Systems Analysis Investigations

HSE Guidelines for the Systems Analysis Investigation of Incidents

Part 1: Quick Reference Guide

Part 2: Guidelines

Revision 3
August 2016
**Document Control and Approval Details**

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<td>HSE Leadership Team</td>
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<td></td>
<td>Mr. Patrick Lynch, National Director for Quality Assurance and Verification</td>
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<td>August 2019</td>
<td>QAV National Incident Management and Learning Team</td>
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**Note:** The term “Incidents” in this guideline also includes incidents that have been identified through service user reported complaints.
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Part 1: Systems Analysis Investigation of Incidents

Quick Reference Guide

(To be read in conjunction with the HSE Guidelines for Systems Analysis Investigations)
Systems Analysis Investigation of Incidents: Quick Reference Guide
(To be read in conjunction with the HSE Guidelines for Systems Analysis Investigations)

1. Introduction

Every year health service workers have millions of interactions with patients and service users. These interventions are often complex, delivered in high-pressure environments and involve multiple professionals working within multidisciplinary teams. Excellent care and outcomes are usually the result, but modern health care also carries significant risks. Adverse events happen and patient harm can and does occur. In many cases this harm could have been prevented. The consequences of these events for patients, service users, families, staff and organisations are so significant, that they warrant the mounting of a comprehensive response. It is the policy of the HSE that all safety incidents are identified, reported and investigated.

2. Safety Incident Management

Good safety incident management means being prepared in advance to effectively respond to a safety incident once it occurs. The HSE Safety Incident Management Policy describes the requirements for how we respond to serious safety incidents.

The responsibilities of the Safety Incident Management Team (SIMT) include:

1. Remembering that your first responsibility is to support the patient or service user and their families and to ensure the safety of other patients or service users by conducting a risk assessment to identify any immediate actions that may be required.
2. The need for visible leadership in the aftermath of the incident, ensuring an effective and sustained management response. This includes the establishment of a Safety Incident Management Team.
3. The statutory requirement to report all serious adverse events including to the State Claims Agency.
4. Ensuring that all staff affected by the incident are supported.
5. Getting an understanding of what happened and why? This means that following the management of immediate safety concerns, the Safety Incident Management Team must make an informed assessment of the incident to determine the type of investigation required.
6. Learning the lessons from what went wrong is at the heart of preventing future incidents. Identify what is wrong and take positive steps to put it right.

3. Investigations

Investigations are required to identify how and why safety incidents happen. Systems Analysis is a well recognised way of investigating safety incidents that has been adopted by the HSE as the approved approach to safety investigations. Analysis is used to identify areas for change and to develop recommendations which deliver safer care for our patients and service users.

The investigation involves the collection of data from the written and electronic records, individual interviews with those involved in delivering the care or service where the incident occurred and
analysis of this data to establish the chronology of events that led up to the incident. It identifies the Key Causal Factors that the Investigation Team consider had an effect on the eventual adverse outcome, the Contributory Factors, and recommended control actions to address these, for the purpose of preventing future harm arising, as far as is reasonably practicable.

The systems analysis model for investigations focuses on prevention, not blame or punishment. The focus of this type of analysis is on system-level vulnerabilities as opposed to individual performance.

4. Systems Analysis Investigation methodology

Healthcare services carry out incident investigations using systems analysis to find out:

- What happened.
- How it happened.
- Why it happened.
- What the organisation can learn from it and the changes the organisation should make to prevent it happening again.

The Purpose of an investigation is to:

- Improve safety and, by doing this, to improve the quality of services.
- Identify the factors in healthcare and social care systems that contributed to the incident.
- Identify problems or deficiencies.
- Ensure that lessons are learned.
- Act as early warning mechanisms.

The Purpose of an investigation is not to:

- Identify publicly the individuals or locations linked to the incident.
- Apportion blame or fault.
- Exonerate individuals or management.
- Make decisions about clinical negligence.
- Identify legal liability.

5. Steps in the Investigation Process

Step 1: Organise the investigation and gather the data

i. The Chair of the SIMT (the Investigation Commissioner) will with the SIMT commission the Investigation and establish the investigation team (typically 2 members)

ii. An investigation plan is put in place by the SIMT which will be monitored by the SIMT throughout the investigation.

iii. All relevant consent is obtained to access relevant records (e.g. healthcare records).

iv. The Investigation Team collect all pertinent information about the incident and will plan and conduct the required interviews.
Step 2: Determine the incident chronology
i. The Investigation Team will develop a detailed chronology that demonstrates what happened and when.

Step 3: Identify the Key Causal Factors and Incidental Findings
i. From the analysis of relevant data and careful consideration of the chronology, the Investigation Team will determine whether any Key Causal Factors can be identified. Key Causal Factors are ‘issues that arise in the process of delivering and managing health services, which the Investigation Team consider had an effect on the eventual harm’.
ii. Once the Key Causal Factors have been identified, the factors that contributed to each of the Key Causal Factors are identified. The Investigation Team may also highlight Incidental Findings. These are issues identified during the course of an investigation, which in the view of the Investigation Team did not impact on the outcome of care but point to a need for system improvement.

Step 4: Identify the Contributory Factors
i. The Contributory Factors Framework is used to analyse each identified Key Causal Factor and incidental findings (if appropriate) and to determine the Contributory Factors related to each of the Key Causal Factor(s). A Contributory Factor is defined as ‘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’.
ii. Contributory factors are identified under the following areas:
   o Individual affected or harmed.
   o Task and technology related factors.
   o Individual (Staff) factors.
   o Team factors.
   o Work environmental factors.
   o Organisational and management Factors.
   o Institutional context Factors.

Step 5: Make recommendations
i. Recommendations are developed to address each Contributory Factor. In the context of the Systems Analysis Investigations, recommendations are ‘reasonable courses of action based on the best available evidence. They should address the identified Contributory Factors, and should have the best potential for preventing or reducing the risk of future harm arising from these Factors’.
ii. If the Contributory Factor is one that might exist somewhere else across the health service, this should be reflected in the investigation report and the relevant recommendations should be communicated by the Investigation Commissioner to other relevant parts of the health service for learning and quality and safety improvement purposes.
Step 6: Write the investigation report and submit to the Investigation Commissioner

The purpose of the report is to convey the methods and findings of the investigation and the proposed risk reduction and quality and safety improvement recommendations. These should be detailed in a logical, concise and comprehensive manner. The report itself will describe;

- The Investigation Team and the Terms of Reference for the Investigation
- The sources of information that were used (e.g. interviews/review of healthcare records etc.)
- The sequence of events or chronology that led to the incident or complaint.
- Analysis of the Key Causal Factors identified.
- Recommendations to prevent these causes from resulting in an incident in the future

The recommendations contained in the Final Report of the investigation must inform the development of an action plan for how the organisation will manage the causes of harm identified by the investigation.

6. Fair Procedure and Natural Justice

The investigation process must at all times ensure that fair procedures are afforded to all parties involved in the investigation.

7. Publishing reports

Final investigation reports are anonymised in terms of location and identifiable persons. They should be provided to the patient or service user and his/her family member or advocate, unless they have expressed a wish not to receive the final report. They are also made available to relevant stakeholders who have responsibility for making decisions, allocating resources, planning for and implementing related recommendations.

HSE investigations would usually only be published widely by the Commissioner, such as on the internet, when this is specifically requested by the patient or service user and where they have explicitly granted permission for investigation report to be published.

8. Associated policies and guidelines

The HSE Safety Incident Management Policy and Open Disclosure: National Guidelines
Figure: Process Map of overall Systems Analysis Investigation Procedure

(Relevant sections of the HSE Guideline are referenced in the process map)

Terms of Reference of Systems Analysis Investigation Agreed

Investigation Team commences the 6 steps of Systems Analysis Investigation

Section 7.2
Step 1: Organise the investigation and gather the data

Section 7.3
Step 2: Complete the Incident Chronology

Section 7.4
Step 3: Identify Key Causal Factors (KCFs) and Incidental Findings

Can KCFs be identified?

Yes

The Investigation Team details the KCFs in the report. Several KCFs may be identified for the incident.

Step 4: Identify the Contributory Factors related to the KCFs and/or Incidental Findings

The Framework of Contributory Factors are used to identify the Contributory Factors related to each of the KCFs and/or Incidental Findings

Step 5: Make Recommendations that will Reduce Risk and Improve Quality and Safety

Section 7.6.3: If a contributory factor/hazard is one that may exist somewhere else on the HSE this should be reflected in the Investigation Report by the Investigation Team and the relevant recommendations are to be communicated to other relevant parts of the HSE by the Investigation Commissioner.

Step 6: Write the Investigation Report

Section 7.7

Submit the report to the Investigation Commissioner

Section 7.2.1: Commissioner seeks consent from the person(s) harmed to access their healthcare records

Section 7.2.2: All Information pertinent to the investigation is gathered

Section 7.2.3: A draft chronology of events is developed

Section 7.2.4: Interviews are planned with all relevant individuals

Section 7.2.5: Conduct Interviews

Section 7.2.6: Confirm the chronology of events

Section 7.2.7: Commence developing ideas re Key Causal Factors and Contributory Factors

Can Incidental Findings be identified?

Yes

No

Section 7.7.3.1: The Investigation Team implement principles of Fair Procedure. All who participated in the investigation process are provided with an opportunity to give comments and observations on the sections of the draft report that are relevant to their involvement and to check those sections for factual accuracy.

Section 7.7.3.2: Include an apology in the Investigation Report if Key Causal Factors were identified.

Section 7.7.3.4: The Investigation Team audit the Investigation Report

The Investigation Team clearly indicates in the report how they came to this conclusion. Any Incidental Findings are identified.
Part 2: HSE Guidelines for the Systems Analysis Investigation of Incidents
Management and Investigation of Incidents in the Health Service Executive

Framework Documents

The following is the framework of guiding documents that provides HSE staff with the required policies, procedures and guidelines to manage and investigate incidents within the HSE. The Guideline for Systems Analysis Investigation of Incidents must be used in conjunction with the other documents within this framework to ensure that there is proper and considered communication, management and investigation of incidents throughout the HSE.

The Guideline for Systems Analysis Investigation of Incidents falls within the context of the HSE Safety Incident Management Policy (2014, and subsequent revisions). The management and investigation of incidents within the HSE is undertaken in conjunction with the principles of Open Disclosure.

Please find all current versions of the above documents in the Quality Assurance and Verification section of the HSE website at http://hsenet.hse.ie/qav/
1.0 Policy Statement
This guideline must be read in the context of the HSE Safety Incident Management Policy (2014 and any subsequent revisions of the policy).

It is the policy of the Health Service Executive (HSE) that all safety incidents are identified, reported and investigated in accordance with the HSE Safety Incident Management Policy. Safety Incidents also include:
- Serious Reportable Events and those
- Incidents reported through the HSE complaints process.

Incidents will be disclosed in accordance with the guidance provided in the HSE / State Claims Agency (SCA) Open Disclosure: National Guidelines (2013 (and any other subsequent revisions)).

Following the management of immediate safety concerns, local managers must make an assessment of the safety incident to determine:
- If an investigation is required.
- The type of investigation required in line with the Safety Incident Management Policy i.e., systems analysis investigation, look back review or aggregate review. For Serious Incidents (defined in the glossary as incidents resulting in death or serious harm) the assessment must occur within 24 hours after the incident occurred.

Where the assessment identifies that an investigation is required, all Serious Incidents must be investigated using the systems analysis methodology and an investigation must be commissioned within 24 hours of a senior accountable officer being informed of an incident.

A systems analysis investigation is a methodical investigation of an incident which involves the collection of relevant data\(^1\), written and electronic records, individual interviews with those involved in delivering the care/service where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident, identifying the Key Causal Factors that the Investigation Team consider 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.

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\(^1\) Data to include relevant evidence based practice, standards and guidance.
2.0 Purpose

The purpose of this guideline is to:

- Provide a standardised methodology (six steps) for systems analysis investigations undertaken by the HSE\(^2\);
- Ensure that HSE investigations are valid, reliable and generalisable;
- Ensure that HSE investigations are carried out in line with the principles of fair procedure, natural justice and open disclosure.

This guideline has been designed to assist and guide investigators to conduct robust investigations using the systems analysis method and good investigation practice to:

- Ensure **appropriate Terms of Reference** are developed for the investigation;
- Use appropriate literature searches, literature appraisal processes, data collection methods and proper and comprehensive record keeping throughout the investigation process;
- Determine the **chronology** of events;
- Identify any **Key Causal Factors** that may exist;
- If any Key Causal Factors are identified, to analyse these to identify the **Contributory Factors** associated with each Key Causal Factor;
- Make **recommendations** to address the Contributory Factors in accordance with an agreed hierarchy of preferred control measures (as defined in section 7.6 of this guideline);
- Conduct fair investigations in a manner that is cognisant of fair procedures and data protection requirements;
- Conduct investigations in a manner that balances the need for the HSE to achieve its safety objectives with the need not to jeopardise the rights of individuals in concurrent or future internal investigations by the HSE and/or investigations by external agencies including the State Claims Agency, An Garda Síochána or the professional regulators etc.

**The Aims of Systems Analysis Investigations carried out using this guideline are:**

- To find out the full facts about what happened for all those affected by and involved in the incident.
- To identify causes so that these can be addressed to prevent future harm arising from them.

\(^2\) For the purposes of this guideline, the term “HSE” is intended to incorporate HSE and HSE funded services. Please see scope in section 3.0 of this guideline.
To improve the safety and quality of systems and processes involved in the delivery and management of health services

**It is not the aim of Systems Analysis Investigations to:**
- Identify individuals or locations linked to the incident;
- Apportion blame or fault;
- Be used to exonerate individuals or management;
- Decide negligence;
- Identify legal liability.

This guidance document replaces the HSE Guideline for Systems Analysis Investigation of Incidents (Revision 2, 2015).

**3.0 Scope**

This guideline applies to all employees of the HSE and all agencies funded wholly by the HSE including Section 38 and Section 39 service arrangements.

For the purposes of this guideline, the term "HSE" is intended to incorporate both HSE and HSE funded services.

This guideline applies to the investigation of incidents identified through the processes outlined in the HSE Safety Incident Management Policy as requiring a systems analysis investigation.
4.0 Legislation/ Other Related Policies

Legislation
The key legislation informing this document is as follows:
- Safety, Health and Welfare at Work Act 2005 and 2010
- The Health Acts 1947- 2014
- Freedom of Information (Amendment) Act 2014

Key Policies/ Procedures/Guidelines informing this document (current and any subsequent revisions of) are as follows:
- QPSD-D-060-1 HSE Safety Incident Management Policy (2014)
- Good Faith Reporting Policy (2011)
- Protected Disclosures of Information in the Workplace (2009)
- National Consent Policy (HSE 2013)
- HSE Health and Safety investigations including those related to the Health Safety and Welfare at Work Act 2005 and other Relevant Legislative requirements pertaining to the Health, Safety and Wellbeing of employees and those affected by work activities of the HSE
- Serious Reportable Events (SREs), HSE Implementation Guidance Document (Jan 2015)
- Quality and Safety Committee(s) Guidance and Sample Terms of Reference (2013)
- Developing and Populating a Risk Register Best Practice Guidance (2009)
- Policy for Preventing and Managing Critical Incident Stress (2012)
- Health Service Policy on Record Retention Periods (HSE, 2013)

Policies being replaced by this policy:
- This guidance document replaces the HSE Guideline for Systems Analysis Investigation of Incidents (Revision 2, 2015).
### 5.0 Glossary of Terms and Definitions

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<tr>
<th>Term</th>
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<tr>
<td>Accident</td>
<td>An unplanned, unexpected, and undesired event, usually with an adverse consequence.</td>
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<tr>
<td>Adverse Event</td>
<td>An incident which resulted in harm.</td>
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<tr>
<td>Contributory Factor</td>
<td>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.</td>
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<td>Generalisability of investigations</td>
<td>The generalisability of investigations refers to the ability of an investigation of a specific incident to identify problem causes (i.e. Contributory Factors) and solutions (i.e. Recommendations) that are applicable to the wider health system outside of the site where the incident occurred.</td>
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| 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.                                                                            |
| HIQA                              | Health Information and Quality Authority                                                                                                    |
| HPRA                              | Health Products Regulatory Authority                                                                                                       |
| Incident / Safety Incident        | An event or circumstance which could have, or did lead to unintended 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 complaints 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 |
| Incidental Findings               | Issues that arose in the process of delivering and managing health services identified during the course of an investigation which the Investigation Team consider did not impact on the outcomes but which serve to identify issues for system improvement e.g. issues relating to documentation, communication etc. |
| 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 / or Look-back Review Process Guidelines. |
| Investigation Team                | A team of investigators assigned by the commissioner of the investigation, to investigate an incident.                                         |
| Just Culture                      | A just culture seeks to balance the need to learn from mistakes and the need to take disciplinary action.                                        |
| Key Causal Factors                | Key Causal Factors are issues that arise in the process of delivering and managing health services which the Investigation Team considers had an effect on the eventual harm\(^3\). |

\(^3\) McCaughan *et al.*, (2013)
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<th><strong>Term</strong></th>
<th><strong>Definition</strong></th>
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<td>Look back</td>
<td>Review where a number of people may 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.</td>
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<td>MHC</td>
<td>Mental Health Commission</td>
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<tr>
<td>Near-miss</td>
<td>An incident which could have resulted in harm, but did not either by chance or timely intervention.</td>
</tr>
<tr>
<td>Objective</td>
<td>A specific result that a person or system aims to achieve within a time frame and with available resources.</td>
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<tr>
<td>Open Disclosure</td>
<td>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.</td>
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<tr>
<td>Person Harmed</td>
<td>In the context of this guideline, Person Harmed refers to the Patient / Service User / Staff Member who has been harmed by the incident and which is being investigated by the Systems Analysis Investigation. In the case of a minor, vulnerable person, of if the person harmed has died or is unable to partake in the investigation due to capacity issues etc., the term “Person Harmed” may also apply to parent(s) family/ next of kin. This will be determined on a case to case basis.</td>
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<tr>
<td>PPPG</td>
<td>Policies, Procedures, Protocols, Guidelines</td>
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<td>Reliable</td>
<td>Consistently good in quality or performance; able to be trusted. Giving the same result on successive trials.</td>
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<td>Risk</td>
<td>The probability of an adverse outcome/ harm.</td>
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<td>Risk Management Process</td>
<td>The systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating (i.e. reducing/ preventing/ mitigating), monitoring and reviewing risk.</td>
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<td>Safety Incident Management Team</td>
<td>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 (Serious Incidents). 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.</td>
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<td>Senior Accountable Officer</td>
<td>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’s Chief Executive Officer and in the Community Health Office it is the Chief Officer).</td>
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<td>Serious Harm</td>
<td>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. • The HSE Impact table provides a description of Serious Harm for both clinical and non-clinical incidents.</td>
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<tr>
<td>Serious Incident</td>
<td>An incident that results in death or serious harm.</td>
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<td>Serious Reportable Event (SRE)</td>
<td>One subset of all Serious Incidents is described by the HSE as Serious Reportable Events (SREs). These are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.</td>
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<td>Service User</td>
<td>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.</td>
</tr>
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<td>Term</td>
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<tr>
<td>Systems analysis investigation of an incident (previously known as</td>
<td>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), individual 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 the investigator(s) considered 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.</td>
</tr>
<tr>
<td>Valid</td>
<td>Having a sound basis in logic or fact; reasonable or cogent; Well-grounded or justifiable: being at once relevant and meaningful.</td>
</tr>
</tbody>
</table>
6.0 Responsibilities
This section provides a general overview of the responsibilities of key personnel in relation to the implementation of the Guideline for the Systems Analysis Investigation of Incidents. Specific roles and responsibilities in relation to implementation of the 6 steps of Systems Analysis Investigations are outlined in the relevant sections of this guideline.

6.1 Responsibilities of HSE and HSE Funded Agency Employees
It is the role of HSE and HSE funded agency employees to comply with this guideline and associated policies and guidelines; and to co-operate with and to participate in investigations conducted in accordance with this guideline and related policies and guidelines.

In particular, it is the responsibility of HSE and HSE funded agencies employees to:
- Comply with this guideline in relation to the systematic analysis of incidents;
- Ensure that prior to undertaking a systems analysis investigation they are trained in systems analysis methodology. Employees should receive training in relation to incident management and investigation appropriate to their role and responsibilities;
- Ensure that safety incidents are reported, managed and investigated in a timely manner;
- Participate and co-operate with investigations conducted in accordance with this guideline;
- Participate, as appropriate to their role, in the implementation of safety recommendations identified as a consequence of a safety investigation.

In circumstances where an HSE employee is not available/ unable to participate in an investigation due to specific reasons (e.g. sick leave, retirement etc.), efforts should be made to accommodate the employee to participate in the investigation at a date and time that is suitable to them. Occupational health advice should also be sought on whether the employee is fit to participate in the investigation. Such circumstances should be dealt with on a case by case basis.

In such circumstances efforts should be made to accommodate the staff member to participate in the investigation at a future date and time that is suitable to them. Such circumstances should Any matters identified that fall within the remit of the Disciplinary Procedures will be dealt with in accordance with those Procedures. All employees will be advised that where significant
shortcomings, failings or misconduct are identified, those matters may give rise to disciplinary proceedings pursuant to the applicable HSE policies and procedures.

6.2 Responsibilities of Managers

In relation to systems analysis investigations of incidents it is the responsibility of all Managers to:

- Ensure that they and their employees are aware of and comply with this guideline and related policies;
- Ensure that they and the employees who are assigned to undertake incident investigations are trained in order to effectively undertake systems analysis investigations of incidents;
- Facilitate incident management and systems analysis training for employees where necessary;
- Ensure that all incidents are reported to the appropriate personnel and agencies (internal and external);
- Put processes in place to ensure the timely reporting of incidents and the management and investigation of same in line with this guideline and the HSE Safety Incident Management Policy (2014);
- To have clear processes in place for the communication/escalation of incidents as appropriate in line with this guideline and the HSE Safety Incident Management Policy;
- Ensure that safety recommendations from safety incident investigations are implemented in a timely and effective manner;
- Monitor and conduct regular audits of compliance with this guideline and related policies, procedures and guidelines.

6.3 Responsibilities of Investigation Commissioner

In relation to systems analysis investigations of incidents, the Investigation Commissioner is the senior accountable officer who commissions the investigation. It is the responsibility of the Investigation Commissioner (in conjunction with the Safety Incident Management Team) to:

Upon Commissioning the Systems Analysis Investigations

- Commission an Investigation Team within two working days following notification of a serious incident;
- Agree the Terms of Reference for the systems analysis investigation in line with the requirements of this guideline;

It will be considered a disciplinary offence to intimidate or exert pressure on any person who may be involved in an investigation or to attempt to obstruct the investigation process in any way.
During the Investigation

- Identify a link person who is familiar with the investigation process that can meet and/or communicate with individuals who will be included in the investigation (i.e. persons harmed/families/staff etc) to communicate the investigation process, including the interview process, and address any concerns and queries individuals may have about the process;
- Arrange to provide care required to those affected (including to staff) without delay;
- Ensure immediate safety concerns are addressed;
- Ensure that contingency plans are developed as appropriate;
- Ensure that internal and external communications including communications with those affected and the media are managed appropriately and effectively;
- Ensure that the systems analysis investigation process is implemented in line with the requirements of this guideline;
- Ensure that costs associated with the investigation are managed efficiently;
- Ensure/facilitate considered and appropriate communications and linkages between the various investigation/regulatory bodies e.g. An Garda Síochána, the State Claims Agency, HIQA, MHC, HPRA, Medical Council, Nursing and Midwifery Board etc;
- Ensure that all relevant consent procedures are adhered to throughout the investigation process and that they are in line with the National Consent Policy (HSE, 2013);
- Ensure there are adequate processes in place to ensure that all required confidentiality requirements are adhered to throughout the investigation;

Post Investigation

- Ensure there are clear systems of governance in place to implement the recommendations of investigation reports.

6.4: Responsibilities of the Investigation Team

It is the responsibility of the Investigation Team to

- Ensure the developed Terms of Reference comply with the requirements set out in this guideline prior to commencing the investigation;
- Ensure that they are satisfied that they can achieve the Terms of Reference prior to commencing the investigation;
- Undertake the investigation in line with this guideline and the HSE Safety Incident Management Policy;
- Comply with all relevant principles in conducting an investigation i.e. confidentiality, data protection, fair procedure and natural justice;
- Notify the Investigation Commissioner of immediate safety concerns, issues arising with the investigation etc at the earliest opportunity so as to facilitate the immediate action by the Commissioner to address the issue(s) highlighted.;
- Be methodical and demonstrate compliance with the HSE Systems Analysis Investigation Process Checklist included as Appendix 1 to this guideline.
7.0 Guidelines for Systems Analysis Investigation of Incidents

7.1 The Context of the Systems Analysis Investigation Procedure.

7.1.1 Commencing the Systems Analysis Investigation

Upon commissioning of Investigation, the following tasks are carried out by the Investigation Commissioner in conjunction with the Safety Incident Management Team:

- Identify investigators to investigate the safety incident. Note: guidance re competencies to be considered in the identification of appropriate investigators is included in Appendix 15 of this guideline.
- Establish an Investigation Team\(^5\) within two working days of being notified of the serious incident as per the HSE Safety Incident Management Policy.
- Ensure there is clarity in relation to the roles of both the Safety Incident Management Team and the Investigation Team.
- Ensure there are clear reporting arrangements defined for purposes of communication between the Investigation Team and the Safety Incident Management Team.
- Provide clarity about communication linkages with person(s) harmed, families, staff etc at the various stages of the investigation process. The Safety Incident Management Team must identify a link person who is familiar with the investigation process that can meet and/or communicate with individuals who will be included in the investigation (i.e. person(s) harmed/families/staff etc) to communicate the investigation process, including the interview process, and address any concerns and queries individuals may have about the process. Communication and linking processes with the person(s) harmed/family need to be in line with the National guidelines on Open Disclosure: Communicating with service users and their families following adverse events in healthcare (HSE, 2013). It is not appropriate to assign these liaison responsibilities to any member of the Investigation Team.
- Ensure that all relevant consent procedures are adhered to throughout the investigation process and that they are in line with the National Consent Policy (HSE, 2013).

\(^5\) It is recommended that the investigation team should not consist of more than 2-3 people, one of which is assigned as the Lead Investigator. At least one member of the Investigation Team, ideally the Lead Investigator, should have completed Systems Analysis Investigation Training. In addition, it is important to ensure that members of the Investigation Team are not responsible for the service within which the incident occurred; that they had no prior involvement in any aspect of the issue being investigated and that they were not involved in the decision to undertake the systems analysis investigation.
• Ensure there are adequate processes in place to ensure that all required confidentiality requirements are adhered to throughout the investigation.

7.1.2 Terms of Reference

Before an investigation commences the Terms of Reference must be agreed by the Investigation Commissioner. The Terms of Reference must be developed in line with the requirements of this guideline. The template Terms of Reference attached as Appendix 2 should be used for all systems analysis investigations.

Prior to finalising the Terms of Reference they should be reviewed and confirmed as being appropriate and in line with this guideline by the Investigation Team. If the Investigation Team has any concerns with the Terms of Reference presented to them then this must be communicated to the Investigation Commissioner prior to commencing the investigation. Once the Terms of Reference have been agreed by the Investigation Commissioner they cannot be changed.

The Terms of Reference cover:

- Purpose of the investigation
- Scope of the investigation (i.e. the time frame that the investigation will cover)
- Investigation Team
- Investigation Method
- Process for management of external expert support if required
- Report
- Recommendations and Implementation
- Communication Strategy

Upon finalising the Terms of Reference the systems analysis investigation will commence. The systems analysis investigation will follow 6 key steps as outlined in figure 1.

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6 The prescriptive nature of the TOR is required to ensure that there is a standardisation of process in relation to the systems analysis investigation of incidents. However, there is always scope within investigations for the Investigation Team to consider issues raised by the family. These issues are generally raised when the Investigation Team meet with the patient/family in the first instance and the Investigation Team will always consider any issues raised within the scope of the Terms of Reference.

7 Note: Excerpt from Terms of Reference (Appendix 3):

- The “time frame” in question here is the “scope in time” that was reviewed in the investigation (e.g. from the time of admission to the time surgery commenced)
- The timeframe must be the shortest sufficient period of time to ensure the investigation purposes as outlined will be achieved.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent during the investigation process.
Please read this investigation process through at least once before embarking on the stages.

7.1.3 Time Frames for completion of the investigation

The Investigation Team must conduct the investigation and deliver the investigation report to the Investigation Commissioner in as timely a manner as possible. Delivering investigations in a timely manner means that those affected/harmed by incidents get accurate information about the incident, its causes and solutions as soon as possible and the organisation gets the opportunity to address the causes of safety problem as early as possible so that the factors that caused harm in the case of the specific incident under investigation can be identified and managed expeditiously so that they do not cause further harm as far as this is reasonably practicable.

The target for completion of an investigation report is 120 days, or less, from the date the incident occurred. If the Investigation Team becomes aware that the investigation report will not be completed within 120 day time frame, then this must be immediately communicated, with reasons for the delay and a projected new completion date to the Investigation Commissioner. The Investigation Commissioner will, in turn, ensure that this is immediately communicated to the person(s) harmed, staff involved in the incident and other relevant persons.
Figure 2: Systems Analysis Investigation Process: Key Time Frames

1. **Serious Incident occurs**
   - 24 hours

2. **Senior Accountable Officer (SAO) notified of incident within 24 hours**

3. **Within 24 hours of being notified of the incident, the SAO will ensure that an assessment is carried out to determine the level of investigation (if any) that is required**

   - 48 hours

   - **Systems Analysis Investigation Required?**
     - **Yes**
     - The SAO in conjunction with the Safety Incident Management Team will commission an investigation and establish an Investigation Team within 48 hours of SAO being notified of incident
     - **Terms of Reference of Systems Analysis Investigation Agreed**
     - Investigation Team commences the 6 steps of Systems Analysis Investigation
     - Systems Analysis Investigation completed within 120 days of the date the incident occurred

   - **No**
     - Refer to 7.2.3 of HSE Safety Incident Management Policy
7.1.4 Other Ongoing Investigations

In the interest of safety it is the policy of the HSE that safety incident investigations should always proceed where possible. However, the Investigation Commissioner may, where necessary, refer to other investigation/review processes in the course of, or after the completion of the safety incident investigation. In those circumstances, the Investigation Commissioner must ensure there is separation between the processes to ensure that each process remains robust and retains the integrity to achieve the intended outcome.

A safety incident investigation may also be carried out while external investigations are ongoing or anticipated relating to a safety incident. Examples of external investigations include: civil litigation and risk reviews managed by the State Claims Agency (SCA), inquests by Coroners and investigations by the Health and Safety Authority (HSA), Health Information and Quality Authority (HIQA), the Mental Health Commission (MHC), the Medical Council, the Nursing and Midwifery Board, and/or An Garda Siochána.

In cases of HSE investigations coinciding with investigations by the An Garda Siochána, the Commissioners of HSE investigations must link with An Garda Siochána prior to commencing the systems analysis investigation to inform them of the investigation and to ensure that the commencement of the Systems Analysis Investigation will not compromise/ adversely affect the investigation being undertaken by An Garda Siochána.

If a criminal investigation is ongoing, the Commissioners of HSE Investigations must ensure that nothing is done in carrying out the systems analysis investigation that may compromise/ prejudice the criminal investigation. On this basis there may be a requirement to defer the systems analysis investigation pending certain steps being taken by An Garda Siochána. Deferrals are only likely to occur in a minority of cases and decisions in relation to same will be made on a case by case basis by the Investigation Commissioner.

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

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*In cases where a Trust in Care Investigation has commenced, in general, the systems analysis investigation should only need to proceed if the preliminary assessment of the Trust in Care process has identified it is possible for the abuse to have occurred. It is possible to run a systems analysis investigation and a Trust in Care investigation concurrently.*
Note: In relation to investigations of incidents involving allegations of abuse/ incidents of a criminal nature, it is appropriate to apply this guideline only in relation to the investigation of issues that arose in the process of delivering and managing services that may have contributed to the alleged action or event i.e. the Investigation Team is not trying to establish if the abuse/ criminal action occurred but only if systems and processes were in place that would have allowed such abuse/ criminal action to take place.

7.1.5 External Expert Advice:

External expert advice is not always needed in order for the Investigation Team to complete a systems analysis investigation. This will be determined on a case by case basis.

As part of the systems analysis investigation process, the Investigation Team will undertake a comprehensive review of all relevant data\(^9\), written and electronic records, individual interviews with those involved in delivering the care/service where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident. Once the Investigation Team is equipped with this information, they will endeavour to complete the systems analysis investigation without requiring additional expert advice. External expert advice should not be sought when the Investigation Team is being established. However, there may be instances where external expert advice should be sought\(^10\). The decision to request external expert advice should be made by a competent Investigator as part of the work of the Investigation Team.

Requests for external expert advice may be:

1. To answer a specific clinical or technical question.
2. To validate that the final draft report prepared by the Investigation Team is clinically/technically accurate and addresses the clinical/technical issues highlighted appropriately.

Based on the limited availability of clinical/technical experts to participate as members of Investigation Teams; requests for input should as far as is reasonably practicable be limited to the two options above.

Regarding requests for validation of the final draft report, prior to submission to an external specialist for validation, the investigation report should:

A. have gone through the factual accuracy checking process and

\(^9\) Data to include relevant evidence based practice, standards and guidance.

\(^10\) This process applies to both HSE and HSE funded services
B. be reviewed using the Investigation Report Checklist included as Appendix 19 of this guideline.

If expert opinion is sought, and the external expert assigned requests to interview persons involved in the incident in order to clarify facts, this request should be facilitated as far as is reasonably possible by the Investigation Commissioner and as long as this is done in a manner that complies with fair procedures for all involved.

7.1.6 Legal Advice
Legal advice is not a mandatory requirement for all systems analysis investigations. However, where the Investigation Team has concerns about the legal implications/ issues associated with the investigation, this must be communicated to the Investigation Commissioner for a decision in relation to obtaining legal advice.

*There are 2 key situations when legal advice is required:*

1. *Where there is a specific legal question/ issue requiring legal advice;*
2. *Where the investigation involves external expertise where indemnity is required it is a requirement of the indemnity for the external expert that a legal review of the case and the investigation is undertaken.*

7.1.7 Reporting and Management of Immediate Safety Concerns
The Investigation Team should immediately convey any safety concerns that they identify during the course of the investigation to the Investigation Commissioner who will, in turn, identify the appropriate course of action to address the safety concern.
Figure 3: Process Map of overall Systems Analysis Investigation Procedure

- Terms of Reference of Systems Analysis Investigation Agreed
- Investigation Team commences the 6 steps of Systems Analysis Investigation
  
  **Section 7.2**
  - Step 1: Organise the investigation and gather the data
  
  **Section 7.3**
  - Step 2: Complete the Incident Chronology
  
  **Section 7.4**
  - Step 3: Identify Key Causal Factors (KCFs) and Incidental Findings
    - Can KCFs be identified?
      - Yes
        - The Investigation Team details the KCFs in the report. Several KCFs may be identified for the incident.
      - No
        - The Framework of Contributory Factors are used to identify the Contributory Factors related to each of the KCFs and/or Incidental Findings
        - Can Incidental Findings be identified?
          - Yes
            - The Investigation Team implements principles of Fair Procedure. All who participated in the investigation process are provided with an opportunity to give comments and observations on the sections of the draft report that are relevant to their involvement and to check those sections for factual accuracy
          - No
            - Section 7.6.3: If a contributory factor/hazard is one that may exist somewhere else on the HSE this should be reflected in the Investigation Report by the Investigation Team and the relevant recommendations are to be communicated to other relevant parts of the HSE by the Investigation Commissioner

  - Section 7.7
    - Step 6: Write the Investigation Report

- Section 7.2.1: Commissioner seeks consent from the person(s) harmed to access their healthcare records
- Section 7.2.2: All Information pertinent to the investigation is gathered
- Section 7.2.3: A draft chronology of events is developed
- Section 7.2.4: Interviews are planned with all relevant individuals
- Section 7.2.5: Conduct Interviews
- Section 7.2.6: Confirm the chronology of events
- Section 7.2.7: Commence developing ideas re Key Causal Factors and Contributory Factors

- Section 7.2.1: Where sections of the draft report reflect adversely on an individual or organisation, the individual or organisation is afforded the opportunity to review and provide comments on those sections prior to others viewing those sections of the report

- Section 7.7.3.2: Include an apology in the Investigation Report if Key Causal Factors were identified.
- Section 7.7.3.4: The Investigation Team audit the Investigation Report

Submit the report to the Investigation Commissioner
7.2 **STEP 1 Organise the investigation and gather the data**

In **Step 1**, the Investigation Team must ensure that:

- All relevant consent has been obtained by the Investigation Commissioner to access relevant records e.g. healthcare records;
- They collect all pertinent information about the incident;
- They plan and conduct interviews with relevant individuals.

### 7.2.1: Obtain Consent to access Records

#### 7.2.1.1 Seeking and Obtaining Consent

The principles of the National HSE Consent Policy (2013, and any subsequent revisions) will be adhered to at all times when conducting systems analysis investigations.

It is the policy of the HSE that all reasonable efforts should be made by the Investigation Commissioner to seek consent from the person(s) harmed to access relevant sections of their healthcare records for the purposes of individual incident investigations of all safety incidents. This is the case for all investigations even if the investigation is being carried out internally by the service.

A sample letter informing the person harmed of the investigation and seeking consent to access their records is included as **Appendix 3** of this guideline. A sample patient information leaflet and consent form is included in **Appendix 4A and 4B** of this guideline.

Signed consent forms from the person harmed or evidence of consent must be provided by the Investigation Commissioner to the Investigation Team.

In line with the National HSE Consent Policy (2013), no other person such as a family member, friend or carer, and no organisation, can give or refuse consent to a health or social care service on behalf of an adult service user unless they have specific legal authority to do so.

#### 7.2.1.2 Where consent is not/can not be provided or consent is withdrawn

Where consent is not provided/ cannot be provided (e.g. due to lack of capacity) or consent is withdrawn, the Investigation Commissioner must make a determination whether or not to proceed with an investigation, balancing the wishes of the person harmed/ family on the one hand against the safety imperative placed on the organisation to investigate safety incidents on the other.
Principles for the Investigation Commissioner to take into account when determining the appropriate action where no consent has been given are:

- If the incident investigation may have wider safety implications to the service or broader health services/public good.
- If it is deemed that the only way to identify the causes of any harm is by undertaking an investigation.

**Where consent is not provided and a decision is made to proceed with the investigation:**

- The rationale for this decision must be clearly documented by the Investigation Commissioner;
- This decision must be communicated to the person(s) harmed/family;
- The person(s) harmed/family should still be offered the opportunity to engage with the investigation and should be offered the opportunity to receive updates regarding the progress of the investigation; such offers should be repeated periodically throughout the investigation.
- Only those parts of the healthcare record that are relevant to the incident investigation should be provided to the Investigation Team. Where possible, and where doing so does not adversely impact on the ability of the Investigation Team to achieve the objectives of the Terms of Reference of the Investigation, the records provided should be redacted (i.e. private or sensitive information removed from the records) and the person(s) harmed should not be identifiable.

Where consent is withheld and a decision is made not to proceed with the investigation, the Investigation Commissioner must ensure that:

- The data from the National Incident Report Form is captured for aggregate review.
- The decision not to investigate further and the reasoning/factors influencing this decision are noted clearly in documentation and conveyed to all involved, including person(s) harmed and staff 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.

**7.2.1.4 Consent to access records where the subject of the investigation has died**

In those cases where the person harmed has died, in the best interest of patient safety, the Investigation Team may access the deceased person’s healthcare records to undertake the investigation in order to identify any safety issues. Wherever possible, this should be done in conjunction with the deceased person’s family/next of kin. While consent from family/next of kin is not required to access the deceased person’s records/charts, the Investigation Commissioner
should inform the family of the decision to carry out the investigation and to access the records/charts as part of the investigation. The Investigation Commissioner should endeavour to work with the family/next of kin so that the Investigation Team can review the deceased person(s) records with the family’s approval.

The Investigation Commissioner will link with the family of the deceased in the first instance to inform them of the intention of the HSE to undertake a systems analysis investigation of the incident, to discuss the scope and the terms of reference of the investigation. A link person will also be identified to liaise and communicate with the family.

7.2.1.5 Where the person(s) harmed decline to be involved in the investigation

Where the person(s) harmed decline to be involved in the investigation or where the person(s) harmed has died and the family decline to be involved in the investigation, the Investigation Commissioner and/or Investigation Team as appropriate, should endeavour to include the person(s) harmed/ family in the investigation process if the Investigation Commissioner/Investigation Team think that they might have information that would be helpful to achieve the purpose of the investigation.

If the person(s) harmed/family continue to decline to be involved in the investigation, this is respected by the Investigation Commissioner and the Investigation Team. The person(s) harmed/family are informed that they may contact the link person at any time if they have queries or concerns or if they require assistance.

Once the draft report has been prepared and the factual accuracy process begins, the Investigation Team should contact the person(s) harmed/ family to inform them that the chronology is complete and give them the opportunity to review the chronology for inaccuracies and to furnish the Investigation Team with any comments and observations they may have (see sample letter in Appendix 12).

Prior to completing the final report, the person(s) harmed/ family should be offered another opportunity to review the chronology of the report. The decision to do this will be made by the Investigation Team and Investigation Commissioner on a case by case basis.
The person(s) harmed/family may continue to decline any involvement in the investigation and this decision is to be respected and documented clearly in the investigation report by the Investigation Team.

After the investigation report has been completed the Investigation Commissioner should contact the person(s) harmed/ family, advising them that the final report is complete and available to be shared with them if they would like to receive it.

### 7.2.2 Collect all pertinent information

As soon as possible after the incident, the Investigation Team must collect all pertinent information and physical items related to the incident where appropriate. Any equipment involved in the incident should be secured for examination (where possible).

The Investigation Team should identify and collate any information that will assist them with investigating the incident including information about the service in which the incident happened, including standards, policies, procedures, guidelines, rosters, governance structures etc. This will provide the Investigation Team with background and contextual information that will assist their understanding of the incident and the contexts within which the incident occurred.

**Information to be collected may include but is not limited to the following:**

- **All relevant records** (e.g. Health/ Social Care records);
- **Documentation related to the incident being investigated** (e.g. policies, procedures, guidelines and national incident report forms, letter of complaint etc.);
- **Statements**: Statements are not a requirement for investigations but if they are available or generated for other processes, they may be considered by the Investigation Team, with the permission of the person who developed the statement, in the context of developing the chronology of events in relation to the incident;
- **Physical evidence**: including relevant materials, equipment or supplies that may have contributed to the safety incident must be preserved and retained (while ensuring that the collection of same does not impede on an investigation being carried out by another body e.g. Health and Safety Authority, An Garda Síochána, etc.);
- **Information about relevant conditions affecting the event** (e.g. staff rota, availability of trained staff, etc.);
Photographs: 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.

The use of a tracking system for information and other data sources, including physical evidence, is important. The following is an example of a tracking form that could be adapted to suit local needs (Table 1).

Table 1: Example of a tracking form for information and other data sources

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Information/Data Source</th>
<th>Date requested</th>
<th>From whom?</th>
<th>Date received</th>
<th>Location of data</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Electronic laboratory records.</td>
<td>12.03.14</td>
<td>Business Manager</td>
<td>Not received.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7.2.3: Draft the Chronology of events

Begin to draft the chronology of events based on examination of the records, prior to conducting interviews.

Drafting a chronology in advance of interviews will assist the Investigation Team to identify the ‘gaps’ and will allow the Investigation Team to begin to understand the context of the incident, it will also assist in identifying specific questions to ask / information that requires clarification during interview and helps the Investigation Team to identify the staff to be interviewed.

Section 7.3 and the template report in Appendix 18 provide further guidance in the development of the chronology.

7.2.4 Plan and undertake interviews with all relevant individuals

The Investigation Team must plan and conduct interviews with all relevant individuals who have been identified by the Investigation Team as having been involved in the incident being investigated.

Conducting interviews can be very resource intensive but can yield substantial information. The individuals that need to be interviewed should be carefully identified and interviewed as soon as possible after the incident. However, some individuals may be traumatised by an incident and this should be considered sensitively when planning interviews.
The Investigation Team informs the Investigation Commissioner of those individuals to be interviewed and the Investigation Commissioner will send those individuals letters of invitation to interview (attached as Appendix 5A to this guideline).

The following are key elements to consider in planning interviews:

7.2.4.1 Interviews should be conducted in a supportive and understanding manner. Interviews should not be judgemental or confrontational. Diplomacy, tact, sensitivity, empathy and objectivity are important skills for investigators. Interviewees should be treated with dignity and respect at all times. Investigators should also be aware of the pitfalls of investigator bias including hindsight bias; confirmation bias; outcome bias etc. The application of fair procedures is a mandatory requirement (see section 7.7.3.1). Further information in relation to investigator bias is provided in Appendix 16.

7.2.4.2 The Investigation Commissioner must have identified a link person (also referred to in section 7.1.1) who is familiar with the investigation process that can meet and/or communicate with individuals who will be involved in the investigation process to advise them with regard to the investigation process, including the interview process, and address any concerns and queries individuals may have about the process. This link person should not be an investigator but may be a member of the Safety Incident Management Team if desired.

7.2.4.3 The Investigation Team interview the person(s) harmed
Wherever possible, it is helpful to interview the person(s) harmed prior to interviewing staff involved in the incident being investigated. This helps to clarify the views of the person(s) harmed on the pertinent issues and to get a sense of their experience. The Investigation Commissioner will inform the person(s) harmed of the investigation and of the arrangements to meet with the Investigation Team (see Appendix 3)

7.2.4.4 The Investigation Team must interview staff involved in the incident.
The Investigation Team must interview all staff who can give information that is pertinent to the incident being investigated.

In relation to the sequence of interviews, it is helpful to interview more senior managers in the first instance as they will help to give the general context of the incident. Then, interview those who
were directly involved in the incident. However, it is recognised that due to duty rosters, annual leave, sickness absence etc scheduling of interviews in many instances will be determined by the availability of interviewees.

Interviewers must also take account of the fact that some individuals may need to be interviewed more than once and that the scheduling of interviews will need to be flexible in order to enable interviewees to attend multiple interviews.

Repeated non-attendance by interviewees at interview must be reported by the Investigation Team to the Investigation Commissioner for resolution.

**Interviews via Phone or Alternative Media Resources**

While it is preferable to undertake face to face interviews, in circumstances where it is not possible for the interviewee to attend for interview (e.g. living/ working abroad and unable to travel), the Interview Team may consider undertaking the interview via phone or similar media such as Skype or Web-ex etc.

The interviewers must ensure that the interview is in a private and confidential environment and that all confidentiality requirements are met prior to and during the interview. The interviewee must have received all necessary information prior to the interview (as per section 7.2.4.7 of this guideline) to ensure that he/she is appropriately informed prior to the interview.

**7.2.4.5 The Investigation Team must arrange for interviews to take place in a private, confidential and comfortable environment.**

Interviews should be conducted in private, where there will be no interruptions and the confidentiality of the interview can be assured. Ideally, interviews should be conducted away from the place where the incident occurred.

**7.2.4.6 Ensure Appropriate Support is provided.**

The Investigation Commissioner must ensure that appropriate support is available as required for all involved in the investigation, such as counselling and, in the case of employees, employee assistance services. Further advice is provided on this in the HSE Safety Incident Management Policy.
7.2.4.7 Ensure that interviewees get sufficient notice and information about the interview.

The Investigation Team must endeavour to give each interviewee a minimum of 10 working days notice of the interview date (as far as is reasonably possible) in order to allow the interviewee to prepare for the interview.

Notice of the interview should be communicated to those involved in the incident in a letter from the Investigation Commissioner (see Appendix 5A) and should include a copy of the Terms of Reference for the investigation (see Appendix 2); and details of the link person (see section 7.2.4.2) who can arrange to address any concerns or queries about the interview in a positive and supportive manner. The “Introduction to Interviews” in Appendix 6, may be included in communications sent to interviewees and/or may be fully explained at the start of interviews.

In the case of all interviews (including the interview with the person(s) harmed):

- Interviewees must be furnished with the Terms of Reference for the Investigation and information in relation to the investigation process in advance of interview, for their consideration.
- Interviewees should be advised that information provided by them at interviews may be disclosed to third parties and used in the Report, which may be published (see 7.2.4.10 for further details).
- Interviewees should be advised that copies of records or documentation relevant to the investigation and the interviewee’s involvement in the incident (e.g. healthcare records), will be made available to them on request prior to interview and as far as is reasonably practicable original records will be available for them to refer to within the interview. Requests for records or related documentation should be made by interviewees to the Investigation Commissioner via the designated link person.

Please see the following support documents in relation to communications to interviewees.

- **Appendix 2** Template Investigation Terms of Reference for an Investigation
- **Appendix 5A** Letter of invitation to go from investigation commissioner to HSE interviewees
- **Appendix 6** Introduction to Interviews
- **Appendix 7** Information sheet for complainants/those affected/staff to address frequently asked questions about systems analysis investigations
7.2.4.8 Interviewees are advised that they may be accompanied if they wish.

Interviewees may be accompanied at the interview for support purposes if they wish. The person(s) harmed will be advised that they may be accompanied by a legal representative, staff representative, family member, advocate etc as appropriate.

Interviewees who are staff members involved in the incident may be accompanied by e.g. a colleague, union representative or legal representative etc. It is not appropriate that HSE employees should be accompanied at interview by a family member or by a colleague directly involved in the incident or any other individual who may be interviewed by the Investigation Team.

If interviewees are accompanied, consideration needs to be given to confidentiality and privacy issues. All accompanying persons who are not HSE employees must sign a confidentiality agreement prior to the commencement of the interview (see Appendix 9A/9B for confidentiality agreement for accompanying persons).

If an accompanying person attends more than one interview they need to sign a confidentiality agreement for each interview attended. The confidentiality agreement for accompanying persons should also be referred to in the letter of invitation to interview. A confidentiality agreement is not required from an accompanying person who is a HSE employee as all HSE employees owe the employer a duty of confidentiality and fidelity which must be reiterated to them by the Investigation Team prior to commencing the interview.

7.2.4.9 Request by HSE/ HSE funded employee and/or employee representative for access to relevant clinical notes prior to interview

The consent form to access healthcare records completed by the person(s) harmed outlines that their records (e.g. healthcare records) may also be sought and will be made accessible to other parties (e.g. staff and/or their employee representative body) to enable a staff member to participate in the investigation.

In the event that a request is made prior to interview by a staff member and/or employee representative body for access to such records, in the interest of fair procedure, the Investigation Commissioner will arrange for a copy of the clinical notes to be made accessible to the interviewee and/or employee representative.
Only those sections of the records that are absolutely relevant to the incident being investigated will be provided while also ensuring that any restrictions on the availability of records does not impede on the interviewee's right to natural justice.

**Key confidentiality requirements for the recipient of the record(s) include:**

- They must not copy or reproduce the record(s) in any format whatsoever or share the records with a third party;
- When they no longer require access to the records, they must return the records to the Investigation Commissioner by registered post or confirm to the Commissioner by email or letter that the records have been destroyed.

**Note:** There may be circumstances where it is not considered appropriate to provide copies of the records. In these cases, the reasons for this decision need to be set out in writing. If required, the Investigation Commissioner should seek legal advice.

**A. Request for records from Interviewee who is employed by HSE/ HSE funded services**

If the request for records is made by an employee of HSE/ HSE funded service, a confidentiality agreement is not required as all HSE employees owe the employer a duty of confidentiality and fidelity which must be reiterated to them when they are provided with access to the records.

Staff will be provided with on-site access to the relevant sections of the healthcare records. The requested records will not be sent to the employee except for situations where it is not reasonable for the employee to access the records at the site at which the record is held. In such cases a copy of the relevant sections of the healthcare records may be sent to the employee by the Investigation Commissioner with a letter highlighting the employee’s duty of confidentiality and fidelity (example letter attached as Appendix 10B).

**B. Request for records from employee representative**

Upon receipt of a request for records from the employee representative, the Investigation Commissioner will request that a confidentiality agreement (Appendix 9B) is signed and dated by the employee representative and returned to the Investigation Commissioner.

Once the signed and dated confidentiality agreement is received, the records will be made available by the most appropriate means by the Investigation Commissioner to the employee representative.
These will be accompanied by a letter (draft letter attached as Appendix 10A) outlining clear requirements for confidentiality and responsibilities in relation to the management of the records.

7.2.4.10 Advice regarding Legal Protection/ Freedom of Information

Interviewees should be made aware that a report (anonymised by location and individuals) and the working documents of the Investigation Team may be disclosed in a number of different ways to include the following:

- The HSE may decide to publish the report;
- A Data Protection / Freedom of Information request may be made;
- In judicial review proceedings;
- In the defence of a personal injuries claim;
- As part of a Coroner’s Inquest\(^\text{11}\);
- An investigation by the Office of the Ombudsman;
- A HIQA investigation;
- An investigation by An Garda Síochána.

Therefore, as stated in 6.5 of this guideline, interviewees must be advised that there is currently no specific legislation or common law dealing with the protection of individual data, confidential data, data disclosed on the basis of confidence etc and no guarantee can be given by the HSE that information received as part of an incident investigation will not be disclosed. In such circumstances, disclosure of the names of the individuals in the Investigation Report may be sought and released.

The above information is included in the document “Introduction to Interviews” in Appendix 6, and may be included in communications sent to interviewees and must be fully explained at the start of interviews.

\(^{11}\) In January 2012, the State Claims Agency advised the HSE that investigation reports should be provided to the Coroner if so requested. However the Agency advised that if there is a concern that a report addresses issues of civil or criminal liability, that the HSE should first obtain legal advice before making a decision on the release of the report.
7.2.4.11 The Investigation Team should prepare a preliminary set of questions for each interview.

These questions should derive from the analysis of the documentary evidence and the formulation of the draft chronology of events leading up to the incident.

If, in advance of the interview, an interviewee requests an outline of the questions to be asked at the interview, these may be provided. However, the interviewee must be informed that the interview will not be limited to the questions provided and that additional questions may be asked at the interview in order to enable the interviewers to ascertain the facts about the incident.

7.2.4.12 Allocation of roles in conducting the interviews

As stated previously, Investigation Teams should generally consist of not more than 2-3 people and one member of the Investigation Team is assigned the role of Lead Investigator.

While all members of the Investigation Team should participate in the interviews, it is recommended that interviews are generally conducted by the Lead Investigator. However, the Investigation Team may alternate the role of interviewer and note-taker. The allocation of roles is to be agreed by the Investigation Team prior to each interview.

At the start of each interview, the Investigation Team will inform the interviewee which investigator will conduct the interview and which investigator will take notes.

7.2.4.13 Recording of Interviews by the Investigation Team

It is recommended that Interview notes are only recorded in writing.

Tape recording of interviews by the Investigation Team is not recommended for the following reasons:

- The risk of confidentiality breaches is increased due to the increased processing requirements of taped interviews;
- The process to be implemented in relation to tape recording interviews will considerably add to the investigation timeline e.g. the requirement to fully transcribe the interview from the recording;
- There is potential for considerable cost and resource implications in relation to transcribing tape recorded interviews;
There is no evidence that the quality of investigation reports where interviews were tape recorded is better than the quality of those investigation reports where interviews were documented in writing.

Interviewees will be informed at interview by the Investigation Team that they do not provide copies of the interview notes to the interviewee unless they are specifically requested by the interviewee. However, the interviewee will be informed of the process for factual accuracy checking as per section 7.2.5 and section 7.7.3.

7.2.5 Commencing the interview
The Investigation Team will undertake the following prior to commencing the interview:

A. Introductions
- Introduce the Investigation Team to the interviewee (and to any individual accompanying the interviewee) and will inform them how the interview process will be conducted including the roles of the interviewers in the interview.
- If there is an individual accompanying the interviewee, ensure that they understand the need for confidentiality and that the accompanying person signs the confidentiality agreement (if non-HSE employee) (See Appendix 9A/9B).
- Ensure that the information contained in Appendix 8 (Headings to be included at top of each Note of an Interview) is communicated to the interviewee.
- Ensure that the interviewee has received and read a copy of the Terms of Reference for the investigation and that they understand the purpose of the investigation and why they were invited to attend for interview. It is recommended that the Investigation Team have copies of the Terms of Reference available at the interview in the event that an interviewee wishes to review the Terms of Reference again prior to the commencement of the interview.
- It is also recommended that the Investigation Team arrange that the healthcare records and documentation relevant to the interview are available for referral where required during the interview.

B. Information on Factual Accuracy Check
- The person(s) harmed will be advised by the Investigation Team that in order for them to check for factual accuracy and to furnish the Investigation Team with any comments and observations they may have, they will get a copy of the chronology and any other section of the report that
relies on any direct observations of the person(s) harmed (see section 7.7.3.1 (Fair Procedures)).

- The Investigation Team will advise the interviewees who are staff members/ personnel involved in the incident being investigated, that in order for them to check for factual accuracy and to furnish the Investigation Team with any comments and observations they may have, they will get a copy of the sections of the draft report of the investigation that are relevant to them (see section 7.7.3.1 (Fair Procedures) for further guidance on this).
- Interviewees will also be informed that they are entitled to comment on any information contained in the report that is adverse to them or that they perceive as being reasonably adverse to them i.e. that they are not limited to factual accuracy only.

C. Request by Interviewee/ Accompanying person to Record/ Take notes at Interview

If the interviewee indicates to the Investigation Team that they wish to record the interview, the Investigation Team will point out to the interviewee that:

- It is not the policy that interviewees may record their interview and that this is in order to maintain the confidentiality of the interview;
- The interviewee will have an opportunity to review the sections of the draft report that relates to information they have provided to check for factual accuracy and to furnish the Investigation Team with any comments and observations they may have;
- The interviewee may request a copy of the interview notes and on this basis that tape recording should not go ahead.

However, if the interviewee insists on recording the interview, the Investigation Team will remind the interviewee that the recording of interviews is outside recommended guidelines that the recording of the interview will be documented by the Investigation Team in the interview notes and they are also reminded that they treat the information confidentially and sensitively.

Where the person accompanying the interviewee indicates that they intend to take notes of the interview, the Lead Investigator will remind the accompanying person that the notes taken are bound by the confidentiality agreement that they have signed at the start of the interview.

D. Immediately prior to commencing interview

- Before starting the interview provide an opportunity for the interviewee to become comfortable and to settle in. Be aware that the interviewee may be apprehensive so make sure that
explanations are reinforced and that the interviewees understanding in relation to the interview is checked.

- Advise the interviewee that the interview will be conducted in a positive and supportive manner where all involved will be treated with dignity and respect, and that if they have any concerns as the interview proceeds, they should communicate this to the interviewer.

### 7.2.6 The Investigation Team will confirm/further develop the chronology of events during the interview process

- Determine the role of the interviewee in the incident and the limits of their involvement.
- Determine the chronology of events as the interviewee saw them.
- Questions should focus on what happened, to who, where, when, how and why. The interviewer should start by requesting that the interviewee use “free recall” to take them back to the events that occurred e.g. “tell me what happened on ………, start from the beginning, when did you come on duty, what was happening…….”
- Be aware that interviewees will not necessarily remember things in the correct order but do not interrupt the interviewee. Once they have recounted everything, go through the sequence of events with them and recap e.g. “so you said that you came in at ….. you were involved in ……… and you saw ………. Is that correct?”
- It may be helpful to use a semi-structured questionnaire to ensure that all of the issues identified have been covered.
- Compare new information with what is known of the overall sequence drafted prior to interview.
- Ask the interviewee if they have any recommendations that could help reduce the likelihood of the incident occurring again
- Where necessary revisit aspects of the interview that are not clear.

**Note:** In the interest of fair procedures and natural justice, during the course of the interview, the interviewer should put to the interviewee any comments made about them by another (including person(s) harmed/ family/ staff member) in order to provide the interviewee with the opportunity to respond to these comments.

### 7.2.7 Use the information from the interview to develop ideas about Key Causal Factors and Contributory Factors

The information gleaned from the interviews will assist the Investigation Team to develop the chronology and assist in identifying Key Causal Factors and associated Contributory Factors which
they can probe further in further interviews/ re-interviews. To assist with the identification of Key Causal Factors and Contributory Factors Interviewers should:

- Identify all acts or omissions made by staff that were important in the chain of events leading up to the incident/complaint.
- Identify any incidental findings, i.e. issues identified in the course of the investigation which did not impact on the outcome but are system development issues
- Record variances between accounts as to the course of events
- Review relevant policies, procedures and / or guideline to determine whether there were major departures from accepted practice.

7.2.8 Close the interview:

At the end of the interview, the Investigation Team will ask the interviewee:

- If they have any other comments to make, or questions to ask.
- To contact the interviewers if they think of any information that is pertinent to the investigation after they leave the interview.

At the end of the interview, the Investigation Team will advise the interviewee:

- The Investigation Team may contact them again if they need further information;
- They may be asked to attend another interview if information comes to light that only they can clarify e.g. conflicting information is given. Explain that this is not unusual, and that it is not a cause for concern;
- That they will receive a copy of the relevant sections of the Draft report/ chronology (as appropriate) in order to check for factual accuracy and to furnish the Investigation Team with any comments and observations they may have;
- Of the process for returning their comments and draft copies to the Investigation Team and the requirement for continuing confidentiality in this regard;
- Of the timescale for the interviews and plans for concluding the report.

Finally, the Investigation Team should thank the interviewee for giving of their time to the interview and for the important contribution they made.

7.2.9 Interview Notes

Interview notes should be kept safely and securely at all times. Notes of interviews should have headers as per Appendix 8 ‘Headings to be included at top of each Note of an Interview’.
In order to protect the sensitive and confidential information provided by interviewees at the interview, only the Investigation Team should have access to the notes of the interview after the interview in order to develop the chronology and draft the investigation report.

All who participate in the investigation process should be provided with the chronology or sections of the draft investigation report that are relevant to their involvement in order to check these sections for factual accuracy (see section 7.7.3.1 for further detail).
Figure 4: Summary of Step 1 of Systems Analysis Investigation Process

Terms of Reference of Systems Analysis Investigation Agreed

Investigation Team commences the 6 steps of Systems Analysis Investigation

Section 7.2
Step 1: Organise the investigation and gather the data

Section 7.2.1: Commissioner seeks consent from the person(s) harmed to access their healthcare records

Section 7.2.2: All information pertinent to the investigation is gathered

Section 7.2.3: A draft chronology of events is developed

Section 7.2.4: Interviews are planned with all relevant individuals

Section 7.2.5: Conduct Interviews

Section 7.2.6: Confirm the chronology of events

Section 7.2.7: Commence developing ideas re Key Causal Factors and Contributory Factors

Section 7.3
Step 2: Complete the Incident Chronology
7.3 **STEP 2** Complete the Incident Chronology

The Investigation Team must review notes of interviews, records and other information relevant to the investigation to further develop a detailed chronology that demonstrates what happened and when.

Using the format outlined in the report template (Appendix 18) outline the chronology of events as follows:

- Specify the date and time of each event. In chronological order, put the **exact date and time** in bold font in the left-hand margin. Where the exact time of certain events is unknown, but where it can be approximated by placing chronologically in the order at which events occurred, state the approximate time of occurrence and indicate that the exact time is unknown and that the time in the chronology is an approximation.

- Under each time describe the events that took place at this time, the individuals involved in or witness to the incident, using the information from the entries made in records and from information received during interviews with employees.

- All personnel should be referred to by their title and by the code e.g. Staff Nurse 1, Consultant A, etc. Carefully consider the coding system used and take additional care if only a single or small number of people can be identified by the description. Where this is a concern perhaps terms such as *Senior Manager with responsibility for X* could be considered.

- Information related to the location of the service should be anonymised and service delivery areas such as wards, building names etc should also be anonymised (e.g. Ward A, Unit B etc.).

- The key to the codes allocated must be retained as part of the back-up file (see 7.8.3) for the Incident investigation (but not linked on any correspondence issued during the investigation process, e.g. factual accuracy checks).

- The first time clinical or technical terms are used the full text should be included in the report in the first instance and abbreviations may be used thereafter. All abbreviations included in the report, must be included in a glossary.

- Explanations and definitions of terms used in the chronology must be included as footnotes and/or in the glossary.
• Variances in recollections must be clearly identified. Where there is variance of recollection with regard to events, all recollections are reflected in the chronology. If there is information/evidence available to the Investigation Team that supports a particular recollection of events e.g. a phone conversation that is supported by phone records, this fact must be stated in the chronology.
### 7.4 **STEP 3 Identify Key Causal Factors and Incidental Findings**

Key Causal Factors are issues that arise in the process of delivering and managing health services which the Investigation Team consider had an effect on the eventual harm.

Examples of Key Causal Factors are:
- Deviation from existing Policies, Procedures, Protocols or Guidelines
- Failure to monitor, observe or act
- Incorrect (with hindsight) decision
- Not seeking help when necessary/ Failure to seek advise and/or supervision
- Failure to communicate significant information
- Failure to recognise significant changes in condition [e.g. clinical and/or non clinical]

From the analysis of relevant data and careful consideration of the chronology developed, the Investigation Team should determine whether any Key Causal Factors can be identified using the definition outlined above.

This can be the most complex part of the investigation process, while in many cases it will be easy to identify Key Causal Factor(s), for other cases it may take time to isolate and identify them.

It is important that careful consideration is given to the identification of the Key Causal Factor(s). Where necessary, the Investigation Team should discuss, debate and agree the Key Causal Factors(s). Once Key Causal Factors have been identified, the Contributory Factor(s) related to each Key Causal Factor should be identified (as described in Section 7.5). Care should be taken not to confuse the Contributory Factors with the Key Causal Factor(s).

**Note: Several Key Causal Factors may be identified for the incident being investigated.**

There are instances where an incident may have occurred but the investigation determined that the care provided was in line with good standards of practice and did not contribute to the occurrence of the incident (i.e. it was not actually an incident of harm caused by an issue that arose due to the process of delivering and managing health services).
If the investigation does not identify any Key Causal Factors then it will not be possible to identify any Contributory Factors. However, the investigation may highlight **Incidental Findings** which will have associated Contributory Factors and which may require consideration where appropriate (see section 7.5.2).

The final report should clearly indicate how the Investigation Team came to their conclusion that there were no Key Causal Factors.
7.5 **STEP 4** Identify the Contributory Factors related to the Key Causal and Incidental Findings

7.5.1 Identify Contributory Factors

A Contributory Factor is defined as 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.

Therefore, Contributory Factors are hazards as they are the cause of harm in the incident being investigated and potential causes of future harm if not mitigated.

Use the Contributory Factors Framework in table 2 (next page) to analyse each identified Key Causal Factor and incidental findings (if appropriate) and to determine the Contributory Factors related to each of the Key Causal Factor(s) identified. The list of Contributory Factors outlined within the Contributory Factors Framework is not an exhaustive list of all possible Contributory Factors. Therefore, it is important for the Investigation Team to be vigilant in order to identify Contributory Factors that are not listed in table 3 (next page).

Each Key Causal Factor may be associated with several Contributory Factors.

A useful tool that may be used to organise ideas and to illustrate the Contributory Factors identified as they link to each Key Causal Factor is the *fishbone* diagram (figure 2 below)

**Figure 5: Fishbone diagram to aid the identification of Contributory Factors**
### Table 2: Framework of Contributory Factors

(adapted from Systems Analysis of Clinical Incidents, The London Protocol (Taylor et al., 2004)).

Refer to **Appendix 17** for a detailed breakdown of each Contributory Factor (Sub-Components Underpinning the Framework of Contributory Factors Influencing Practice).

<table>
<thead>
<tr>
<th>Factor Types</th>
<th>Contributory Factor (i.e. potential causes related to each key causal factor and incidental finding identified in Step 3)</th>
</tr>
</thead>
</table>
| Individual affected/harmed        | Condition (complexity & seriousness)  
                                 | Language and communication  
                                 | Personality and social factors  
                                 | Psychological state, existing mental health condition, stress |
| Task and Technology Factors       | Task design and clarity of structure  
                                 | Availability and use of protocols, policies, standards  
                                 | Policies etc. relevance ambiguity, accuracy and practicality  
                                 | Availability and accuracy of test results  
                                 | Decision-making aids  
                                 | Availability and appropriateness of technology |
| 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 |

As Contributory Factors identified within the investigation process are circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident they should be addressed as per step 5 below (Section 7.6).
In cases where Contributory Factors can not be addressed immediately they should be put onto the relevant *risk register* and dealt with as part of the overall service risk management process. Refer to HSE Guidance on *Developing and Populating a Risk Register* for further information.

### 7.5.2 Incidental Findings

Incidental findings are issues that arose in the process of delivering and managing health services, identified during the course of an investigation and which the Investigation Team consider did not impact on the outcome but which serve to identify issues for system improvement e.g. issues relating to issues surrounding documentation, communication etc.

Such incidental findings should be listed under a section in the report entitled ‘Incidental Findings’ and relevant recommendations to address these findings should be identified and included within the recommendations section of the report.
7.6 **STEP 5 Make Recommendations that will Reduce Risk and Improve Quality and Safety**

### 7.6.1 Overview of Making Recommendations

In the context of the Systems Analysis Investigation Process, recommendations are reasonable courses of action based on the best available evidence, developed to address the identified Contributory Factors, and that have the best potential for preventing or reducing the risk of future harm arising from these Contributory Factors.

Making recommendations to improve the quality and safety of services is an important element 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 and state a Timeframe for completion (SMART). However, applying the SMART concept to the development of recommendations should not prevent the Investigation Team from considering innovative solutions that may not currently exist.
- Recommendations are made with input from those directly involved in the incident where possible. This input may be obtained through the interview process, and/or through feedback on the draft report.
- **Note:** The recommendations section of the draft investigation report may also be provided to the Safety Incident Management Team for their input if the Investigation Team deems that by doing so would help to better achieve the objectives as set out in the TOR)
- Reference existing safety initiatives including national and / or local standards and guidelines.

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**Example:**

**Non-SMART Recommendation:** Ward A must establish a Patient Safety Culture

**SMART Recommendation (For example only to demonstrate SMART principles)**

Establish a Quality and Patient Safety committee which should meet on a monthly basis by the end of Quarter 1, chaired by the Clinical Nurse Manager II. The agenda of which must include review of incidents, complaints and audits occurring or completed within the previous month and the implementation of recommendations from all relevant reports e.g. investigations. The committee should prepare a 6 monthly report related to the work of the committee which should be submitted to and reviewed by the Hospital Governance Committee.
If the contributory factor/hazard is one that may exist somewhere else in the HSE this should be reflected in the investigation report by the Investigation Team (see section 7.6.3) and the relevant recommendations should be communicated to other relevant parts of the HSE for learning and quality and safety improvement purposes by the Investigation Commissioner.

7.6.2 Hierarchy of hazard controls (recommended actions)
The recommendations made to address the 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 hierarchy of hazard controls (Table 4) can be used to help ensure that the most effective hazard control measures/recommendations are made.

7.6.3 Recommendations that may have applicability in other parts of the HSE
The Investigation Team must consider whether the Contributory Factors/hazards identified in their investigation may exist in other parts of the HSE. If they could exist elsewhere, the Investigation Team will indicate in the investigation report if the recommendation is potentially a nationally applicable recommendation.

As detailed in 7.7.3.5 of this guideline and section 7.3.1 of the HSE Safety Incident Management Policy, the Commissioner of the investigation is responsible for ensuring that the local managers responsible for the service where the incident occurred implement the recommendations of the investigation report.

The Investigation Commissioner is also responsible for communicating potentially nationally applicable recommendations to the relevant National Director(s) for national implementation. See section 7.1 of the HSE Safety Incident Management Policy (2014): “Monitoring the implementation of recommendations”.
### Table 3: Hierarchy of Hazard Controls

<table>
<thead>
<tr>
<th>Strength of control</th>
<th>Category of Control</th>
<th>Comments/ Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strongest Control</strong></td>
<td>Elimination</td>
<td>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. Examples of controls may be to stop providing service; discontinue a particular procedure; discontinue use of a particular product, service or piece of equipment. <em>If hazard elimination is not successful or practical, the next control measure is substitution.</em></td>
</tr>
<tr>
<td></td>
<td>Substitution</td>
<td>Replacing the material or process with a less harmful one. Re-engineer a process to reduce potential for “human error”. <em>If no suitable practical replacement is available the next control measure is engineering controls</em></td>
</tr>
<tr>
<td></td>
<td>Engineering Controls</td>
<td>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. <em>If no suitable engineering control is available, the next control measure is administrative procedures.</em></td>
</tr>
<tr>
<td></td>
<td>Administrative Procedures</td>
<td>Ensure that administrative policies, procedures and guidelines are in place. Ensure staff are appropriately trained in these. Monitor compliance with policies, procedures and guidelines through audit. <em>If no administrative procedure is available the next control measure is work practice controls.</em></td>
</tr>
<tr>
<td></td>
<td>Work Practice Controls</td>
<td>This is the last control measure to be considered. Change the behaviour of staff, e.g. make staff wear personal protective equipment, etc. <em>Work Practice controls should be only considered after all the previous measures have been considered and found to be impractical or unsuccessful.</em></td>
</tr>
</tbody>
</table>
7.7 **STEP 6 Write the Investigation Report**

7.7.1 **Purpose and Format of an Investigation Report**

The purpose of the report is to convey the methods and findings of the investigation and the proposed risk reduction/quality and safety improvement recommendations in a logical, concise and comprehensive manner.

**The Format of an Investigation Report**

Investigation reports must include, but not limited to the following sections detailed in Table 4 below (see also Appendix 18 for the template investigation report which it is recommended should be used by the Investigation Team and which provides greater detail on each of the sections of the report).

**Table 4: Contents and Layout of Investigation Reports**

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title Page</td>
<td>Date, Title, Reference Number and Authors, Date incident occurred, date of incident investigation commenced, date incident investigation completed</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>Detailing key sections and page numbers</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>The executive summary should include Key Causal Factors and recommendations</td>
</tr>
<tr>
<td>Apology</td>
<td>An apology should be included/ referred to in a report if Key Causal Factors were identified. The authors may apologise on behalf of the organisation or they may refer to the fact that they are aware that the site where the incident occurred apologised or intend to apologise. See section 7.7.3.3 for further information</td>
</tr>
<tr>
<td>Acknowledgement</td>
<td>The contribution service users/ family members and staff make to investigations can be extremely important. If service user/ their family members participated in the investigation, it is important to acknowledge this. Staff participation should also be acknowledged.</td>
</tr>
<tr>
<td>Glossary</td>
<td>Definition and explanation of terms and abbreviations used in the report</td>
</tr>
<tr>
<td>Methodology</td>
<td>Outlines of the method of the investigation including the HSE Guidelines that were followed, the sources of information and the terms of reference for the investigation</td>
</tr>
<tr>
<td><strong>Background</strong></td>
<td>Describes the background to the incident, including relevant background information on the person(s) harmed.</td>
</tr>
<tr>
<td><strong>Chronology</strong></td>
<td>Details the chronology of events leading up to and including the incident.</td>
</tr>
<tr>
<td><strong>Aftermath of incident</strong></td>
<td>A brief summary of what happened immediately after the incident and what happened in the longer term if this is known.</td>
</tr>
<tr>
<td><strong>Key Causal Factors</strong></td>
<td>Provides details of the Key Causal Factors identified.</td>
</tr>
<tr>
<td><strong>Contributory Factors</strong></td>
<td>Outlines the Contributory Factors framework and the Contributory Factors identified for each key causal factor and incidental finding (where any incidental findings are found).</td>
</tr>
<tr>
<td><strong>Incidental Findings</strong></td>
<td>Defines the incidental findings i.e. issues that arose in the process of delivering and managing health services but which the Investigation Team consider did not impact on the incident but are areas for system improvement identified during the investigation (where any incidental findings are identified).</td>
</tr>
<tr>
<td><strong>Recommendations</strong></td>
<td>Risk reduction/quality and safety improvement recommendations linked to the Contributory Factors identified and should be the product of an assessment of the risk associated with the hazards/Contributory Factors for each Key Causal Factor and incidental finding using the hierarch of preferred controls.</td>
</tr>
<tr>
<td><strong>Bibliography</strong></td>
<td>Provides details of references, publications, policies etc included in the investigation report.</td>
</tr>
<tr>
<td><strong>Appendices</strong></td>
<td>May include supporting data/material</td>
</tr>
</tbody>
</table>
7.7.2 Redaction, Removal and Anonymisation of Employee or Patient Personal Data

Draft and final investigation reports should comply with good practice in relation to the processing of confidential personal and restricted information.

The following guidance should be considered:

- No staff or patient identifiers should be used within reports. Patient names should not be replaced with initials. Codes that can not be linked to individuals should be devised to replace identifiers and a key to codes stored securely in the investigation back-up file which is maintained by the Lead Investigator (see section 7.8.3).
- As a general rule, patient / staff sensitive personal information must not be included in the investigation report; this includes but is not exclusive to name(s), electronic or postal address, photographs, date of birth, racial or ethnic origin, physical or mental health, sexual life, religious or philosophical beliefs, political views, criminal convictions. Personal information should only be included if it is necessary to achieve the purpose of the investigation report in line with the terms of reference.
- Alternatives to patient age should be considered e.g. a descriptive such as neonate, infant, young adult, middle age, elderly etc.
- Service / hospital locations should not be recognisable in investigation reports.
- Gender and other potential staff identifiers (title, grade, years or experience etc) should not be included or be redacted where possible.

7.7.3 Finalising the Report and Fair Procedures

7.7.3.1 Fair Procedures

The investigation process must uphold and protect the rights of both the service / staff members and the patient / service user at all times and ensure that fair procedures are afforded to all parties involved in the incident at all times.

All who participate in the investigation process must have an opportunity to give comments and observations into the sections of the draft investigation report that are relevant to their involvement and to check these sections for factual accuracy. Providing comments and observations on draft investigation reports prepared by the Investigation Team is an essential stage in drafting an investigation report in the interest of fair procedures and for the purpose of ensuring that reports are as factually accurate as possible.
Where sections of the draft report reflect adversely on an individual(s) or organisation(s), the relevant individual(s) and organisations should be afforded an opportunity to review and provide comments and observations to those sections before others view those sections of the report.

**Staff**

Staff who participated in the investigation process must have an opportunity to review the sections of the draft report that are relevant to them i.e. the sections of the report that details the information provided by the staff member during the interview process and the sections of the report in which they are referred to by other interviewees.

**Person Harmed/ Family**

The person harmed or their family as appropriate should be given an opportunity to review and give input into the chronology section of the draft investigation report and any sections of the draft investigation report that relies on direct information provided by them to the Investigation Team.

The analysis section of the investigation report (including the identification of Key Causal Factors as defined previously) is based on the Investigation Team’s interpretation of the information provided during the investigation including documentation, information from interviews etc. In recognition of the fact that elements of this interpretation may be incorrect (in draft reports); those involved in the delivery of the service/care i.e. staff members must be provided with the opportunity to comment on these sections in order to ensure that the analysis undertaken by the investigators is valid and reliable prior to the release of the full final report to the person harmed or their family.

**Note:** Staff/ Person harmed/ family will be informed by the Investigation Team that once they have reviewed the chronology/ relevant sections of the draft report, they either:

a. Return the chronology/draft report to the Investigation Team either by registered post or
b. Confirm to the Investigation Team by email or letter that they have destroyed the chronology/draft report and you have not copied or reproduced them in any format whatsoever.

(Please see template letters attached as Appendices 12 – 14)
7.7.3.2 Finalising an investigation report: Managing responses received on draft reports

To improve the accuracy of draft and final investigation reports the Investigation Team must consider and take account of the responses received. All feedback will be accepted, and all suggested amendments made, unless making these amendments detracts from the factual accuracy of the report or from the ability of the report to attain the objectives of the investigation as set out in the terms of reference. Where feedback is not accepted by the Investigation Team an explanation will be given by the Investigation Team in relation to this decision.

It should be noted that where there is variance of recollection with regard to events, all recollections are reflected in the report. If there is information/evidence available to the Investigation Team that supports a particular recollection of events e.g. a phone conversation that is supported by phone records, this fact must be stated in the report.

The Investigation Team must keep records of all correspondence seeking feedback on draft reports, feedback and responses received and record any decision(s) made by the investigator(s) when considering feedback. The Investigation Team must also keep a record of all emails and postal correspondence confirming that respondents and any representatives have permanently destroyed or deleted draft reports sent to them following the preparation of their feedback.

Please see Appendices 12, 13 and 14 for suggested content of registered letter/secure e-mail inviting feedback to the first and final draft investigation reports. In addition, refer to section 7.8 in relation to collation, storage and management of information.

7.7.3.3 Write an Apology

An apology should be included/ referred to in the incident investigation report if Key Causal Factors were identified. The authors may apologise on behalf of the organisation (e.g. Hospital A/ CHO X and the Health Service Executive would like to sincerely apologise to the patient and their family for the events that occurred on date xxx related to incident xxx) or they may refer to the fact that they are aware that the site where the incident occurred has already apologised or intend to apologise.

While ensuring that the investigation process upholds and protects the rights of both the service / staff members and the patient / service user, where Key Causal Factors have been identified, those negatively affected by the incident deserve an expression of sympathy and apology for any distress, concern or delay they have experienced while in the care of, or working for, the HSE.

Explanations and apologies within an investigation report should include the following:
The reasons for harm caused identified within the investigation report (i.e. the Contributory Factors linked to the Key Causal Findings);

- An apology for any hurt, inconvenience or hardship caused;
- An assurance that all steps will be taken so that lessons will be learned and improvements put in place to help prevent an incident happening again.

**Note: Please see template report in Appendix 18 of this guideline for suggested wording**

**7.7.3.4 Acknowledgement**

The contribution service users/ family members and staff make to investigations is extremely important. If service user/ their family members participated in the investigation, it is critical to acknowledge this. Staff participation should also be acknowledged.

**7.7.3.5 Plain English Check**

Investigation reports should be well structured and comprehensive. Reports should be written in plain English taking account of the target audience, the expectations of the different people to whom the report will be sent and the different level of knowledge they may have on the issues giving rise to the incident which has led to the investigation.

Investigation reports should:

- Use everyday words and avoid jargon
- Only use words you really need
- If you must use specialised language, give definitions or examples
- When using abbreviations, define each one the first time you use it e.g. Emergency Department (ED)
- Do not use Latin and French phrases and Latin abbreviations
- Be consistent with words used and use the same words for the same concept throughout e.g. heart attack v coronary event.
- Ensure medical and technical terms are accompanied by plain English definitions and that where definitions are used the source of the definition is referenced
- Include a glossary of terms and abbreviations

**Quality Assurance Process**

Prior to finalising the report, the Lead Investigator must ensure that the Investigation Team apply a quality assurance process to ensure compliance of the investigation process with the systems
analysis guidelines prior to delivery of the final report to the Investigation Commissioner. The Investigation Commissioner should seek assurance that the quality assurance process has been completed. The Investigation Report Checklist attached as Appendix 19 to this guideline may be used by the Investigation Team to assist with his process.

7.7.3.6 Present Final Report to Investigation Commissioner
The final investigation report must meet the following requirements:
- Be written to high professional standards (including plain English checks);
- Be methodical and demonstrate compliance with the Investigation Report checklist included as Appendix 19 to this guideline;
- Be supported by documentation and processes that demonstrate that an investigation process was fair to all and followed section 7.7.3.1 of this guideline;
- Establish the facts about what happened for all those affected and involved;
- Identify the Key Causal Factors and Contributory Factors so that these can be addressed to prevent future harm arising from them;
- Provide Investigation Commissioners with recommendations (linked to the causes of harm identified) that are achievable, realistic and likely to avoid future harm arising from the Contributory Factors in this case at both service level and at national level (where applicable).

Upon meeting the above requirements, the final report should be presented by the Lead Investigator to the Investigation Commissioner for appropriate onward circulation in accordance with good practice in data protection and with the need to protect privacy and confidentiality.

Final reports should be provided by the Investigation Commissioner to person(s) harmed or families where appropriate (i.e. if the person harmed is deceased), provided this is in accordance with the wishes of the family.
7.7.3.7 Manager assumes responsibility for implementation of the recommendations

The Investigation Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred implement the recommendations of the investigation report.

The Investigation Commissioner is also responsible for communicating nationally applicable recommendations to the relevant National Director(s) for national implementation. See section 7.1 of the HSE Safety Incident Management Policy (2014) in relation to monitoring the implementation of recommendations.
Figure 6: Summary of Steps 2 – 6 of the Systems Analysis Investigation Process

Section 7.3
Step 2: Complete the Incident Chronology

Section 7.4:
Step 3: Identify Key Causal Factors (KCFs) and Incidental Findings

Can KCFs be identified?

Yes

The Investigation Team details the KCF(s) in the report. Several KCF may be identified for the incident.

No

The Investigation Team clearly indicates in the report how they came to this conclusion. Any Incidental Findings are identified.

Section 7.5
Step 4: Identify the Contributory Factors related to the KCF(s) and/or Incidental Findings

Section 7.6
Step 5: Make Recommendations that will Reduce Risk and Improve Quality and Safety

Section 7.7
Step 6: Write the Investigation Report

Section 7.7.3.1: The Investigation Team Implement principles of Fair Procedure.
All who participated in the investigation process are provided with an opportunity to give comments and observations on the sections of the draft report that are relevant to their involvement and to check those sections for factual accuracy.

Section 7.7.3.2: Include an apology in the Investigation Report if Key Causal Factors were identified.

Section 7.7.3.4: The Investigation Team audit the Investigation Report

Section 7.7
Submit the report to the Investigation Commissioner
7.8 Collection, Storage and Management of Information

7.8.1 General Guidance

Investigations into incidents and complaints are conducted in private and all information obtained by an investigator shall be deemed to be confidential information which he/she may not discuss, communicate or disclose except as is necessary for the proper investigation of the incident/complaint. The information gathered must be treated as confidential at all times and stored away in a locked filing cabinet when not in use.

There is currently no specific legislation or common law dealing with the protection of individual data, confidential data, data disclosed on the basis of confidence etc., and no guarantee can be given by the HSE that information received as part of an incident investigation will be protected from legal discovery or disclosure.

Interviewees should be made aware that a report (anonymised by location and individuals) and the working documents of the Investigation Team may be disclosed in a number of different ways to include the following:

- The HSE may decide to publish the report;
- A Data Protection / Freedom of Information request may be made;
- In judicial review proceedings;
- In the defence of a personal injuries claim;
- As part of a Coroner’s Inquest\(^\text{12}\);
- An investigation by the Office of the Ombudsman;
- A HIQA investigation;
- An investigation by An Garda Siochana.

All parties involved in the investigation including the person(s) harmed/ family (as appropriate) and relevant employees should be made aware of this.

For the purposes of data classification and handling, all information received, processed and stored as part of a systems analysis investigation is considered highly sensitive and should be treated as confidential and restricted information in line with the HSE Information Classification and Handling Policy version 1.1 (2013).

\(^{12}\) In January 2012, the State Claims Agency advised the HSE that investigation reports should be provided to the Coroner if so requested. However the Agency advised that if there is a concern that a report addresses issues of civil or criminal liability, that the HSE should first obtain legal advice before making a decision on the release of the report.
At all stages during the investigation process the collection and storage of information must comply with our obligations under the Data Protection Acts 1988 and 2003. That is, the information must be obtained and processed fairly; kept only for one or more specified, explicit and lawful purposes; used and disclosed only in ways compatible with these purposes; kept safe and secure; kept accurate, complete and up-to-date; adequate, relevant and not excessive; retained for no longer than is necessary for the purpose or purposes for which it was collected and a copy given to the individual of his/her personal data on request.

7.8.2 Electronic means of sending and storing information

The use of electronic means for sending and storing this information must be done in compliance with the Health Service Executive’s Information & Communication Technology Policies for the use of Information Technology (I.T.) Resources. Sensitive information such as draft investigation report findings and notes of interview should be stored on a secure segment of a local area network or within a separate dedicated network for sensitive information with restricted access rights. Consideration should be given to the encryption of investigation data using appropriate encryption software.

Where at all possible, sensitive documentation should not be transmitted via email. Where it is deemed absolutely necessary to use email the following guidance is recommended:

- Sensitive and confidential information should only be sent to an email address which ends in: @hse.ie (for HSE funded services, information should only be sent within the organisation’s internal email structure).
- In exceptional circumstances where it is necessary to send sensitive and confidential documents to an email address that is not within the HSE domain, the documents must be encrypted\(^\text{13}\). The transfer of such information outside of the HSE domain must be authorised by a HSE line manager (at Grade VIII level or above).
- Emails containing sensitive information should be tracked and monitored.
- Emails should be addressed to named individuals and should not be copied or accessed by an authorised recipients’ support staff or personal assistant.
- Recipients should be asked to confirm secure receipt of sensitive and confidential information sent via email, as advised in the HSE Electronic Communications Policy.

\(^{13}\) Encryption software is available through HSE Information Communication Technology departments. Requests should be made, with line manager approval, via ICT Department helpdesks.
Passwords should not be communicated to recipients via the same medium used to send the confidential and sensitive information. Passwords should comply with the HSE Passwords Standards Policy.

It is preferable for passwords to be communicated via a personal telephone call to the authorised recipient.

In particular the following HSE National policies are most relevant to electronically held and transmitted information:

- Information Security Policy
- I.T. Acceptable Usage Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_I_T_Acceptable_Use_Policy.pdf
- Electronic Communications Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Electronic_Communications_Policy.pdf
- Encryption Policy
- Password Standard Policy

In short, the information gathered as part of an investigation should not be held outside of HSE offices and must be adequately protected and stored while in the possession of the HSE.

### 7.8.3 Investigation Files

The Investigation Team need to maintain appropriate and up to date files related to the investigation process so that all relevant information can be stored and accessed as it is requested.

The Lead investigator should maintain the back-up files containing:

- Copies of all correspondence issued and received by the Investigation Team
- Interview notes (including transcripts from taped interviews)
- Reference to the literature reviewed
- Copies of Policies, Procedures, Protocols, Guidelines reviewed
- Feedback on draft reports circulated
- Copy of each version of draft report circulated
- The 'key' to the individuals referenced in the investigation report
- Any other relevant documentation pertaining to the investigation
• Patient’s chart number and identity
• Copy of this Check-list of Information in Back-up File

(Note: copies of or extracts from the patient’s healthcare records should not be maintained in the back-up file and should be destroyed upon submission of the final investigation report to the Investigation Commissioner)

**As far as is reasonably practicable, the Lead Investigator should also maintain an Electronic copy to include:**
• Copy of each draft version of Report
• Copy of the Final Report
• Interview notes (if available in electronic format)
• Correspondence sent/ received
• Key to individuals referenced in the investigation report
• Patients Chart Number and Identity

The back-up file should be maintained and stored inline with the requirements outlined in sections 7.8.1 and 7.8.2 above.

7.8.4 **Management of Information: Feedback on Draft Reports**
Where individuals are requested by the Investigation Team to provide feedback on the draft and final draft reports they should be requested:
• To return the draft report securely to be destroyed, or to confirm to the Investigation Team in writing that they have destroyed the draft report.
• Not to return any personal data within their comments unless they are being returned by secure email (i.e. password protected or encrypted) or by secure postal mail.

7.8.5 **Management of Information: External Investigators**
Where external investigators are contributing to HSE investigations, external investigators must have signed a confidentiality agreement (attached as **Appendix 11**) prior to being given access to information related to HSE investigations (including a request for external investigators to return all data to the HSE at the end of the investigation process).
7.8.6 Management of Information: Representatives
Representatives of employees that are involved in a safety incident must also have signed a confidentiality agreement (attached as Appendix 11) prior to being given access to information related to safety investigations.

7.8.7 Retention of Systems Analysis Investigation Records
This section to be read in conjunction with the Health Service Policy on Record Retention Periods (HSE, 2013)

Record Retention: Legal obligation and good practice
The Health Service Executive must comply with the provisions of section 2(1) (c) of the Data Protection Acts 1988 and 2003. The Acts set out the principle that personal data shall not be kept for longer than is necessary for the purpose or purposes for which it was obtained. This requirement places a responsibility on the HSE to be clear about the length of time personal data will be kept and the reasons why the information is being retained.

For the purpose of investigation reports a copy of the final investigation report should be retained permanently by the Investigation Commissioner and the Lead Investigator both in hard copy and on a disk in a secure, fireproof location (e.g. fireproof, lockable cabinet).

The hard copy back-up file and electronic back-up file to be retained for 7 years from the end of the calendar month following the last entry on the record.
8.0 Implementation Plan

This Guideline will be implemented through the following channels:

• This guideline will be uploaded on to the National Incident Management and Learning Team link on the HSE website
• Email notification of the new revision of this guideline will be sent to all HSE staff through appropriate HSE communication channels
• This guideline will be incorporated in to all future Systems Analysis Investigation training courses
• All attendees at past Systems Analysis Training course delivered since the launch of Revision 1 of this Guideline will be notified of the new revision of the guideline

9.0 Review and Audit

• This guideline will be reviewed on at least a three yearly basis or sooner if indicated.
• The Systems Analysis Investigation Process should be checked using the checklist attached as Appendix 1 to this guideline.
• The report of the systems analysis investigation should be checked using the Investigation Report Checklist attached as Appendix 19 of this guideline.
• The implementation of this guideline will be assessed through the ongoing review of the quality of a sample number of Investigation Reports by the National Incident Management and Learning Team.
• The implementation and effectiveness of this guideline will also be assessed through a programme of on-going evaluation of stakeholder experiences of the systems analysis investigation process.
10.0 References and Bibliography Used to Inform the Development of this Guideline

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