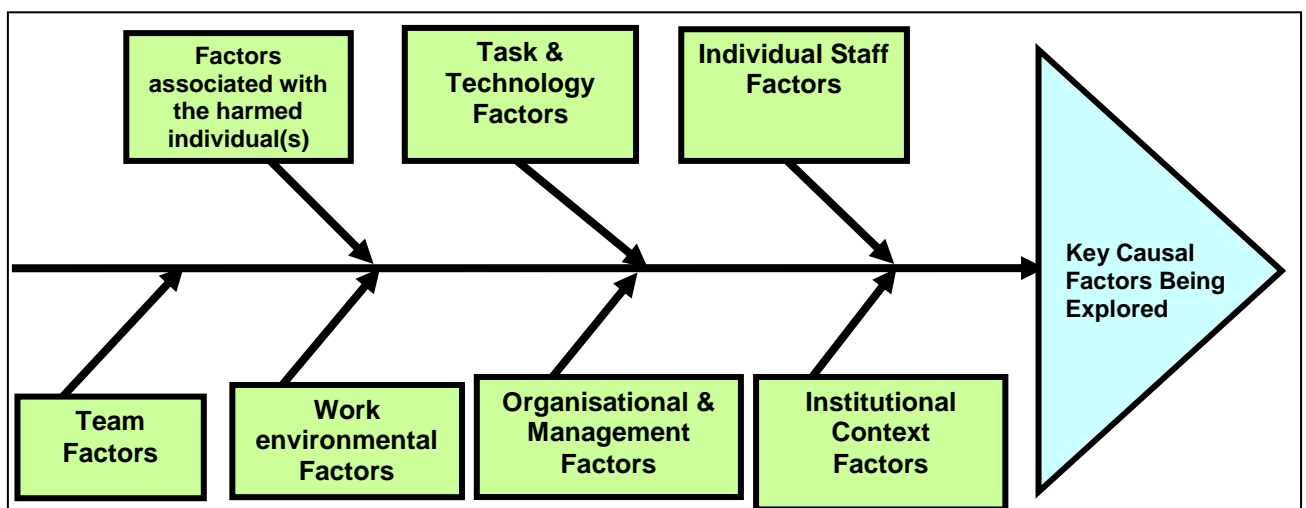
Appendix 16: Hierarchy of Recommended Control Actions

The recommendations made to address hazards identified are known as control measures. Certain types of controls are preferable to others. For example, it is usually preferable to eliminate the hazard wherever possible rather than to train staff to avoid or manage the hazard. Indeed, any controls that rely on people are inherently potentially weak as people are fallible and make errors.

The table below outlines a hierarchy of hazard controls, which can help ensure that the most effective hazard control measures / recommendations are made. If the strongest control is not feasible or practical, only then should a weaker control be considered. Work Practice Controls should only be considered after all the previous measures have been considered and found to be impractical or impossible.

Strength of control	Category of control	Comments/Examples
Strongest control ⬍ **Weakest control**	Elimination	The work process or task is redesigned so as to remove the Hazard/contributory Factor. However, the alternative method should not lead to a less acceptable or less effective process e.g. stop providing service; discontinue a particular procedure; discontinue use of a particular product or service, e.g. stop using a particular type of equipment.
	Substitution	Replacing the material or process with a less harmful one. Re-engineer a process to reduce potential for 'human error'.
	Engineering controls	Installing or using additional equipment. Introduce 'hard' engineering controls, e.g. installation of handling devices for moving and handling people and objects, e.g. Re-engineer equipment so that it is impossible to make errors.
	Administrative procedures	Ensure that administrative policies, procedures and guidelines are in place. Ensure staff are appropriately trained in these.Monitor compliance with policies, procedures and guidance through audit.
	Work Practice Controls	This is the last control measure to be considered. Change the behaviour of staff, e.g. make staff wear personal protective equipment, etc.

Appendix 17: Guidelines for External Independent Experts nominated to HSE Safety Investigations

Information for external agencies **that nominate independent experts to give input to HSE safety incident investigations**

- Arrange nomination of an individual with suitable expertise to address the specific issues arising from the HSE safety incident investigation as per HSE Safety Incident Management Policies and Guidelines.
- Nominees should generally be from within the HSE. If the nominee is a HSE employee, his/her contribution to the HSE safety investigation will be undertaken as part of his or her normal employment and he/she will be indemnified to do this work as per the a HSE's professional indemnity policy.
- If the nominee is not an HSE employee, the Investigation Commissioner will arrange for the nominee to be paid for his/her contribution to the investigation in accordance with the HSE's codes of good practice for making such payments. The Investigation Commissioner will arrange for the nominee to be indemnified to do this work as per the HSE's Special Review Board's policy.

Guidelines for external independent experts **nominated to HSE safety incident investigations**

- Confirm they have expertise in the area where the specific issues arise.
- Confirm they have no conflict of interest in relation to the matters being investigated. **Note:** Generally cases will be anonymised to protect the privacy and confidentiality of service users and employees; to ensure that there is no bias arising out of the external expert having knowledge of the staff implicated in the incident; and that no conflict of interest arises. Nominees will not be informed as to the location of the incident that is being investigated, nor in relation to the identity of the employees and the service users involved, where possible/appropriate.
- Treat all information received and communicated for the purpose of the investigation as sensitive, private and confidential and in a manner that complies with data protection legislation and the rights of all to privacy, confidentiality, due process, natural and constitutional justice, and the HSE Guidelines for systems analysis investigation of incidents and complaints (2012).
- Ensure the investigation is conducted and that the report is written in a manner that is impartial, objective, fair, evidence based and devoid of bias including outcome bias and hindsight.
- Ensure the issues the external expert addresses are put in the context of the most up to date literature and best practice.
- Provide a draft report (if required) of the findings to the HSE Investigator for factual accuracy check and to contribute to the HSE investigation. Such draft reports should:
  - Not contain personal identifiers of either patients or employees and should rather be anonymised in terms of patients and employees involved. i.e. The patient or Patient X; Consultant Radiologist A; Nurse B; Midwife C etc.
  - Be marked: *"Strictly private and confidential. This document outlines the opinions of the author following a paper based review of the relevant documentation. This document is intended to contribute to the HSE investigation of* Include incident investigation Reference Number*). It should only be read in the context of the agreed final report of the HSE investigation of* Include incident investigation Reference Number. *This document is not for copying or for onward circulation except in accordance with the terms of reference for this investigation."*
  - Answer the specific questions/issues raised by the HSE Investigators
  - If issues are identified with care/services delivered, the report should include a summary of the current evidence in the scientific literature in relation to the rate and documented causes of these issues. The HSE Investigators can then identify contributory factors and make relevant recommendations to address these.

- o Make reference to the issue of hindsight bias and outcome bias including references to the fact that the nominee was aware of the outcome for the patient/individual(s) harmed; that there was a complaint made/incident reported in relation to the case (if this is the case)

- Review the final draft report of the HSE investigation, which will include and be informed by the expert's input and / or report, to confirm whether his/her input / report is reflected accurately in the final draft HSE investigation report.

- Receive and consider feedback, through the HSE Investigator, from those involved in the investigation about the factual accuracy of the draft report. The external expert must document reasons for accepting or rejecting amendments suggested by those involved. The HSE policy is that all feedback will be accepted, and all suggested amendments will be made, unless making these amendments detracts from the factual accuracy of the report or detracts from the ability of the report to attain the objectives of the investigation set out in the terms of reference.

Appendix 18: Template Letter to external independent nominees who provide expertise to a HSE investigation of an incident

<div align="right">

[insert Commissioners Name]

[Insert Commissioners Address]

</div>

[insert title, name]

[insert address]

[insert date]

Dear [write title & name]

I would like to sincerely thank you for agreeing to provide expert input to the members of the HSE investigation of [insert incident reference number] and I welcome your contribution to this important safety process which seeks to:

- Find out the facts about what happened for all those affected and involved

- To identify causes so that these can be addressed to prevent future harm arising from them in as far as is reasonably practicable

Our intention is that your input will provide answers to specific questions posed by the draft HSE safety investigation and inform the development of the draft(s) and final HSE investigation report. There are a number of documents attached to this letter that outline established HSE processes that staff follow to produce high quality investigation reports to address any safety issues identified.

Terms of Reference

Please find attached copy of the agreed terms of reference for [Include incident ref no]. It is important that at all times the investigation team and you in your role as external expert contributing to a HSE safety investigation work to the agreed terms of reference and the systems analysis methodology. Further explanation of the terms key causal factors, contributory factors and recommendations to address contributory factors used within the terms of reference can be found in the attached document HSE *"Guideline for Systems Analysis Investigation of Incidents and Complaints"* (2012) which is discussed further below.

[Clinical] Support Request Form

Attached you will also find a completed request form that the investigation team have prepared. This outlines the specific assistance that the investigation team would be grateful if you could provide. It is the intention of the investigation team that your input will answer the specific questions/issues raised by their draft investigation report and/or the healthcare record. If any issues are identified with the care or services provided the investigation team will require that a summary of the current evidence in the scientific literature be included that outlines the rate of such issues (in Ireland and elsewhere) and the documented causes of such issues. The draft and final HSE investigation report prepared by the investigation team will be informed by your input and/or any report prepared by you in this regard.

HSE Guidelines for Systems Analysis Investigations (2012)

Please refer to the attached 2012 *"Guideline for Systems Analysis Investigation of Incidents and Complaints"* (QPSD-GL-52-1.1).

All HSE investigations of safety incidents and complaints follow the attached guidelines. I would like to draw your particular attention to section **6.7.3.1** which outlines the fair procedures process which all investigations must follow. All draft HSE investigation reports will be subject to factual accuracy checking and this is also a condition of the indemnity insurances in place and assurances to staff. This guideline also provides guidance on the use of up to date literature to support the findings of any investigation and the requirement for draft reports to be anonymised and to refer to any associated hindsight bias or outcome bias that may occur when an individual is aware of the outcome for the patient/individual(s) harmed when reviewing a healthcare record or draft report.

Contact Details for Investigation Chairperson

The investigation team is being chaired by [insert investigation chairpersons name] Mr/Ms [insert investigation chairpersons name]   will be your main point of contact on the investigation team. Mr/Ms [insert investigation chairpersons name] contact details are:

[Insert contact details for the investigation chairperson]

Confidentiality Agreement

To comply with data protection requirements to access and hold the relevant documentation please sign the enclosed confidentiality agreement and send by post to Mr/Ms XXX (at the postal address above). On receipt of this form, Mr/Ms [insert investigation chairpersons name] will then arrange for you to have access to all relevant documentation including medical records and a copy of the [name the documents/information] in order for you to commence your work, including a first meeting with the investigation chairperson and investigation team members. Please refer to the attached confidentiality agreement.

Professional Fees for non-HSE employees

As outlined in the [clinical] support request form all costs for this investigation will be overseen, submitted to and signed off by [Insert contact details for the person who will be responsible for overseeing the costs of the external nominee i.e. the budget holder or their nominee]. [The agreed fee rate will be XXX per day/hour]. When you have had time to review the documentation received and assessed the level of input required I would appreciate if you could prepare an estimate of your anticipated involvement in terms of anticipated days/hours. I appreciate that this may be subject to change should there be unforeseen circumstances that might alter the level of input required by you during this process. In any case I would be very grateful to receive an initial estimate of your anticipated fees. If for any reason during this process you become aware that your fees are likely to be greater than anticipated I require that you would inform me of this in writing. Should this work exceed the initial estimate I withhold the right to revisit the per diem/hourly rate for any outstanding work or propose a capped fee rate in consultation with you.

When preparing payments consideration will be given to HSE Financial Guidelines with regard to tax compliance.

Professional Indemnity Insurance

As outlined in the [Clinical] Support Request Form my office has arranged professional indemnity insurance to cover your participation in the HSE investigation. Please see attached certificate of insurance which is linked to the HSE review boards policy that has been set up to provide cover for external nominations to HSE investigations such as this.

HSE investigations must always be carried out in a manner that ensures the rights of all involved to privacy, confidentiality, due process and natural and constitutional justice.

Any required legal advice to ensure that the above processes have been complied with will be arranged though the investigation chairperson.

Notification of Conflict of Interest

If following receipt of the confidential details of this investigation you should become aware of any conflict of interest that has the potential to be viewed as introducing a bias to your contribution to this investigation please notify me in writing at your earliest convenience.

When the investigation report for [insert incident number] is finalised the investigation team will issue their report to me in my role as Investigation Commissioner.

Notification of any Immediate Safety Concerns

In addition, it is essential that should immediate safety concerns arise during the course of the investigation, the details of these safety concerns should be conveyed to me as soon as possible through the investigation chairperson.

If you would like to arrange to receive training in systems analysis investigation methods prior to commencing this investigation, please contact this office.

Once again I would like to sincerely thank you for your contribution to this safety incident investigation process.

Yours sincerely,

_____

[insert name of the commissioner of this investigation/senior accountable officer]

CC: Mr/Ms XXX Chairperson Investigation Team Incident Number