An Stiúrthóireacht um Ardchaighdeáin agus Sábháilteacht Othar
Oifig an Phríomhoifigigh Cliniciúil

National Quality and Patient Safety Directorate
Office of the Chief Clinical Officer

Guideline for Conducting a Look-back Review

Revision 3

November 2022

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About National Quality and Patient Safety Directorate

The National Quality and Patient Safety Directorate (NQPSD) was established in mid-2021 as a result of the HSE Central Reform Review. The NQPSD is part of the HSE Office of the Chief Clinical Officer, and is led by Dr Orla Healy, National Clinical Director, Quality and Patient Safety.

Purpose

The NQPSD works in partnership with HSE operations, patient representatives and other internal and external partners to improve patient safety and the quality of care by:

- building quality and patient safety capacity and capability in practice,
- using data to inform improvements,
- developing and monitoring the Incident Management Framework and Open Disclosure policy and guidance,
- providing a platform for sharing and learning; reducing common causes of harm and enabling safe systems of care and sustainable improvements.

Teams

In line with the "Patient Safety Strategy 2019-2024", the NQPSD delivers on its purpose through the following teams:

- **Patient Safety Programme**: Oversee and monitor the implementation of the HSE Patient Safety Strategy.
- **QPS Improvement:** Use of improvement methodologies to address common causes of harm.
- **QPS Intelligence:** Using data to inform improvements in quality and patient safety.
- **QPS Incident Management:** developing and monitoring the Incident Management Framework, Open Disclosure Policy and National Incident Management System.
- **QPS Education**: Enabling QPS capacity and capability in practice.
- **QPS Connect:** Communicating, sharing learning, making connections.
- Establishment and operation of the **National Centre for Clinical Audit.**

Connect With Us

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Reader Information

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Foreword

The Management and Review of Incidents in the Health Service Executive

Commitment 3 of the HSE Patient Safety Strategy states that health and social care services will be trusted by patients to identify and manage risks to their safety, learn from things that go wrong, learn from examples of good practice and show measureable progress in reducing levels of preventable harm.

The Incident Management Framework (IMF) provides HSE staff with the required policies, procedures and guidelines to manage and review incidents within the HSE. The Incident Management Framework is underpinned by the HSE Patient Safety Strategy and seeks to put in place a person centred, effective and timely approach to the management of safety incidents. Central to this is a commitment to learn from safety incidents so as to improve the safety and quality of services.

The Guideline for Conducting a Look-back Review falls within the context of the HSE Incident Management Framework and must be used in conjunction with the Incident Management Framework and HSE Open Disclosure Policy to ensure that there is proper and considered communication, management and review of incidents throughout the HSE.

A Look-back Review is defined in the Incident Management Framework as a 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. The Look-back Review process consists of four key steps:

1. Consideration of the Preliminary Assessment Form (as per the Incident Management Framework) to identify the need for a Look-back Review
2. Implementation of a Look-back Review Risk Assessment to identify the need to progress to the Audit and Recall Stages of the Look-back Review Process
3. Audit Stage
4. Recall Stage

The decision to conduct a Look-back Review is a difficult and complex one and should not be taken lightly. A Look-back Review should only be considered in circumstances where it is indicated, following careful risk assessment.

A Look-back Review cannot identify the necessary systems learning to improve the safety of our health systems and does not replace the requirement to undertake an incident review. Services must undertake incident reviews in conjunction with the Look-back Review for system learning i.e. Systems Analysis Review or Aggregate Review of cases as appropriate.

Central to the management and review of incidents, including Look-back Reviews, are the principles of Person Centeredness, Open Disclosure, Just Culture and Fair Procedure and Natural Justice. The IMF defines Just Culture as one which refers to a values based supportive model of shared accountability. It states that individual staff should not be held accountable for system failings over which they have no control. Instead, organisations need to encourage staff to report such incidents and near-misses and apply system-learning to improve patient safety. The IMF also acknowledges that within a Just Culture, acts of deliberate harm and complete disregard of policies and procedures

without due consideration by staff are not acceptable which is equally important to maintain patient safety.

Current revisions of the HSE Patient Safety Strategy, the Incident Management Framework, the HSE Open Disclosure Policy, and information in relation to patient safety programmes, education, supports and resources, including Just Culture and the National Incident Management System may be accessed in the Quality and Patient Safety Directorate section of the HSE website at https://www.hse.ie/eng/about/who/nqpsd/.

Dr Orla Healy,
National Clinical Director,
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1.0 Policy Statement

A Look-back Review is conducted as a matter of urgency where a number of people have potentially been exposed to a specific hazard in order to identify if any of those exposed have been harmed and to identify the necessary steps to ameliorate the harm.

Reasons for considering a Look-back Review may include but are not limited to the following:

- Audits showing that the results delivered by either a service or an individual were not in line with best practice standards and there is a concern that there was potential harm caused to a cohort of service users as a result;
- Identification of a faulty batch of medicines/ vaccines.
- Equipment found to be faulty or contaminated in a manner that may put people at risk of harm;
- Concern about missed, delayed or incorrect diagnoses related to diagnostic services such as radiology/pathology services etc.;
- Identification of a staff member who has been involved in exposure-prone procedures when there are indications that the staff member should not have done so e.g. Hepatitis B infected;
- Where concerns were raised due to staff competence, practice, treatment or care provided by a staff member/group of staff;
- As a result of findings of an incident review.

The existence of a hazard exposing a number of people to a risk of harm is not always immediately apparent. A review of a specific incident of harm may unearth such a hazard and trigger a preliminary assessment to determine if a Look-back Review may be required. Conversely, it may be immediately apparent that a number of people have been exposed to a hazard and so a Look-back Review is immediately triggered. In these cases an additional review of individual cases may still be required to identify and address if necessary the factors that contributed to the incident. Incident reviews must be undertaken in line with the HSE Incident Management Framework

In addition to this Look-back Review guideline, there are national policies and guidelines in place that define both the actions to be taken and the individual roles and responsibilities in relation to specific incidents, such as incidents of blood-borne diseases in the healthcare setting[1] and incidents requiring a review via the National Independent Review Panel[2] etc., which must be referred to in conjunction with this guideline (please refer to scope below).

A Look-back Review does not replace the requirement to undertake an incident review. Services must undertake incident reviews in conjunction with Look-back Reviews for system learning i.e. Systems Analysis Review or Aggregate Review of cases as appropriate.

2.0 Purpose

The purpose of this guideline is to provide a standardised methodology for the implementation of Look-back Reviews undertaken by the HSE (and by HSE funded services) to ensure that they are valid, reliable and carried out in line with best practice and principles of Person Centeredness, Open Disclosure, Just Culture and Fair Procedure and Natural Justice.

[1] *The Prevention of Transmission of Blood-Borne Diseases (BBD) in the Health-Care Setting" Department of Health and Children 2005*
[2] National Independent Review Panel information available at https://www.hse.ie/eng/about/who/nqpsd/nirp/

3.0 Scope

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

Note: Any reference to HSE services in this guideline includes agencies funded by the HSE.

Many Look-back Reviews involve infectious diseases. In such instances, the Medical Officer of Health has a statutory function in relation to the surveillance and control of notifiable infectious diseases and outbreaks. In addition, the Department of Health has developed specific guidance in relation to the prevention and management of infections and blood-borne diseases. Further information is available on the HPSC website at https://www.hpsc.ie/publications/.

In addition, some category 1 incidents may be reviewed via the National Independent Review Panel (NIRP)[3] which may require a Look-back review process as part of the overall review methodology.

This guideline is not intended to supersede any regulatory or statutory obligations and is to be used as guidance for a Look-back Review process in the broader healthcare settings while being cognisant of any regulatory or statutory requirements.

4.0 Policy and Legislative Context

The Guideline for Conducting a Look-back Review must align with the following legislation, policies, procedures and guidelines (please see section 10 of this document for references):

4.1 Legislation

- Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 (once enacted)
- Civil Liability (Amendment) Act, 2017, Part 4 Open Disclosure
- Safety, Health and Welfare at Work Act 2005 (S.I. 10 of 2005 – and the Safety Health and Welfare at Work (General Application) Regulations 1993 SI44 Part X.
- The Health Act 2004.
- Data Protection Acts 1988-2018
- General Data Protection Regulation (GDPR) (EU) 2016/679
- Freedom of Information (Amendment) Act 2003.

4.2 Related policies, procedures and guidelines

Related Policies, Procedures and Guidelines include the following and any subsequent revisions of same.

- HSE Incident Management Framework and Guidance (2020)
- HSE Just Culture Guide (2022)
- HSE Open Disclosure Policy (2019, revised in 2022)
- Assist Me: A Model of Staff Support following Patient Safety Incidents in Healthcare
- Integrated Risk Management Policy (2021)
- HSE Consent Policy (2022)
- HSE and the Department of Health Communication Protocol, Communications in relation to major/significant patient/service user safety incidents and issues of concern (February 2022) (referred to as the Patient Safety Notification (PSN) Protocol in this guideline).

[3] National Independent Review Panel at https://www.hse.ie/eng/about/who/nqpsd/nirp/

5.0 Glossary of Terms and Definitions

Note: Please refer to the Incident Management Framework for a complete list of Terms and Definitions

Term	Definition
Adverse Event	An incident which results in harm, which may or may not be the result of an error
Audit	In the context of the Look-back Review process, audit involves the systematic review of care against explicit standards and criteria.
Contributory Factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Category 1 Incident	Clinical and non-clinical incidents rated as Major or Extreme as per the HSE's Risk Impact Table.
Category 2 Incident	Clinical and non-clinical incidents rated as Moderate as per the HSE's Risk Impact Table.
Category 3 Incident	Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table.
Harm	Harm to a person: Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications that result from an incident. Degrees or levels of harm include: • None – outcome for affected person is not symptomatic or no symptoms have been detected and no treatment is required. • Mild – outcome for affected person is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required. • Moderate – outcome for affected person is symptomatic, requiring intervention (for example, additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function. • Severe – outcome for affected person is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function. • Death – on balance of probabilities, death was caused or brought forward in the short-term by the incident. (As adapted from the World Health Organisation's Conceptual Framework for the International Classification of Patient Safety, 2009.) Harm to a thing: Damage to a thing may include damage to facilities or systems, for example environmental, financial etc. *For the purposes of the risk assessment the Risk Impact Table (Appendix 2, HSE Incident Management Framework) should be applied*
Hazard	A circumstance, agent or action with the potential to cause harm.
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user 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

Term	Definition
	• the environment
Incident Review	Incident review involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally
Integrated Risk Management	A continuous, proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective.
Review Commissioner	The person who commissions an incident review. For Category 1 incidents it is the Senior Accountable Officer (SAO) or person who has a direct reporting relationship to the SAO. For Category 2 incidents it is the Local Accountable Officer.
Reviewer	An individual who has training and experience in conducting reviews in accordance with HSE guidelines i.e. Incident Management Framework and / or Look-back Review Guidelines.
Just Culture	Just culture refers to a values based supportive model of shared accountability.
Local Accountable Officer (LAO)	This is the local manager who is responsible for the service in which the incident occurred e.g. Assistant Director of Nursing, Person In Charge, Business Manager, Clinical Lead.
Look-back Review (LBR)	A process consisting of four key stages: Preliminary Assessment, Look-back Review Risk Assessment, Audit and Recall. This process is initiated where a number of people have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and what needs to be done to take care of them.
Near-miss	An incident which could have resulted in harm, but did not either by chance or timely intervention.
Open Disclosure (OD)	Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)
Patient Safety Incident	A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means "an incident which occurs during the course of the provision of a health service" which: (a) has caused an unintended or unanticipated injury, or harm, to the Patient (b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm or (c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented. (Civil Liability Amendment Act 2017) Therefore a patient safety incident includes harm events, no harm events and near miss events.
Look-back Risk Assessment	A thorough assessment of potentially affected areas of the health service to determine the chance of harm and the seriousness of that potential harm following notification that a Look-back Review may be indicated. The Look-back Risk Assessment will be used to determine if the Look-back Review Process should proceed to the Audit and Recall Stages.
Recall	An act or instance of officially recalling someone or something. In the context of the Look-back Review Process, the Recall will involve the examination of the patient/ service user and/ or the review of all relevant records in line with the Terms of Reference and will identify any deviations from required standards of care. Appropriate corrective actions will be identified as appropriate.
Relevant Person	Relevant person", in relation to a patient, means a person— (a) who is— (i) a parent, guardian, son or daughter, (ii) a spouse, or (iii) a civil partner of the patient, (b) who is

Term	Definition
	cohabiting with the patient or (c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed (Civil Liability (Amendment) Act 2017) (as defined in the HSE Open Disclosure Policy) Note : This definition must not be conflated with the definition of "relevant person" in the Assisted Decision-Making (Capacity) Act 2015
Serious Incident Management Team (SIMT)	A Serious Incident Management Team (SIMT) is a standing group whose role it is to oversee the management of all serious incidents relating to the service. It is also convened following notification of a Category 1 incident. It is chaired by the Senior Accountable Officer (SAO) or a person nominated by the SAO who has a direct reporting relationship to the SAO. Decisions in relation to the review of Category 1 incidents must be made within one working week of notification of the incident to the SAO.
Senior Accountable Officer (SAO)	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 or hospital group, it is the hospital or hospital group chief executive officer).
Service User	The term "service user" in relation to a health services provider means a person to whom a health service is, or has been, provided.
Staff	(a) a person who: (i) has entered into, or works under (or where the employment has ceased, had entered into or worked under), a contract of employment, with the health services provider, or (ii) is (or was) placed for the purpose of vocational training with the health services provider, and (b) a fixed-term employee of the health services provider, and a reference to an employee, in relation to a health services provider, shall be construed as a reference to an employee employed by that health services provider. In line with the definition of Employee as defined in the (Civil Liability (Amendment) Act 2017)
Systems analysis Review of an incident	A methodical review 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 led up to the incident, identifying findings that the reviewers considered had an effect on the eventual harm, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable. The principles of systems analysis can be applied using a comprehensive, concise or aggregate approach.

6.0 Roles and Responsibilities

6.1 Role of Senior Accountable Officer (SAO)

As per the Incident Management Framework, the Serious Incident Management Team must be chaired by the Senior Accountable Officer (or designate[4]) in the relevant service area and both the SIMT and the SAO must be at a level appropriate to the potential seriousness and extent of the safety incident/ hazard prompting the Look-back Review (i.e. Service level, CHO/Hospital Group/ NAS level, Regional Health Area[5] or National HSE level as appropriate).

It is the role of Senior Accountable Officers in the HSE (and in HSE funded services) to:

- Ensure that effective Look-back Reviews are carried out when required, in line with HSE policies, procedures and guidelines and that adequate resources are allocated to facilitate effective Look-back Reviews;
- Convene a Serious Incident Management Team when deemed necessary to consider the Preliminary Assessment Form (as per the HSE Incident Management Framework) in order to identify if a Look-back Review should be commissioned. The SAO will also chair the Serious Incident Management Team;
- Commission a Look-back Review if deemed appropriate by the SIMT (if commissioned, the SAO becomes the Look-back Review Commissioner;
- Communicate findings of the Preliminary Assessment and the outcomes of each stage of the Look-back Review, through the appropriate governance channels to the relevant National Director(s)[6] and the HSE as appropriate and as per the agreed communications strategy;
- Implement the Patient Safety Notification (PSN) Protocol[7] where required. (Note: The PSN protocol may be activated at any stage of the Look-back Review when deemed necessary by the SAO.)

6.2 Role of Serious Incident Management Team (SIMT)

The SIMT is an important part of the governance arrangements for the management of Look-back Reviews. It is the role of the SIMT[8] to:

- Convene at the request of the SAO to determine the possible need for a Look-back Review;
- Consider the Preliminary Assessment Form and make a decision in relation to the requirement for a Look-back Review;
- Commission a Look-back Risk Assessment to identify the requirement to undertake the Audit and Recall stages of the Look-back Review;
- Decide on the requirement for progression to the Audit and Recall stages;
- Clarify the Scope and Terms of Reference for each stage of the Look-back Review;
- Oversee the management of all stages of the Look-back Review;
- Ensure the principles of timely Open Disclosure are adhered to and applied at all times and that there is a continuous process of timely and effective communication through the implementation of a comprehensive Communications Plan;
- Ensure that care and support has been provided to the persons affected and that actions have been taken to minimise the risk of further harm to the persons affected or others.
- Develop a Look-back Review Work plan which outlines the methodologies to be implemented in relation to the Audit and the Recall stages of the Look-back Review;

[4] The Senior Accountable Officer may identify an appropriate designate to take on the role of the SAO where required to avoid any unnecessary delays in convening the SIMT due to the absence/unavailability of the SAO

[5] In April 2022, the Government agreed to proceed with setting up six Regional Health Areas (RHAs) within the HSE, on the basis of the geographical boundaries agreed by the Government in July 2019. The design of the RHAs will be completed in 2022, there will be a phased introduction of the new bodies in 2023 and they will be fully operational from 2024 https://healthservice.hse.ie/staff/news/hse-to-establish-six-regional-health-areas/

[6] i.e. The National Director(s) operationally responsible for the service(s) included in the Look-back Review

[7] HSE and the Department of Health Communication Protocol, Communications in relation to major/significant patient/service user safety incidents and issues of concern, February 2022.

[8] Read in conjunction with the role of the SIMT outlined in the Incident Management Framework

- Ensure that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Look-back Review, for instance; agree referral pathways, rapid access clinics, diagnostic or pathology services, etc.;
- Ensure that service managers allocate the necessary resources to implement the Look-back Review;
- Prepare a detailed anonymised report on the completed Look-back Review
- Ensure timely communication and implementation of recommended actions arising from the Look-back Review;
- Where national learning and recommendations are identified, share these, through the appropriate governance channels, with the National Director and work with them to identify the appropriate national lead and agree the implementable actions with them;
- Ensure that all required details re the Look-back Review are documented on the National Incident Management System (NIMS).

6.3 Role of Audit Team

It is the role of the Audit Team to

- Apply the audit methodology, developed as part of the Look-back Review Work Plan by the SIMT, to the cohort of patients identified through the Look-back Risk Assessment;
- Inform the SIMT of those identified by the audit process as requiring inclusion in the Recall stage of the Look-back Review.

6.4 Role of the Recall Team

Upon completion of the Audit stage of the Look-back Review, it is the role of the Recall Team to

- Undertake an examination of the patient/service user and/or review relevant information and results etc. in line with the Look-back Review Work Plan and the requirements of this guideline;
- Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Review;
- Implement any corrective actions as appropriate and communicate any additional actions to be taken to the SIMT for further action.

6.5 Role of National Director

It is the Role of the National Director to:

- Ensure that the Look-back Review is being undertaken in line with the requirements of this guideline;
- Provide required management advice/guidance and support to the Look-back Review Commissioner, the SIMT and the Recall Team as required;
- Provide assurance on the progress of the Look-back Review to the National Quality and Patient Safety Directorate;
- Ensure that required actions identified by the Look-back Review are implemented;
- Liaise with national leads where national recommendations have been identified to ensure the national leads are aware of the findings and they are implementable.

6.6 Role of the Director of Quality and Patient Safety (QPS) or Heads of Quality, Safety and Service Improvement (HQSSI)

It is the role of the Director of QPS (within each Hospital Group)) or Heads of Quality, Safety and Service Improvement (within each Community Organisations) (or their designate) to:

- Provide procedural support and advice through the SIMT as required in relation to the implementation of the processes outlined in this guideline;
- Provide support to the Look-back Audit and Recall teams in relation to the procedures to be implemented;
- Advise and support timely and effective communications and Open Disclosure throughout the Look-back Review;
- Advise in relation to the completeness and quality of the Look-back Review Report.

6.7 Role of the National Quality and Patient Safety Directorate

It is the role of the National Quality and Patient Safety Directorate to:

- Provide procedural support and advice to the HSE in relation to the implementation of the Look-back Review Guideline;
- Seek updates and assurance in relation to the conduct and findings of the Look-back Review through the appropriate governance line[9];
- Implement a document control process in relation to this guideline and to ensure that the correct version of the guideline is being accessed and utilised;
- Ensure that a process is in place to undertake timely reviews of this guideline and to make the required changes to the guideline in response;

[9] As per the HSE Performance Accountability Framework and as agreed in the HSE and the Department of Health Communication Protocol, Communications in relation to major/significant patient/service user safety incidents and issues of concern (Patient Safety Notification (PSN) Protocol) , (February 2022)

Section 7.0: Look-back Review Process

7.1 Introduction

The HSE Incident Management Framework defines a Look-back Review as a *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*. The circumstances for which a Look-back Review would be considered are:

- Audits showing that the results delivered by either a service or an individual were not in line with best practice standards and there is a concern that there was potential harm caused to a cohort of service users as a result;
- Identification of a faulty batch of medicines/ vaccines.
- Equipment found to be faulty or contaminated in a manner that may put people at risk of harm;
- Concern about missed, delayed or incorrect diagnoses related to diagnostic services such as radiology/pathology services etc.;
- Identification of a staff member who has been involved in exposure-prone procedures when there are indications that the staff member should not have done so e.g. Hepatitis B infected;
- Where concerns were raised due to staff competence, practice, treatment or care provided by a staff member/group of staff;
- As a result of findings of an incident review.

This guideline outlines a four phase approach to the conduct of a Look-back Review i.e. Preliminary Assessment, Look-back Review Risk Assessment; an audit of records to identified those potentially affected; and patient recall.

Decision to conduct a Look-back Review
The decision to conduct a Look-back Review is a difficult and complex one and should not be taken lightly. A Look-back Review should only be considered in circumstances where it is indicated following careful risk assessment. This Risk Assessment may necessitate external peer review and advice from senior management and/or others with knowledge and experience in Look-back Reviews and in the subject area in which a Look-back Review is being considered.

All processes are subject to variation in performance over time (common cause variation).
Sometimes variation is greater than expected, suggesting a specific cause for performance falling outside the usual range (special cause variation). Causes for special cause variation need to be sought in particular, once it is identified (Nolan et al., 1990).

A level of risk and uncertainty pervades all medical practice, and some areas of practice more than others e.g. Radiology. Evidence from the literature would suggest that Look-back Reviews in areas such as Radiology require particularly careful consideration as they are labour and resource intensive and are usually high cost. This can result in resources being diverted away from current patient care (Brady et al., 2012).

Nonetheless, when clearly indicated, a Look-back Review must be initiated where there is a requirement to determine if the level and nature of the risk is above the expected norms and to take the necessary action to identify patients who have been exposed to a hazard and ameliorate any harm.

The decision to undertake a Look-back Review should be based on a rigorous risk assessment process that identifies that patients were (a) exposed to a hazard and (b) that a means of amelioration exists. In circumstances where these criteria are not met but there is a requirement to conduct a review other methodologies e.g. audits or case reviews should be employed; for instance, when there is a demand for

retrospective reviews for the purpose of detecting and disclosing historic adverse events for which clinical remediation/intervention is not available, often in response to or anticipation of public or political demand.

Look-back Reviews by their nature are high volume, high-complexity and high cost. They involve multiple stages, logistical challenges and cumulative delays. Once a decision has been reached to undertake a Look-back Review, the process should be resourced and expedited along with parallel investigations linked to but not part of the Look-back Review.

Other Investigation/Review Processes

Look-back Reviews are carried out to in order to identify if any of those exposed to a hazard has been harmed, and to identify the necessary steps to take care of those harmed. Parallel reviews or investigations will be required to identify Contributory Factors related to the event in the first place as this may lie outside the scope or not be evident from the Look-back Review Process. In some circumstances a Look-back Review may be prompted by a preceding incident review.

Look-back Reviews may raise issues of professional competence/conduct, or a competence review may prompt a Look-back Review in the first place. Competence assurance is a matter for regulatory and professional training /accreditation bodies and performance is managed through executive and clinical governance structures in accordance with contractual conditions and relevant HSE HR policies and procedures.

Finally, external agencies such as the Health Information and Quality Authority (HIQA) are empowered to undertake independent external reviews of patient safety issues in the public health system and have done so since their establishment in 2007. This does not negate the service responsibility to conduct its own internal investigations/reviews and to conduct Look-back exercises when merited in the interest of patient care and safety.

Stages of the Look-back Review

The Look-back Review is divided in to four distinct stages:

1. **SIMT and Preliminary Assessment Stage (section 7.2)**
2. **Look-back Review Risk Assessment Stage (section 7.3)**
3. **Audit Stage (section 7.4)**
4. **Recall Stage (section 7.5)**

The following sections and process map outline the steps to be taken when commissioning and conducting a Look-back Review in the HSE.

Figure: 1A: Look-back Review Process Map: Stage 1 and Stage 2

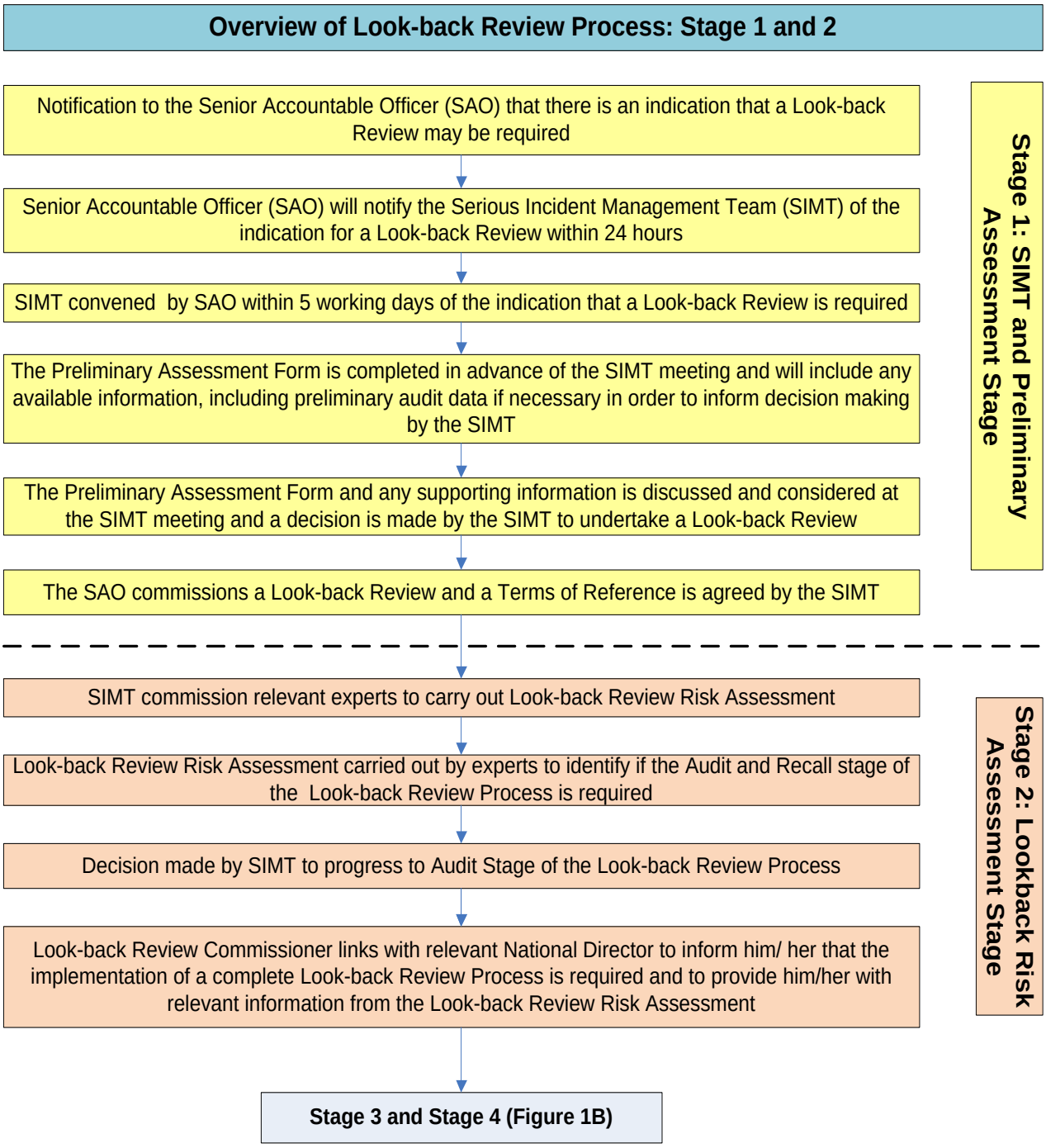
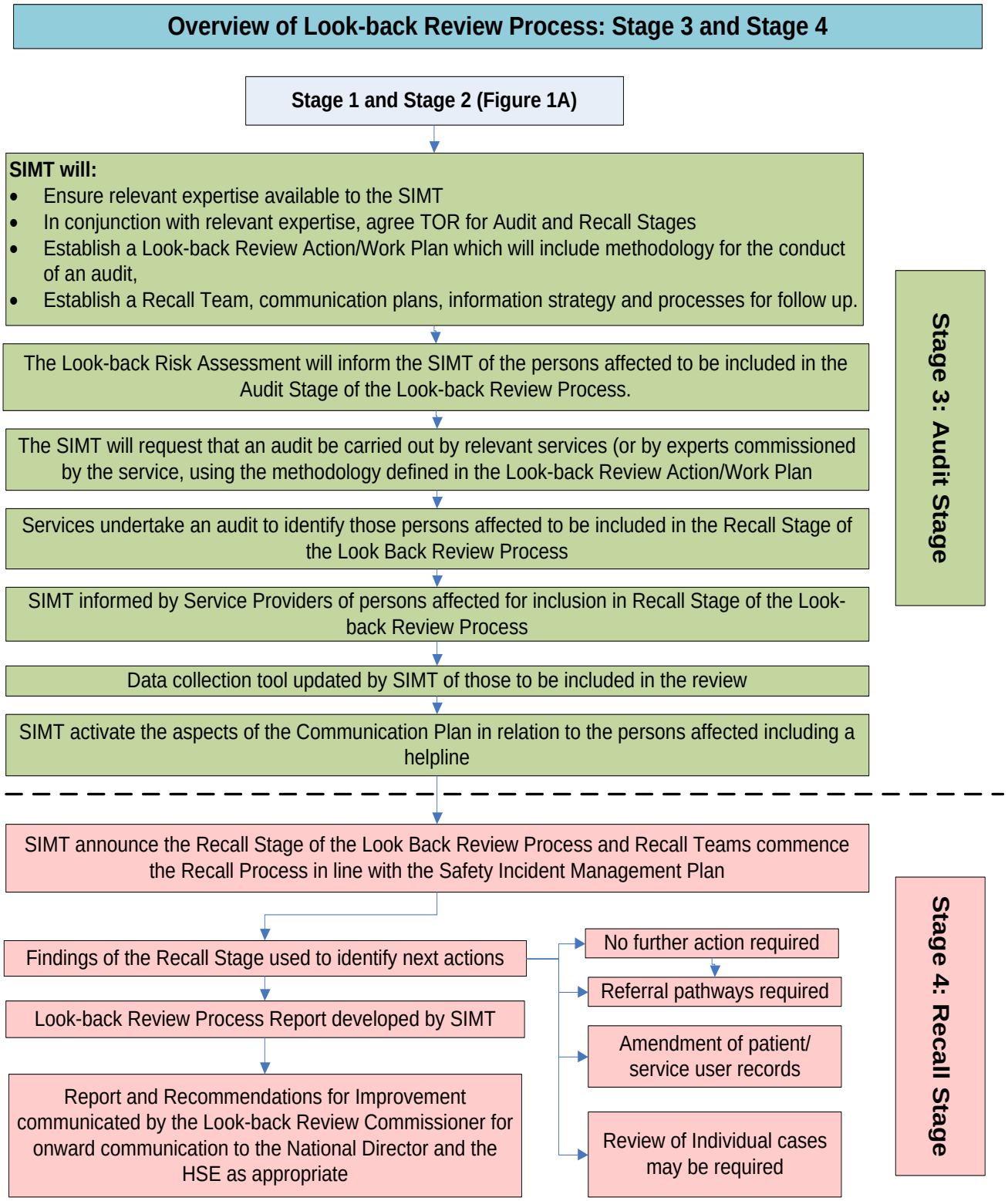
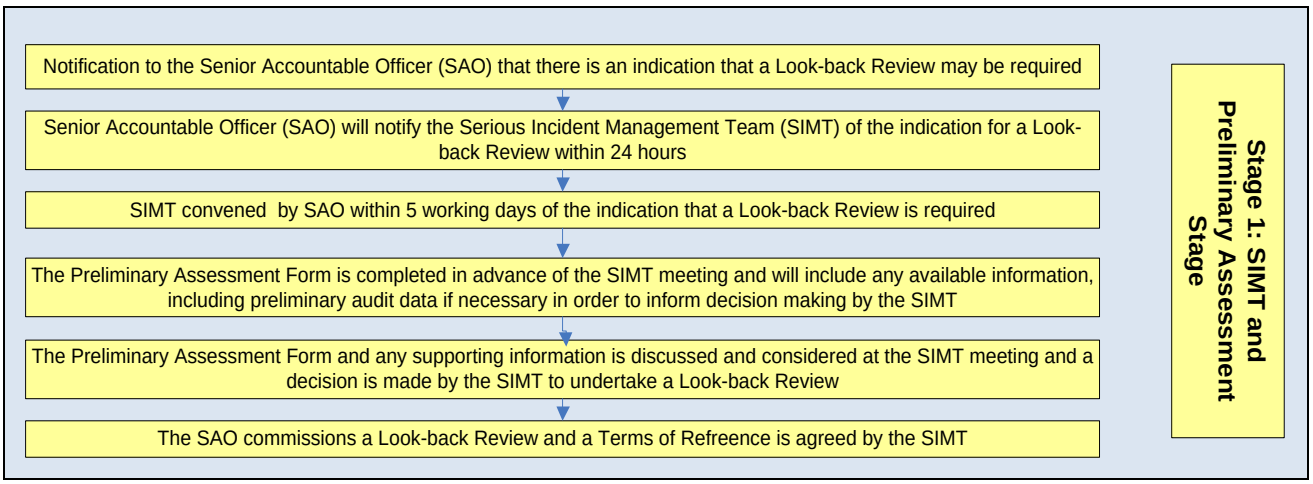


Figure: 1B: Look-back Review Process Map: Stage 3 and Stage 4



Note: One page diagram of the Look-back Review Process is available on the Incident Management Webpage at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/

7.2 Stage 1: Senior Accountable Officer (SAO) Notified and Preliminary Assessment Undertaken.



7.2.1 The SAO for the service within which the safety incident/ hazard has been identified must be immediately notified that such an event has been identified and that a Look-back Review may be required.

7.2.2 The SAO will notify the SIMT of the safety incident/ hazard within 24 hours and, in line with the HSE Incident Management Framework (IMF), the SAO will convene a meeting of the SIMT as soon as possible and no later than 5 working days of the SAO being notified of the safety incident/hazard. The composition of the SIMT is detailed below.

Composition of the Serious Incident Management Team

The composition of the SIMT will be dependent on the service involved and the nature and extent of the Look-back Review Process but must not involve personnel who may have been directly involved in the event/hazard that triggered the Look-back Review. The level and membership of the SIMT must be appropriate to the potential seriousness and extent of the safety incident/ hazard prompting the Look-back Review. Recommended membership of the SIMT to support the management of the Look-back Review includes but is not limited to:

- Look-back Review Commissioner (Chair)
- Relevant Service Managers
- People with expertise (including clinical) in the services/ processes which are the subject of the Look-back Review Process
- People with expertise in the look-back Review and Incident Management Process
- Director of Quality and Patient Safety (QPS) or Heads of Quality, Safety and Service Improvement (HQSSI) (or designate)
- Communications Manager
- HR Manager
- IT Support
- Medical Records Manager

Depending on the situation, certain functions may attend the SIMT on an as required basis and at the discretion of the SAO.

Non-HSE members of patient representative groups may be included as members of the SIMT if required. In these instances, a confidentiality agreement must be signed by the patient representative.

Sub teams may be established within the SIMT to support the Look-back Review e.g.

- Clinical Expert Team
- Communications Team
- ICT Team etc.

The membership of the SIMT may need to be reconsidered and amended as more information becomes available and additional support and expertise is required.

Note: In general, expertise already available from within the HSE should be sufficient to undertake Look-back Reviews. *If, in exceptional circumstance, experts external to the HSE are required to support any stage of this process, as per the HSE Incident Management Framework, the Chair of the SIMT may use locally agreed processes to identify appropriate experts or may request a nomination for external expert support to the Look-back Review via the Forum of Postgraduate Training Bodies[10], a form for which is available on the QPS Incident Management section of the National Quality and Patient Safety Directorate website at* https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management

7.2.3 In order to assist decision making at the SIMT meeting, the SAO must ensure that all available information in relation to the safety incident/hazard is gathered in order to inform the completion of Part A of the Preliminary Assessment Form (as per the IMF). This information may include a Healthcare Record Review or an initial exploratory audit of a sample of records, databases etc. to provide additional clarity about the potential effects of the safety incident/hazard.

7.2.4 At the SIMT meeting, the SIMT will review the Preliminary Assessment Form and all available supporting information and will make a decision as to whether or not a Look-back Review is required.

7.2.5 Regardless of the decision in relation to a Look-back Review, once identified that a patient or service user was harmed then there must be Open Disclosure as soon as reasonably practicable and in line with the HSE Open Disclosure Policy following the incident so that discussions in relation to the Look-back Review do not delay the Open Disclosure process.

7.2.6 If the SIMT determine that a Look-back Review is not required, this is documented along with the rationale supporting the decision on Part B of the Preliminary Assessment Form. This decision must be referred to the relevant Quality and Safety Committee (or equivalent committee) for review where the decision can be ratified or referred back to the SAO[11].

7.2.7 Where a decision is made by the SIMT that a Look-back Review is required the SAO will commission the Look-back Review Process.

7.2.8 Details of the Preliminary Assessment and the decision made must be immediately documented on NIMS.

Key Message: Documenting the Look-back Review on NIMS
One overarching incident may be reported for the Look-back Review detailing how many patients were affected and the outcomes of the stages of the Look-back Review. However, individual incidents of patient harm and which are included in the Look-back Review, must be recorded separately on NIMS (i.e. recorded as individual incidents) and linked on NIMS to the Look-back Review incident. This allows for the identification of all incidents linked to the Look-back Review and the management of open disclosure requirements on NIMS.

[10] The completed Request Template and an appropriate Terms of Reference should be submitted to the QPS Incident Management Team via QRS.tullamore@hse.ie who act as the point of contact with the Forum of Irish Postgraduate Medical Training Bodies.
[11] As per the IMF, even if a decision not to undertake a Look-back Review is taken, through the completion of the preliminary assessment and the information gathering, areas for improvement or requiring focus may have been identified and must be considered by the SIMT and the relevant Quality and Safety Committee.

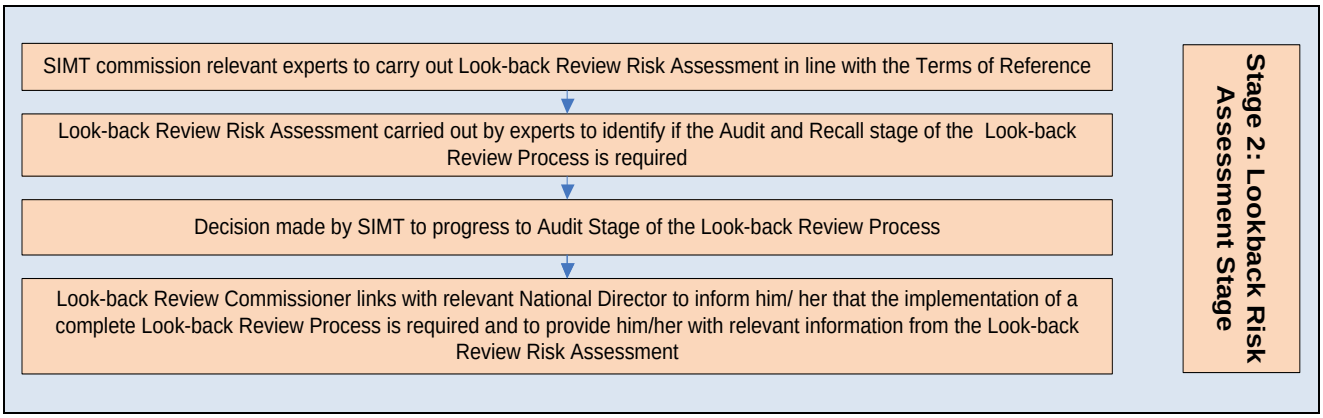
7.2.9 The SIMT will develop and agree the Terms of Reference for the Look-back Review (see **Appendix 6A**).

7.2.10 A Look-back Review does not replace the requirement to undertake an incident review. The SIMT will also identify if a review of the safety incident/hazard is required (if not already being undertaken) for the purposes of system learning and this will be initiated in line with the HSE Incident Management Framework and relevant Terms of Reference agreed in terms of scope, etc.

7.2.11 Where the Look-back Review stems from a review of an incident, a SIMT will already be in place and in this case the role of the SIMT is extended to include the management of the Look-back Review. The composition of the team should be reviewed to ensure that the Team consists of the appropriate personnel and expertise to manage the Look-back Review.

Reminder: Open Disclosure:
Open Disclosure must be implemented in line with the HSE Open Disclosure Policy; it must be considered and applied at every stage of the Look-back Review and must be central to the Look-back Review Communications Plan.

7.3 Stage 2: Look-back Review Risk Assessment



In all cases, if a Look-back Review is commissioned by the SAO, the Look-back Review Risk Assessment is undertaken to identify if there is a requirement to progress to the Audit Stage and the Recall Stage of the Look-back Review. Each of these stages is described in detail in the following sections of this guideline.

7.3.1 The first phase in the Look-back Review is to undertake a Look-back Review Risk Assessment to determine whether the Look-back Review should progress to the Audit and Recall stages.

7.3.2 A decision to undertake the complete Look-back Review has major consequences for service users, providers and resources. The risk assessment, therefore, should provide a thorough assessment of the chance of harm and the seriousness of that potential harm. It must be conducted in a manner that balances the need to identify and address all cases where there might be safety concerns on the one hand, with the need not to cause any unnecessary concern to patients or to the public on the other.

7.3.3 The SIMT will commission relevant experts to undertake this Look-back Review Risk Assessment and must ensure that the Risk Assessment is informed by subject matter experts (clinical or otherwise). Relevant experts will be from within the HSE and may include but are not exclusive to people with expertise in the services/ processes which are the subject of the Look-back Review, Risk Managers, and Public Health Specialist etc. This will be determined by the SIMT on a case by case basis.

7.3.4 Where expert and specialist opinion, external to the HSE, is required the HSE Incident Management Framework provides guidance for accessing external independent experts for HSE Safety Incident Reviews.

7.3.5 The Look-back Review Risk Assessment will look at:

- **The potential extent of the issue and the level of exposure to the safety incident/ hazard;**
- **Evidence of harm that has occurred;**
- **The likelihood of future harm occurring;**
- **The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc.;**
- **The potential impact of the issue;**
- **The potential cohort of service users affected i.e. age group(s) and timeframe(s) to be considered;**
- **The manner in which harm would be ameliorated (e.g. repeat investigation / onward referral for treatment)**
- **If the Look-back Review Process is limited to one HSE site or if the process will involve a number of HSE sites.**

A template Look-back Review Risk Assessment form is included in **Appendix 1** of this document.

7.3.6 Using the information obtained from the Look-back Review Risk Assessment, the Look-back Review Commissioner and the SIMT must decide if the Look-back Review should proceed to the Audit and Recall stages. If a decision is made not to proceed to the Audit and Recall stages, this decision must be communicated by the Look-back Review Commissioner through the appropriate management structures to the relevant National Director, outlining clear reasons for the decision.

7.3.7 If the Look-back Review Risk Assessment identifies that the Look-back Review should progress to the Audit and Recall stages, the Look-back Review Commissioner will evoke the Patient Safety Notification (PSN) Protocol[12].

7.3.8 The relevant Operational National Director and Clinical National Director of NQPSD will be alerted through the PSN Protocol, who will inform the Chief Operating Officer and Chief Clinical Officer respectively. The COO and CCO will then communicate this to the CEO of the HSE and the Safety and Quality Committee of the HSE Board.

7.3.9 During all stages of the Look-back Review, the SIMT must ensure the following:

- That Open Disclosure requirements are adhered to at all times during the conduct of the Look-back Review. Following initial Open Disclosure, there may be a requirement for further disclosure as the Look-back Review progresses.
- Any immediate safety concerns that arise at any stage of the Look-back Reviews are addressed promptly. These would include but are not limited to:
    - Taking preventative action such as the removal of the hazard;
    - HR management of staff member(s)/service whose caseload is under review as part of the Look-back Review[13];
    - Notification of relevant authorities/regulatory bodies as required, including bodies outside Ireland[14];
    - Clinical management and support of patients / service users/ staff identified by the Preliminary Risk Assessment and suspected of being adversely affected;
    - Providing support to staff involved.
    - Any identified patient safety or quality issues are addressed appropriately.
- The fact that a full Look-back Review is being considered can often become publicly known at the planning stage. Even if this does not occur, the SIMT needs to consider **Communications** and **Open Disclosure** as critical processes in managing the Look-back Review (See section 7.7).

7.3.10 At all stages of the Look-back Review, the Look-back Review Commissioner and the SIMT will ensure that service managers are implementing contingency plans for service continuity where necessary. This will include providing for additional health care demands which may arise as a consequence of the Look-back Review Process, for instance; agree referral pathways, rapid access clinics, diagnostic or pathology services etc.

7.3.11 The Look-back Review Commissioner is responsible for ensuring that the necessary resources are allocated to conduct the Look-back Review. If the resources required exceed what is available to the Look-back Review Commissioner, then he/she must escalate this to the relevant National Director.

[12] This is coordinated through the National Quality and Patient Safety Directorate (NQPSD) as per the Patient Safety Notification Protocol

[13] Staff members involved in any stage of the Look-back Review will be made aware by the Serious Incident Management Team of their right to representation by staff representative or trade union.

[14] Refer to IMF for guidance

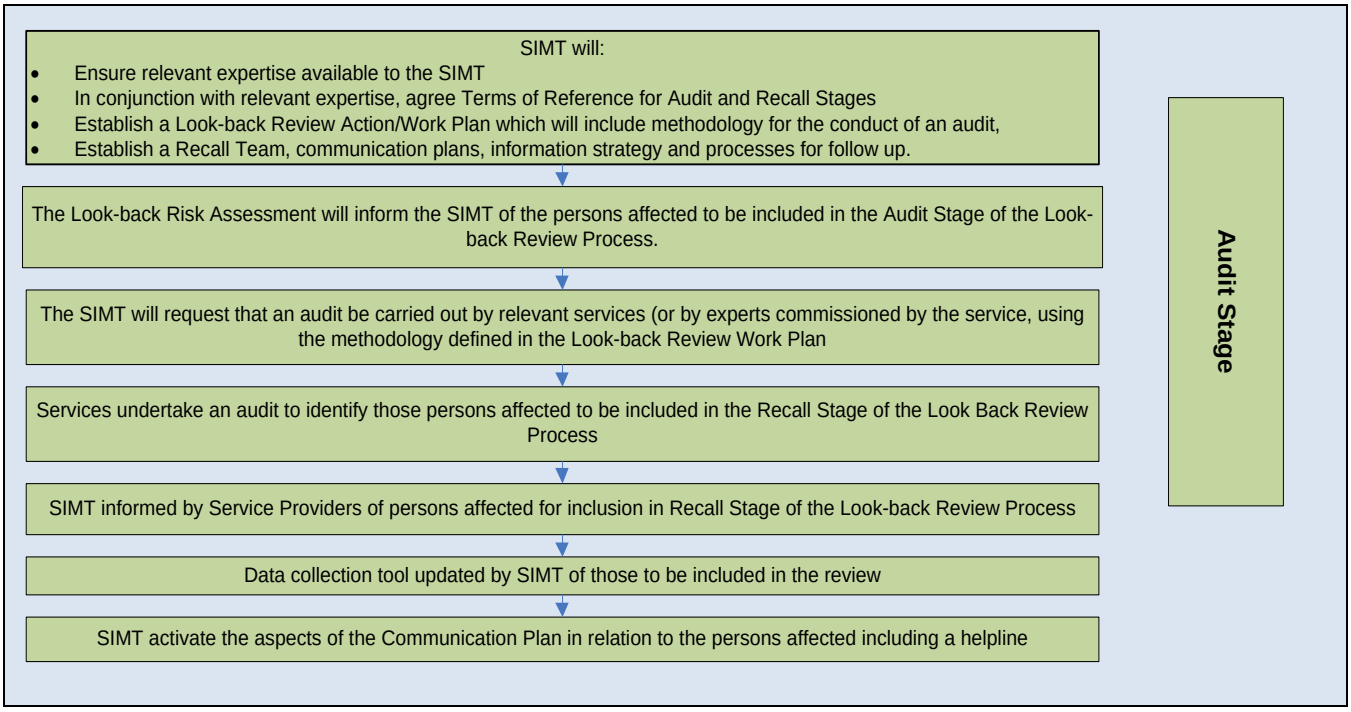
7.3.12 Incident Review

In general, a review of an incident may be initiated before a Look-back Review and may prompt or inform the initiation of a Look-back Review. However, it is also possible that an incident review may be prompted at any stage of the Look-back Review. If it is identified during the Look-back Review that it is appropriate to undertake an incident review in line with the HSE Incident Management Framework, this investigation may run in parallel with the Look-back Review Process and must be undertaken in line with the requirements of the HSE Incident Management Framework Guidance.

This Look-back Review guideline cannot be prescriptive on the timing, nature and number of incident reviews that may be required as this will be specific to each Look-back Review.

7.4 Stage 3: Audit Stage

In the context of the Look-back Review, the Audit Stage involves the review of care/ processes against explicit standards and criteria to identify those who may not have received the required standard of care.. The objective of the Audit Stage is to identify the patients / service users/ staff (persons affected) that must be included in the Recall Stage of the Look-back Review.



7.4.1 Terms of Reference

Immediately following the decision by the SIMT to proceed to the Audit and Recall stages of the Look-back Review, the SIMT will agree the Terms of Reference for the Audit stage of the Look-back Review (See **Appendix 6B** of this guideline).

7.4.2 Inclusions to the Audit Stage

The SIMT will identify from the information obtained by the Look-back Review Risk Assessment, the cohort of patients/service users/staff/services, etc. and the relevant time frame(s) to be included in the Audit stage of the Look-back Review and the Look-back Review Commissioner will communicate this to the relevant service providers.

7.4.3 Look-back Review Work Plan

The SIMT will establish a Look-back Review Work Plan. As required, linkages may be also made with expert resources such as relevant Professional Bodies and Faculties (e.g. The Academy of Clinical Science and Laboratory Medicine, Faculty of Radiologists, Royal College of Physicians of Ireland, Royal College of Surgeons of Ireland, Irish Nursing Board etc.) to assist with the development of this plan and to ensure that the plan is in line with evidence based best practice.

The Look-back Review Work Plan will include (but is not limited to):

- The management of immediate safety issues;
- Care for those harmed/affected including service users, the public and staff;
- Contingency planning for service continuity;
- Clear processes for the Audit stage (the function of which is to identify the patients/ service users/ staff (i.e. persons affected) to be included in the Recall Stage). This will include the development/ agreement of the:
    - Audit Criteria (e.g. criteria as to what will be considered within acceptable practice limits, minor or major discrepancy, the clinical significance of these discrepancies, and actions to be

taken in each category and will be guided by national and international best practice, faculty requirements etc.);
    - Scope of Audit (including timeframes and definition of records to be reviewed);
    - Audit Methodology;
    - Audit Tool (may be developed by the SIMT in conjunction with relevant expertise or adopted from existing validated tools);
    - Instructions for analysis of audit data;
    - Process for the submission of audit outcomes to the SIMT
- Procedures for ensuring the validity and reliability of the Audit stage to ensure that all auditors interpret and apply audit criteria in the same way;
- Recall Stage methodology (see section 7.5);
- Communications Plan (see section 7.7);
- Information and Help Line Plan;
- Plans for patient/ service user follow up following both the Audit and Recall Stages;
- Quality and Safety Improvement Plan;
- Composition and expertise of the Recall Team(s) e.g. if the Look-back Review Process is being carried out in multiple HSE sites, a number of Recall Teams may be required and this should be considered as part of the Look-back Review Work Plan.
- **Note:** The SIMT should give special consideration in the Look-back Review Work Plan as to whether or not the cases of deceased persons meet the inclusion criteria, how their records should be handled and how best to communicate with their relatives.

7.4.4 Establishment of a Data Collation Tool

At the earliest stage following the Look-back Review Risk Assessment, a data collation tool is created by the SIMT to collate the details of patients /service users/ staff that have been identified by the Look-back Review Risk Assessment (section 7.3) for inclusion in the Audit Stage of the Look-back Review.

The data collation tool will be used to document the patients /service users/ staff who are included and excluded following each stage of the Look-back Review and each should be allocated a unique identifier number. In general, it will be used to track persons affected and to record actions, interventions and outcomes.

This data collation tool will be held and maintained within the healthcare setting which is subject to the Look-back Review.

Note: The personal information for patients /service users must be treated in the strictest confidence. Patient personal information may be entered on to the data collation tool if access to the data collation tool is strictly limited to the healthcare team who would ordinarily have the right to access personal information belonging to the persons affected.

However, if the data collation tool may be accessed by healthcare personnel who would not have a right to access personal information belonging to the persons affected, and consent has not been provided by the patient for these personnel to view their personal information, then **details for the persons affected must be sufficiently anonymised**. This would ensure that an individual is not identifiable to those viewing the data collation tool. A coding system will be required for the data collation tool in order for the healthcare team(s) for the persons affected to identify the persons affected where required and where they have a right to do so.

Specific data variables (i.e. data to be collected) will be determined by the nature of the incident, and the audit methodology being applied. An extract of this data collation tool may be exported to develop a more detailed data collation tool to facilitate the Look-back Review in later stages.

A suggested core dataset for the Look-back Review data collation tool is outlined in **Appendix 2.** Ideally, the use of a data collation tool already developed by a professional body (e.g. Faculty of Radiologists) or a previous SIMT is preferred.

Prior to commencing the Recall Stage of the Look-back Review, the data collation tool should be cross referenced with any available public records such as Dept. of Social Protection records, Register of Deaths, obituary websites such as www.RIP.ie etc. to help identify any people who may now be deceased. Hospital records and local knowledge (e.g. GPs, Public Health Nurse, Community Welfare Officers, etc.) are also relevant in this process.

As the data collation tool must be updated each time a person affected is being reviewed or has contact with the Look-back Review, it is essential that the Look-back Review Work Plan considers designated responsibility for data collation tool management, providing for constant validation of the data on the data collation tool, insurance against double entry etc. Meticulous attention to detail is required. It should also allow for noting persons affected who may wish to be excluded from the recall stage of the Look-back Review.

Appendix 5 of this guideline also provides details of good practice in relation to the collection and storage of information, confidentiality and data protection.

7.4.5 Undertaking the Audit

The objective of this audit is to identify the persons affected that must be included in the Recall Stage of the Look-back Review. Service providers will be requested by the SIMT to audit the relevant records/ notes etc. of the persons affected identified by the Look-back Review Risk Assessment, using the audit methodology and tools defined in the Look-back Review Work Plan. **Such audits must be conducted in line with legislation and good practice related to data protection and confidentiality.**

Audit Lead and Audit Team

An audit lead should be identified by each Service Provider to coordinate the audit within their service. Service Providers may have the relevant expertise to undertake the audit themselves, they may seek the assistance of those with audit expertise to undertake the audit, or may commission relevant experts to undertake the audit if required.

Key Message: Audit, Consent and Confidentiality[15]
The audit of patient/service user's healthcare records should be undertaken by the healthcare team who would ordinarily have the right to access the patient /service user's healthcare records as part of the delivery of healthcare.

However, if the audit team is extended to include healthcare personnel who would not have a right to access the patient/service user's healthcare records, and consent has not been provided by the patient for these personnel to access their records, then these records must be sufficiently anonymised so that an individual is not identifiable to those undertaking the audit.

[15] **Audit and Consent. The HSE National Consent Policy (2022) states the following:**
If the audit is to be conducted by those involved in the care of the individual or their support staff (e.g. clinical audit staff) then explicit consent is not required provided that the individual:
- Has access to information outlining the possibility that their personal data may be disclosed for local clinical audit; and
- Has been given an opportunity to opt out.

Where clinical audit is to be conducted by an external third party, then the data must be de- identified (therefore no consent would be required). In cases where identifiable data is necessary for clinical audit purposes, the data may only be disclosed to third parties with the explicit consent of the individuals concerned.

Audit Prioritisation
In incidents involving large numbers, the SIMT will determine the order in which the audit should proceed, prioritising on the basis of risk.

Immediate Safety Concerns
As stated previously any immediate safety concerns that arise at any stage of the Look-back Review process are communicated to the Chair of the SIMT for appropriate onward communication and action.

7.4.6 Upon completion of the audit, Service Providers will provide the SIMT with the audit outcomes which will inform the SIMT of the persons affected to be included in the Recall Stage of the Look-back Review. The relevant National Director is informed by the Look-back Review Commissioner of the outcome of the Audit Stage.

7.4.7 Any incidents identified by the Audit Phase of the Look-back Review must be documented individually on NIMS and linked to the overarching Look-back Review incident on NIMS. (See section 7.2.8).

7.4.8 The data collation tool established as per 7.4.4 above will be used by the SIMT to track records through the audit and to record the outcomes of the audit.

7.4.9 Establishment of a Recall Team
Following completion of the audit which will identify all the persons affected whose care/management requires further action/intervention related to the event/hazard covered by the Look-back Review process, the SIMT will establish the Recall Team(s) which will consist of experts in the subject area/ discipline which is covered by the look back process. The SIMT must agree with the Recall Team(s) a realistic work-plan with timelines that reflect the urgency and complexity of the Look-back Review. ***Refer to section 7.5 which details the Recall Phase of the Look-back Review.***

7.4.10 Roll out of Communication Plan
The SIMT will commence rolling out the relevant elements of the Communications Plan as per the Look-back Review Work Plan. Even the most routine and low risk Look-back Review will be a cause of concern for the people involved. From the outset, the HSE must ensure that information for and communication with all persons affected is handled sensitively with care, compassion and consideration. ***Please refer to section 7.7 of this guideline for specific guidance on the content and roll-out of the Communication Plan.***

Key Message: Findings in relation to the Look-back Review Process should not be released into the public domain until the Look-back Review Process is complete, all the findings are known and all persons affected are informed of the implications for them.

7.4.10 Establishment of an Information Line
The SIMT must consider the establishment of an Information Line as part of their communication strategy. People are usually informed of their inclusion in the Recall stage of the Look-back Review by letter (see section 7.5), which will give details of telephone numbers where they can call to acknowledge receipt, and for more information or support. The information line is a general information line, the function of which is to provide general information only about the Look-back Review and to make arrangements for the person ringing the information line to get a return call from the relevant service involved in the Look-back Review to discuss any queries/ concerns the caller may have.

Key message: It is recommended that site specific information lines be established for persons affected and a general HSE information line should be established for the wider public.

The SIMT should be prepared to deal with large numbers of calls to and from persons affected, their families and the wider public. The information line should be staffed by HSE personnel (including nurses and midwives, allied health professionals and doctors) who are adequately trained and informed to manage the information line.

Setting up the information line involves the following tasks:

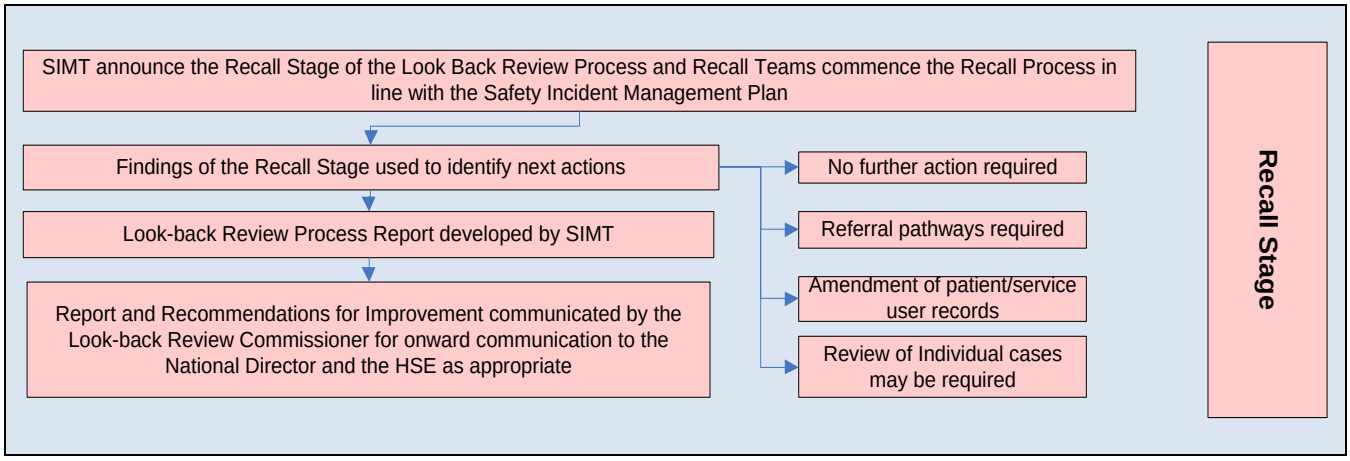
- Identification and appointment of staff to manage all aspects of the information lines;
- Identification of a suitable venue;
- Identification of dedicated telephone numbers and suitable equipment;
- Data collation tool access and ensuring compliance with GDPR;
- Agreeing opening times;
- Staff briefing training and access to standardised documents including FAQ documents, press briefings, letters etc.;
- Agreement on the information to be collected from those contacting the information line[16];
- Production of rotas.

Appendix 3 contains detailed guidance on information lines.

Reminder: Open Disclosure: Open Disclosure processes must be implemented in line with the HSE Open Disclosure Policy; it must be considered and applied at every stage of the Look-back Review and must be central to the Look-back Review Communications Plan.

[16] To the extent that information is recorded arising from such calls, the data subject, the identifiable individual whose data is so recorded, can make an access request pursuant to Section 4 of the Data Protection Acts 1988 and 2003 and that may result in the data subject obtaining a copy of this information. This is an important consideration in terms of what is recorded and will necessitate that individuals have clear guidelines in terms of what they record about an individual, notably that they be careful that descriptions or statements that they make about an individual are accurate and reasonable.

7.5 Stage 4: Recall Stage



7.5.1 Announcing the Recall Stage of the Look-back Review

The Recall Stage is announced to the public by the SIMT in conjunction with the relevant National Director and in line with the communication strategy developed by the SIMT (see Section 7.7 re Communications).

In accordance with the communication principles outlined in section 7.7, **the SIMT should strive to ensure that the Recall Stage of the Look-back Review is not publicly announced until all persons affected have been notified.** Regrettably this is not always possible so media communications should be prepared and ready for issue at all times. It is often the case that the Recall Stage of the Look-back Review is announced when a person affected or a relative notifies the media upon receipt of a letter or call from the SIMT.

Timing of patient communication is critical and every effort should be made to notify the entire group to be reviewed within as short a timeframe as possible; preferably all on the same day. The method of arranging timely communication will depend on the numbers concerned. Practical considerations such as posting letters early in the working week to maximise the personnel available to deal with queries arising and minimise the risk of un-opened letters over the weekend should be taken into account. If a press release is planned then it should be timed for late evening on the day after letters have been posted, to ensure that letters have been delivered and opened.

It is also important to co-ordinate public information with communication with staff and other parties such as advocacy groups etc. Briefing sessions may be necessary for this purpose.

7.5.2 Planning the Recall Stage

Note: Where Recall Stage involves persons affected in multiple locations, the establishment of multiple Recall Teams should be considered. All Recall Teams will be overseen by the Serious Incident Management Team and will operate in line with the Look-back Review Work Plan.

Prior to commencing the Recall Stage, a Terms of Reference for the Recall Stage must be agreed by the SIMT (see **Appendix 6C**). The Terms of Reference should include but is not limited to the following information:

- Purpose
- Scope
- Time frame
- Recall Team Members

- Recall Method
- How recommendations will be communicated and implemented
- Communication Strategy

In planning the Recall Stage, the following factors must be considered by the SIMT:

- Terms of Reference (TOR) for the Recall Phase;
- Venue(s) for the conduct of the Recall stage;
- Administrative support, including:
    - Medical records staff support for the retrieval of notes/x-rays/test results;
    - Appointment system including Did Not Attend (DNA) management;
    - Management arrangements for assisting persons affected to attend for recall stage e.g. maps, locations, public transport, taxis, meals and so forth;
    - Data collation tool management.
- Secure diagnostic clinical support i.e. laboratory/x-ray/pathology etc., including systems for transportation of samples and results;
- Systems for recording of results.
- Requirements of Open Disclosure

A liaison person/team should be appointed to oversee the seamless conduct of each attendance a person affected has as part of the Recall stage, e.g. whether they are clinic appointments or repeat tests/x-rays etc. Responsibilities would include:

- Providing a point of contact for persons affected;
- Ensuring appropriate linkages with vulnerable groups e.g. minors, those without capacity, older persons etc.
- Ensuring the data collation tool is updated after each episode of care;
- Follow-up of DNAs with repeat appointments etc. (See Key Message below);
- Quality assurance of the Look-back Review processes e.g. administrative checks that the correct letter is sent to the correct person affected;
- Critically ensuring that persons affected are appropriately referred into the "system" for subsequent follow-up.

Key Message: The service must ensure that every effort is made to follow up with persons affected that do not attend appointments scheduled with them as part of the Recall Stage. This may involve follow-up letters and phone calls to the person(s) affected and/or GPs. This will be guided by the policy in place within each relevant service for those person(s) affected that do not attend for their appointment(s) (DNAs).

7.5.3 Undertaking the Recall Stage

Upon completion of the audit outlined in section 7.4, the group of potentially affected cases will have been identified for inclusion in the Recall Stage of the Look-back Review.
The Recall Team will then:

- Undertake an examination if necessary of the person affected and/ or review all relevant records in line with the Terms of Reference and will identify any deviations from required standards of care;
- Identify outcomes resulting from deviations from required standards of care;
- Identify if any further action is required;
- Inform the person affected of the outcomes of the examination and Look-back Review and adhere to the requirements of the HSE Guidelines on Open Disclosure
- Where appropriate, implement actions to address deviations from required standard of care or advise the SIMT of the follow up that is required;
- Update the Look-back Review data collation tool to reflect all findings, actions and recommendations for actions.

7.5.4 The Recall Team will update the data collation tool to advise the SIMT on the follow–up required, which may include:

- No further action required;
- Update of patient records and reassurance to the person affected (i.e. that care provided to patient was appropriate and no further action is required)
- Recall/ referral of the person affected for further assessment, investigation and treatment.

In cases where, despite the best efforts of the Recall Team, persons affected cannot be contacted or located for inclusion in the Look-back Review, the Recall Team should also advise the SIMT of all efforts undertaken to make contact/ locate these affected persons.

7.5.5 The Look-back Review Commissioner will communicate findings of the Recall Stage to the National Director and the HSE as appropriate and as per the agreed communications strategy (section 7.7)

7.5.6 Any additional incidents identified by the Recall Phase, or additional information pertaining to incidents already identified by the Look-back Review, must be documented on NIMS and linked to the Look-back Review incident on NIMS.

7.5.7 Referral pathways:

Special arrangements should be in place for situations where the Recall Stage concludes that outcomes for the person affected have been adversely affected by the hazard/ safety incident. Individual case management teams may be required depending on the severity and complexity of each case. In addition to securing rapid access to the appropriate investigation and treatment services, senior clinicians may be required to discuss clinical findings in light of the outcome of the Look-back Review and as much health and social support as appropriate should be offered. It is imperative that the SIMT is assured that the appropriate clinical service has taken over care of persons affected who require follow-up.

7.5.8 The Look-back Review may identify that an incident occurred to a person affected during the course of their treatment and care. Any incidents which are identified by a Look-back Review (i.e. not identified previously) should be reported, managed and investigated further in accordance with the current HSE Incident Management Framework.

As stated previously any immediate safety concerns that arise at any stage of the Look-back Review are communicated to the Chair of the SIMT for appropriate onward communication and action.

The Chair of the SIMT will communicate findings of the Recall Stage to the National Director and the HSE as appropriate and as per the agreed communications strategy (section 7.7)

7.6 Closing the Look-back Review

7.6.1 When all persons affected have been reviewed, the care of patients requiring clinical management has been transferred to the appropriate service, and all persons affected have been written to outlining the outcome of their review, the SIMT will prepare a detailed **anonymised** report on the completed Look-back Review. The HSE Incident Management Framework provides guidance on writing the review report and the same principles apply to the Look-back Review report. The Look-back Review report is separate to the system analysis review report although they will likely refer to one another.

7.6.2 The Look-back Review Report should contain the following sections (See **Appendix 7** for template):

- Introduction including:
    - Details of Terms of Reference(s) (include Terms of Reference(s) in the Appendices section of the report)
    - Composition and roles of the SIMT
    - Composition and roles of the Audit Team
    - Composition and roles of the Recall Team
    - NIMS reference number(s)
- Methodology applied to the Look-back Review including:
    - Methodology applied to Preliminary assessment and decision to commission a Look-back Review
    - Methodology applied to the Look-back Review Risk Assessment and the decision to proceed to the Audit and Recall Stage of the Look-back Review.
    - Clear audit methodology for the Audit Stage including:
        - Audit Criteria
        - Scope of Audit
        - Audit Methodology
        - Audit Tool
    - Procedures for ensuring the validity and reliability of the Audit Stage to ensure that all auditors interpret and apply audit criteria in the same way.
    - Recall Stage methodology
    - Communications Plan, including management of the Open Disclosure Process
    - Information and Help Line Plan
    - Plans for follow up for persons affected following both the Audit and Recall Stages, including the application of Open Disclosure.
    - Quality and Safety Improvement Plan.
- Results/ Findings of the Preliminary Risk Assessment
- Results/ Findings of the Audit stage
- Results/ Findings of the Recall Stage
- Actions taken to date to address findings
- Further recommended actions[17] to address findings
- References
- Appendices

7.6.4 The identification of learning and recommended necessary changes to practice and procedures locally and systemically will be included in the Look-back Review Report and will help inform the system analysis review.

7.6.5 The Look-back Review will be finalised and approved in line with the Governance Approval Process for finalising a review report as detailed in Section 16 of the IMF.

[17] Refer to Incident Management Framework for guidance on the development of CLEAR recommendations.

7.6.6 The Look-back Review Commissioner is responsible for timely communication of recommended actions arising from the Look-back Review to the senior managers within the services included in the Look-back Review. The SAO is also responsible for communicating nationally applicable recommendations to the National Director(s) for communication and national implementation.

7.6.7 The senior managers within each service assume responsibility for implementation of recommendations.

7.6.8 Peer review publication of issues relating to the Look-back Review, for instance, the development of an audit tool, logistics, communications etc. may be of benefit and is encouraged to share learning.

7.6.9 NIMS must be completed with any additional required information and the Look-back review Report and associated documentation should also be uploaded on to NIMS once accepted by the Look-back Review Commissioner.

7.7 Communications Plan

A set of key messages should be agreed by the SIMT to ensure consistent accurate communication throughout the Look-back Review and provide confidence in the process. A spokesperson, ideally a senior clinical member of the SIMT, should be identified to act as media spokesperson and be available for interview. It is vital that media reports in relation to the issue, should they arise, are accurate and do not add to the anxiety of the persons affected and their families.

The Communications Manager on the SIMT should draw up a communications plan to include a suite of standard documents:

- Letter to all persons affected who are to be included in the Look-back Review (see 7.7.1 and **Appendix 4A** for sample letter).
- Letter to General Practitioners/other referrers to the service (see 7.7.1 and **Appendix 4B** for sample letter).
- Press Statements (see 7.7.2) – holding statement and review phase statement. (Note: These should be developed as soon as it is determined that a Look-back Review is required and updated as required as the Look-back Review proceeds.)
- Frequently Asked Questions and Answers (FAQ document).
- Media Q&A document (see 7.7.2) which endeavours to anticipate questions that the incident might generate

  Special attention should be given to the interdependent timing of communications to persons affected and media communications.

  It is vital that Open Disclosure should not be delayed with individuals where there was an identified incident, possibly triggering the need for the Look-back Review.

Key Message: The principle behind all communication should balance reassurance with absolute disclosure. The following principles apply to all communications during a Look-back Review:

- ***People are informed of their inclusion in the Recall Stage of the Look-back Review before the Recall Stage is commenced***
- ***Information on the Look-back Review is first given to the people whose care is being reviewed by the Recall Team***
- ***Information subsequently given to media or others should not exceed what is shared with the people concerned***
- ***The media should be provided with the FAQ document (after information is given to the people whose care is being reviewed by the Recall Team).***
- ***Patient confidentiality should be respected and maintained in all media communications.***
- ***The media should be informed of the communications process and its rationale.***

7.7.1 Communicating with the people included in the Recall Stage

- In most instances, the persons affected who have been identified by the audit for inclusion in the Recall stage of the Look-back Review should be notified by letter, signed by a named senior member of staff and preferably the lead clinician. However, in incidents involving smaller numbers (or for particular subgroups of those being included in the Recall stage) telephone or face to face contact may be appropriate, written information should also be provided in such circumstances.
- Where potentially serious adverse outcomes are suspected, or the team suspects that a person affected may be in a vulnerable state, the Clinician/GP for the person affected should be

consulted regarding how best to communicate with the person affected. In exceptional circumstances it may be appropriate to communicate with the person affected via their Clinician/ GP. This will be determined by the SIMT on a case by case basis.

- Letters should be sent in an envelope marked *Private and Confidential -To be opened by addressee only* and *If undelivered return* to a designated PO Box number/ address.
- It is not advisable to use registered post as this may increase the likelihood of mail not being delivered in a timely manner (due to requirement for the recipient to sign for receipt of mail).
- The earlier validation of the data collation tool is important to prevent letters being posted to those who are deceased.
- The letter to persons affected should;
  - Describe what has happened and that their case is being examined as part of the Recall Stage of the Look-back Review.
  - Apologise for any worry or distresses caused and stress the precautionary nature of the Look-back Review.
  - Provide the FAQ document and encourage persons affected to call the information line with any further queries.
  - Make it clear that they will be contacted again by letter as soon as their case has been reviewed by the Recall Team.
- **The letter should also provide the persons affected with the option to indicate if they do not wish to be included as part of the Look-back Review.**
- The letter should include a unique identifier number (as allocated on the data collation tool). It is useful to include a reply slip with a pre-paid envelope in order for the persons affected to confirm that letters have been received. This will assist in the identification of those who were contacted successfully but who may not wish to call the information line. The reply slip should also allow persons affected to indicate that they do not wish to be included in the Look-back Review.
- **In circumstances where a person affected declines to be included in the Recall stage, this decision will be respected unless they are statutorily required[18] to participate in the Recall stage of the Look-back Review.** The replies should be recorded on the data collation tool so that people do not receive unwelcome further information; their details should be carefully segregated and highlighted on the data collation tool.

Depending on the scope of the Look-back Review, the service may need to identify vulnerable groups, those with diminished capacity, minors, parents who are minors etc., in order to ensure that appropriate contact is made and support is provided in relation to their inclusion in the Look-back Review process. At all times the principles of the HSE Consent Policy must be adhered to.
Every reasonable effort should be made to contact all persons affected identified for inclusion in the Recall stage. People may have moved out of the area, or moved abroad.

With regard to infectious disease incidents, the Medical Officer of Health (i.e. Director of Public Health) should inform persons affected in line with relevant Public Health policies and guidelines. The HSE Health Protection Surveillance Centre (HPSC) can play a role in contacting people at risk who may be abroad. Contact should also be made with the National Director for responsibility for Public Health.

7.7.2 Media communication

Safety incidents, especially those involving Look-back Review, generate intense media attention. Media communications, as is the case with all other communications, should be consistent and truthful. **Regardless of the nature or intensity of media queries, information provided to the media should never exceed that which has been shared with the persons affected.**

[18] For example: In the case of a requirement under communicable disease regulations, if person concerned was a minor or a ward of court.

The media pack is developed by the SIMT in conjunction with relevant communication experts. Draft media statements should be prepared specific to each phase of the process, as time progresses, in anticipation of media interest. It is vital that media reports in relation to the issue, should they arise, are accurate and do not add to the anxiety of persons affected and their families.

In circumstances where a press statement is released (following notification to persons affected), it should:

- State that a Look-back Review is being carried out, and immediately limit the area of concern to the time period, region and service area within which the Look-back Review is being conducted.
- Detail the numbers of persons affected being included in the Recall stage of the process, and the expected timeframe for the completion of the Recall stage, if known.
- State that all persons affected have already been contacted by letter, and that an information line has been established.
- Give the opening time of the information line and a website reference.
- State when the media can expect an update, and
- Never contain any information that could identify patients included in the Recall stage of the Look-back Review.

The FAQ document can also be issued to media, aligning with the briefing material used by the information line staff and ensuring consistent messages.

The prepared media pack is usually issued to all media once the issue becomes public. Alternatively, once everyone involved has been contacted, the communications staff may initiate contact with key media correspondents, advise them of the issue, and provide the media pack and relevant spokespeople as required.

In either case, the press material will be prepared in advance and checked by the Chair of the SIMT, the spokespeople will have committed their availability, and the consistent messages identified at the outset will be repeated in all public and media communications.

8.0 Implementation Plan

This Guideline will be implemented through the following channels:

- This guideline will be available on the Incident Management section of the National Quality and Patient Safety Directorate website https://www.hse.ie/eng/about/who/nqpsd/.
- 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 as appropriate into education and training courses provided by the QPS Incident Management Team.

9.0 Guideline Revision and Audit

- To facilitate regular review and audit of the guideline, all training and education on the HSE Look-back Review Guidelines will include a requirement to provide any feedback on the guideline for the attention of the QPS Incident Management Team to inform future revisions.
- Upon completion of a Look-back Review, the QPSD IM Team will seek feedback from the Commissioner of the Look-back Review to discuss the applicability of this guideline to the process and to identify any required changes to improve the Look-back Review process.
- The National Quality and Patient Safety Directorate will undertake/ commission audits of compliance with the HSE Look-back Review Guidelines where indicated.

10.0 References

- Assist me, a Model of Staff Support following Patient Safety Incidents in Healthcare (2021): https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/assist-me-a-model-of-staff-support-following-patient-safety-incidents-in-healthcare-january-2021-.pdf
- Brady A, Ó Laoide R, McCarthy P and McDermott R. (2012), Discrepancy and Error in Radiology: Concepts, Causes and Consequences. *Ulster Medical Journal*; 81(1):3-9.
- Civil Liability (Amendment) Act, 2017, Part 4 Open Disclosure, https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/legislation-documents.html and https://www.irishstatutebook.ie/eli/2017/act/30/enacted/en/html
- Data Protection Acts 1988-2018 https://www.dataprotection.ie/en/who-we-are/data-protection-legislation
- Freedom of Information (Amendment) Act 2003. https://www.irishstatutebook.ie/eli/2003/act/9/enacted/en/html
- General Data Protection Regulation (GDPR) (EU) 2016/679 https://www.dataprotection.ie/en/who-we-are/data-protection-legislation
- HSE Patient Safety Strategy (2019-2024) https://www.hse.ie/eng/about/who/nqpsd/patient-safety-strategy-2019-2024.pdf
- HSE Incident Management Framework and Guidance, 2020: For the most current version of the Incident Management Framework please access: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/HSE and the Department of Health Communication Protocol, Communications in relation to major/significant patient/service user safety incidents and issues of concern, February 2022 (referred to as the Patient Safety Notification (PSN) Protocol)
- HSE National Consent Policy, 2022, https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/hse-national-consent-policy.pdf
- Just Culture Guide, Section 4, HSE Incident Management Framework and Guidance, 2020: For the most current version of the Incident Management Framework please access: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/
- HSE Open Disclosure Policy available on https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/hse-open-disclosure-full-policy.pdf
- National Independent Review Panel at https://www.hse.ie/eng/about/who/nqpsd/nirp/
- Nolan T and Provost L, (1990), Understanding Variation. *Quality Process*.

- Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, available at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/summary-guide-patient-safety-npsi-bill-2019.pdf and https://www.oireachtas.ie/en/bills/bill/2019/100/
- Safety, Health and Welfare at Work Act 2005 (S.I. 10 of 2005 – and the Safety Health and Welfare at Work (General Application) Regulations 1993 SI44 Part X. https://www.irishstatutebook.ie/eli/2005/act/10/enacted/en/print
- The Health Act 2004. https://www.irishstatutebook.ie/eli/2004/act/42/enacted/en/html

Additional Reading to inform Look-back Reviews

- Nugent M, Galbraith JG, Fitzgerald AP, Gul R, Healy NO., (2014), *Outcomes of a patient recall following early failure of hip hemiarthroplasty.* Ir J Med Sci. 183(4):521-4.
- Safety Incident Management Team Report for NIMLT Case 50796, Final Report (2017), https://www.lenus.ie/handle/10147/621033?show=full
- Look-back Review Report, Safety Incident Management Team (SIMT), South /South West Hospital Group, December 2018 https://www.lenus.ie/bitstream/handle/10147/627060/university-hospital-kerry-look-back-review-report.pdf?sequence=1&isAllowed=y

11.0 Appendices

Note: Templates listed below may be accessed on the QPSD Incident Management Team webpage at https://www.hse.ie/eng/about/who/nqpsd/

Appendix 1: Template for Look-back Review Risk Assessment
Appendix 2: Developing a Data Collation Tool and Sample core dataset for Look-back Review
Appendix 3: Information Lines
Appendix 4A: Letter to Patient informing them of their inclusion in the Recall Stage of the Look-back Review.
Appendix 4B: Letter to GP informing them of their patient's inclusion in the Recall Stage of the Look-back Review.
Appendix 5: Collection and Storage of Information
Appendix 6A: Template Investigation Terms of Reference for Look-back Review
Appendix 6B: Template Investigation Terms of Reference for Audit Stage
Appendix 6C: Template Investigation Terms of Reference for Recall Stage
Appendix 7: Look-back Review Report Template
Appendix 8: Look-back Review Process Check List
Appendix 9: Key Changes to the Look-back Review Guideline
Appendix 10: One Page Overview of Look-back Review Process

Appendix 1: Template for Look-back Review Risk Assessment[19]

Look-back Review Risk Assessment

NIMS Reference Number:	
Date of Look-back Review Risk Assessment (dd/mm/yy):	

Information about the issue that appears to give rise to the need for a Look-back Review:
(include information in relation to any actual harm that has been caused as a result of this issue)

Information about the potential extent of the issue:
(Include information about the number of people that might be adversely affected by the issue and if the Look-back Review is limited to one HSE site or if the process will involve a number of HSE sites)

Information about the potential outcomes of the issue:
(Include information about the potential consequences of the issue e.g. missed diagnosis / missed return appointments / harm from contaminated medicines / harm due to ineffective vaccines etc.)

Information about the potential impact of the issue:
(Include information about the severity of harm that might occur in the people adversely affected by the issue. Use the HSE Impact Table in the Incident Management Framework to rate potential harm)

Please tick one

Extreme:		Additional Details:
Major:		
Moderate:		
Minor:		
Negligible:		

[19] Any individual risks identified through this Look-back Review risk assessment process should be included on the Risk Register for the relevant service and assessed as per the HSE Risk Assessment Guidance.
https://www.hse.ie/eng/about/who/riskmanagement/risk-management-documentation/hse-integrated-risk-management-policy-part-2-risk-assessment-and-treatment.pdf

Information about the potential cohort of service users affected:
(Include information about the number of people that might fall within the look back review; the gender; the age range; category of service user etc.)

Details of immediate actions/controls required:

Recommendations to Serious Incident Management Team regarding Look-back Review.
(Indicate if Look-back Review should progress to Audit Stage. If Yes, include recommendations for the Terms of Reference for the Look Back Review including recommended inclusion and exclusion criteria; and for scoping audit(s) of patients that might fall within the inclusion criteria. If progress to Audit Stage not indicated, please outline reasons why)

Details of personnel who undertook the Look-back Review Risk Assessment:

Name	Title

Appendix 2: Developing a Data Collation Tool and Sample core dataset for Look-back Review

In designing the data collation tool, it is helpful to consider that it will be used for administrative, clinical and safety incident management purposes. For instance:

- Administration:
    - Generating initial and follow up letters to the people affected and telephone contacts if required
    - GP contact
    - Confirming that patients have made contact
    - Tracking attendance, scheduling follow-up investigation and appointment
    - DNA policy assurance
- Clinical:
    - Monitoring adherence to clinical protocol
    - Recording results
    - Consensus on review findings – standards met; minor departure from standard but outcome not adversely affected; serious departure from standard and further investigation/ treatment/ intervention required
- Serious Incident Management Team:
    - Status updates to inform updates, briefings, press releases etc.
    - Look-back Review analysis and final report writing
    - Evaluation and the debriefing process when the Look-back Review has concluded

Some safety incidents require the use of web-enabled systems, shared folders etc. All appropriate actions essential to ensure the security of the data collation tool and the protection of confidentiality must be taken.

Sample Core Dataset:

- Unique identifier number
- Surname
- Forename
- Title
- Date of birth
- Sex
- Address line one (House name, number and road name)
- Address line two (town)
- Address line three (county)
- Phone number
- GP name
- GP address line one
- GP address line two
- GP address line three
- GP phone number
- Named consultant (i.e. treating consultant)
- Inclusion Criteria parameters met
- Exclusion Criteria parameters met
- Audit criteria and outcomes
- Inclusion in Look-back Review Yes/No
- Date of appointment/procedure 1/Investigation
- Date of appointment/procedure 2/Investigation
- Date of appointment/procedure 3/Investigation
- Procedure one/Investigation description
- Procedure two/Investigation description

- Procedure three description
- Reviewer 1 identification
- Reviewer 2 identification
- Data entered by -identification
- Data updated 1 by – identification
- Data updated 2 by – identification
- Data updated 3 by – identification
- NIMS reference number where an incident is identified

Note: The data above is a suggested minimum dataset. It is however subject to change depending on the individual situation.

Appendix 3: Information Lines & Supporting FAQs

Identification of venue for information lines

- Ideally the Information line should not be isolated from the main hub of the organisation, to allow easy access to the Serious Incident Management team for advice and information while the line is operational.
- Cabling to allow sufficient telephones is required.
- Once letters are sent, there is likely to be an influx of calls.
- Each telephone line should be able to handle 100 calls in a 12-hour period. Additional capacity is required during the initial days, with surges of activity following each news bulletin.
- It is advisable to have a failsafe system to capture additional calls if the information line becomes blocked with calls and a good telephone queuing system with an appropriate message is required.
- Personal computers are required for each person to facilitate easy access to patient information. IT staff should assist in accessing the necessary cabling and hardware.

Briefing and back-up documentation for information line personnel

It is important that those providing the telephone information are trained and briefed on the circumstances surrounding the Look-back Review.

The people whose care is being reviewed need to get a consistent message from all our staff, all our letters, all our media interviews and reports. Information line personnel need to be confident in the messages they are giving to callers. An information pack should be provided to each staff member containing:

⇒ Letters sent to everyone affected by the Look-back Review
⇒ Press Release (and any updates)
⇒ FAQ document (updated as queries arise)
⇒ Standard Form for recording caller details
⇒ Algorithms, to help staff to know what to say in given circumstances

Production of Pro forma for information line personnel

As each call is received it is important to maintain a record. A pro forma should be designed to capture the relevant information. It should not be so detailed that the caller feels annoyed, however there needs to be sufficient information to ascertain if follow up action is required.

If the information line personnel believe that follow up is required then a system needs to be agreed to segregate pro-formas, perhaps by identifying follow up calls with a red dot. By the following day these need to have been actively followed up, probably by clinical staff in the speciality being reviewed.

Production of rotas for information line personnel

The information line opening times need to be agreed at the outset so that rotas can be produced. Media coverage tends to impact on when calls are made, so some flexibility and unsocial hours might be required.

As far as possible the information line should be staffed by experienced people with an understanding of how to help worried callers. It is essential to have staff with good communication skills. Staff may need to be released very quickly from their normal duties to assist with this work. There may need to be back filling of these posts to release these staff to assist.

Appendix 4A: Letter to Patient informing them of their inclusion in the Recall Stage of the Look-back Review.

***Note:** Appendix 4A and 4B are **sample letters** only and may be amended as required to reflect individual persons affected and Look-back Review process requirements.*

Commissioner name & address
Date

Patient name& address

Dear [name of person affected],

You recently had a [Procedure] in [Location].

We have reviewed [Procedure] undertaken at the [Location] in [Date(s)/Year(s)] as part of its quality assurance process as we were not satisfied with the quality of a number of PROCEDURES carried out.

I am writing to you because your file has been reviewed as part of this process and our clinical team would like to meet with you to check that your procedure was satisfactory and you have no concerns in this regard.

An appointment has been made for you at [Time] on [Date] in the [Location].

The [Location] is situated [Directions]

On arrival please report to [Location] where some details will be taken. You are asked to bring the following with you:

- Contact telephone number
- List of current medications (name and dose)
- Medical card, if you are the holder of one

I apologise for any anxiety this might cause but wish to reassure you that this is a precautionary measure to ensure your care is of the highest possible standard.

If this time or date above does not suit you, please contact [Name liaison person and contact details]

Kind regards.

Yours sincerely

_____

[Look-back Review Commissioner Name/ Title]

Appendix 4B: Letter to Clinician/ General Practitioner

(Informing them of the inclusion of their patient(s) in the Recall Stage of the Look-back Review)

Note: *Appendix 4A and 4B are* ***sample letters*** *only and may be amended as required to reflect individual Look-back Review process requirements.*

Commissioner name & address
Date

Patient name& address

Dear [Doctor Name],

[Service Name] recently reviewed [Procedure] undertaken at the hospital in [Date(s)/Year(s)]. This review was part of a quality assurance process as we were not satisfied with the quality of a number of [Procedure(s)] carried out. As a precautionary measure our medical advisors have recommended that a number of patients who attended for [Procedure] are offered a [Specialty] outpatients appointment.

Our records show that your patient [Name] previously attended [name of location] for [name of procedure]. We have written to your patient to advise them that their file was reviewed as part of this process and to offer them an outpatient appointment.

If you have any queries about this letter, please contact [Name person and contact details]

Yours Sincerely

_____
[Look-back Review Commissioner Name/ Title]

Appendix 5: Collection and Storage of Information

General Guidance for Look-back Reviews

Reviews of safety incidents/ Look-back Reviews are conducted in private and all information obtained by an investigator/persons undertaking any stage of the Look-back Review shall be deemed to be confidential information which he/she may not discuss, communicate or disclose except as is necessary for the proper review of the safety incident/ implementation of the Look-back Review. The information gathered must be treated as confidential at all times and stored away in a locked filing cabinet when not in use.

For the purposes of data classification and handling, all information received, processed and stored as part of a review/ Look-back Review is considered highly sensitive and should be treated as confidential and restricted information in line with the HSE Information Classification and Handling Policy.

At all stages during the review process/ Look-back Review, the collection and storage of information must comply with our obligations under the relevant Data Protection Acts. 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.

Look-back Review Audit

The audit of patient/service user's healthcare records should be undertaken by the healthcare team who would ordinarily have the right to access the patient/service user's healthcare records as part of the delivery of healthcare.
However, if the audit team is extended to include healthcare personnel who would not have a right to access the patient/service user's healthcare records, and consent has not been provided by the patient/service user for these personnel to access their records, then these records must be sufficiently anonymised, such that an individual is not identifiable to those undertaking the audit.

Data Collation Tool

Patient/service user's personal information must be treated in the strictest confidence. Patient personal information may be entered on to the data collation tool if access to the data collation tool is strictly limited to the healthcare team who would ordinarily have the right to access the patient/service user's personal information as part of the delivery of healthcare.
However, if the data collation tool may be accessed by healthcare personnel who would not have a right to access the patient/service user's personal information, and consent has not been provided by the patient/service user for these personnel to access their personal information, then patient/service user details must be sufficiently anonymised, such that an individual is not identifiable to those viewing the data collation tool. A coding system will be required for the data collation tool in order for the patient/ service user's healthcare team to identify the patient/ service user where required and where they have a right to do so.

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 (or for HSE funded services, this 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[20]. The transfer of such information outside of the HSE domain must be authorised by a HSE line manager (at Grade 8 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.
- 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.

Please refer to the most up to date HSE National Policies and Guidance in relation to electronically held and transmitted information. These are available through the Office of the Chief Information Officer and the following web-links.

- https://www.hse.ie/eng/about/who/oocio/
- https://www.hse.ie/eng/services/publications/pp/ict/
- https://healthservice.hse.ie/filelibrary/staff/end-user-policy.pdf

In short, the information gathered as part of a review/Look-back Reviews should not be held outside of HSE offices and must be adequately protected and stored while in the possession of the HSE.

[20] Encryption software is available through HSE Information Communication Technology departments. Requests should be made, with line manager approval, via ICT Department helpdesks.

Appendix 6A: Template Terms of Reference for Look-back Review

Terms of Reference for Look-back Review

Introduction

These are the terms of reference for the Look-back Review commissioned by [xxx] into [a hazard (describe) that arose at … on … (include date)]

Purpose

The purpose of this Look-back Review is to identify anyone who has potentially been exposed to the hazard detailed above and to identify if any of those exposed have been harmed in order to identify how to take care of them.

The Look-back Review will consist of three distinct stages:

- The Look-back Review Risk Assessment Stage
- The Audit Stage
- The Recall Stage

The Look-back Review Risk Assessment will be undertaken by the Serious Incident Management Team and will determine if the Look-back Review Process should progress to the Audit Stage. The Audit Stage will determine the patients / service users/ persons affected that should be included in the Recall Stage of the Look-back Review.

The Look-back Review Risk Assessment will look at:

- The potential extent of the issue and the level of exposure to the hazard.
- Evidence of harm that has occurred.
- The likelihood of future harm occurring.
- The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc.
- The potential impact of the issue
- The potential cohort of service users affected.
- If the Look-back Review is limited to one HSE site or if the process will involve a number of HSE sites.

If the Look-back Review proceeds to the Audit and Recall Phases, a specific Terms of Reference will be established for the Audit Stage and for the Recall Stage of the Look-back Review Process.

The Serious Incident Management Team includes [add names and titles as appropriate]:

- Chair (Look-back Review Commissioner) [name/title]
- Other team members [names/titles]

Non-HSE members of patient representative groups are included as members of the Serious Incident Management Team. In these instances, a confidentiality agreement has been signed.
These members are:

- [names/ titles]

Sub teams have been established within the Serious Incident Management Team to support the Look-back Review. These are as follows

- [list teams]

If experts external to the HSE are required to support any stage of this process, this will be discussed with the Look-back Review Commissioner who will make a decision in relation to the requirement for external experts.

Scope of the Look-back Review
The time frame of the Look-back Review will be [include the time frame]

Please note:

- The *"time frame"* in question here is the *"scope in time"* that was considered appropriate for the Look-back Review.
- The timeframe must be the shortest sufficient period of time to ensure the purposes of the Look-back Review 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 any of the three stages of the Look-back Review.

Immediate Safety Concerns
Should immediate safety concerns arise during any stage of the Look-back Review the Look-back Review Commissioner will ensure that appropriate actions are implemented within the shortest time frame possible.

Look-back Review Methodology
The Look-back Review will follow the methodology as per the Look-back Review Work Plan and the HSE Look-back Review Guideline and will be cognisant of the rights of all involved to privacy and confidentiality. Where an incident is identified this will be recorded on the National Incident Management System.

Look-back Review Report
Once the Look-back Review process is concluded the Serious Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Review. This report will include:

- The Results/ Findings of the Look-back Review
- Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a Look-back Review process will be fully protected from legal discovery and / or disclosure.

Recommendations and Implementation
The report, when finalised, will be presented to the Commissioner of the Look-back Review.
The identification of learning for improvement and recommended changes to practice and procedures locally and systemically will be included in the Look-back Review Report.
The Commissioner of the Look-back Review will ensure that local managers, responsible for the services included in the Look-back Review, implement the recommendations of the Look-back Review.
The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.
Peer review publication of issues relating to the Look-back Review, for instance; the development of an audit tool, logistics, communications etc. may be required.

Communication Strategy for the Look-back Review.
A communication strategy will be determined. [Give name of Liaison person], will be appointed for the purpose of communicating information pertaining to the Look-back Review to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Look-back Review.

Reference:

- HSE Incident Management Framework
- HSE Guideline for Conducting a Look-back Review

Appendix 6B: Template Terms of Reference for Audit Stage

Terms of Reference for Audit Stage of the Look Back Review

Introduction
These are the terms of reference for the Audit Stage of a Look-back Review commissioned by [xxx] into [an incident/complaint/allegation of … that arose at … on … (include date)]

Purpose
The purpose of this Audit stage is as follows:
The audit team will
→ Evaluate the [diagnostic accuracy/ quality of procedure etc. – add text here appropriate to the hazard identified]
→ Make recommendations in respect to any additional follow-up required
→ Make recommendations in respect to the requirement for the patient/ service user to be included in the Recall Stage of the Look-back Review

Scope of the Audit stage

The time frame of the Audit Stage will be [include the time frame of the audit stage here]

Please note:
- The *"time frame"* in question here is the *"scope in time"* that was considered for inclusion in the Audit Stage of the Look-back Review.
- The timeframe must be the shortest sufficient period of time to ensure the purposes of the Audit Stage 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 Audit Stage.

The Audit Team members
Note: [X number] of Audit Teams are required for the Audit stage of this Look-back Review in [X number] of locations in the HSE. The number of Audit Teams required was determined by the Look-back Review Commissioner/ Serious Incident Management Team and informed by the Look-back Review Risk Assessment Stage.

The Locations and Membership of the Audit team are as follows:
❖ Audit Team Lead [detail]
❖ Other members of the Audit team [detail]

Through the Commissioner of the Look-back Review, the Audit Team will:
❖ Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
❖ Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Lead of the Audit Team will convey the details of these safety concerns to the Look-back Review Commissioner as soon as possible.
Should the Audit Team require external expert input, the Lead of the Audit Team will discuss and agree this with the Look-back Review Commissioner.

Audit Stage methodology
The Audit stage will follow the methodology as per the Look-back Review Work Plan and the HSE Look-back Review Guideline and will be cognisant of the rights of all involved to privacy and confidentiality.

The Audit stage will commence on [xxx] and will be expected to last for a period of approximately [xxx], provided unforeseen circumstance does not arise.

The Audit Team will advise the Look-back Review Commissioner on the follow–up required, which may include:
• No further action required;
• Update of patient records and reassurance to patient (i.e. that care provided to patient was appropriate and no further action is required)
• Recall/ referral of patient for further assessment, investigation and treatment.

The Audit Stage may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the Audit Stage (i.e. not identified previously) should be considered for further investigation in accordance with the current HSE Incident Management Framework.

Upon completion of the audit, the audit team will provide the Look-back Review Commissioner with the results and recommendations of the audit which will inform the Look-back Review Commissioner of those patients / service users to be included in the Recall Stage of the Look-back Review.
The audit results and recommendations will include:

- The Results/ Findings of the Audit stage
- Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised audit report may be published. No guarantee can be given by the HSE that information received as part of a look-back review process will be fully protected from legal discovery and / or disclosure.

Communication Strategy for the Look-back Review.
A communication strategy will be determined for each stage of the Look-back Review. [Give name of Liaison person], will be appointed for the purpose of communicating information pertaining to the Look-back Review to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Look-back Review.

Reference:

- HSE Incident Management Framework
- HSE Guideline for Conducting a Look-back Review

Appendix 6C: Template Terms of Reference for the Recall Stage

Terms of Reference for the Recall Stage of the Look-back Review

Introduction

These are the terms of reference for the Recall Stage of a Look-back Review commissioned by [xxx] into [an incident/complaint/allegation of … that arose at … on … (include date)]

Purpose

The purpose of this Recall stage is to:

→ Undertake an examination of the patient/ service user and/or review relevant patient information/ results etc. in line with the Look-back Review Work Plan and the requirements of the HSE Look-back Review Guideline.

→ Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Review.

→ Implement any corrective actions as appropriate and will communicate any additional actions to be taken to the Serious Incident Management Team for further action.

Scope of this Recall stage

The time frame of this recall stage will be [include the time frame of the recall stage here]

Please note:

- The *"time frame"* in question here is the *"scope in time"* for the Recall Stage that was determined by the findings of the Audit Stage The timeframe must be the shortest sufficient period of time to ensure the purposes of the Recall Stage 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 Recall Stage.

The Recall Team members

Note: [X number] of Recall Teams are required for the Recall stage of this Look-back Review in [X number] of locations in the HSE. The number of Recall Teams required was determined by the Look-back Review Commissioner following the outcome of the Audit stage of the Look-back Review.

The Locations and Membership of the Recall team are as follows:

→ Recall Team Lead (detail)

→ Other members of the Recall Team (detail)

Through the Commissioner of the Look-back Review, the Recall Team will:

→ Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.

→ Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Recall Team Lead will convey the details of these safety concerns to the Commissioner as soon as possible.

Recall Stage methodology

The recall stage will follow the methodology as per the Look-back Review Work Plan and the HSE Look-back Review Guideline and will be cognisant of the rights of all involved to privacy and confidentiality.

The Recall stage will commence on [xxx] and will be expected to last for a period of approximately [xxx], provided unforeseen circumstance does not arise.

The Recall Team will advise the Look-back Review Commissioner on the follow–up required, which may include:

- ❖ No further action required;
- ❖ Update of patient records and reassurance to patient (i.e. that care provided to patient was appropriate and no further action is required)
- ❖ Recall/ referral of patient for further assessment, investigation and treatment.

The Recall stage may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the Recall stage (i.e. not identified previously) should be investigated further in accordance with the current HSE Incident Management Framework.

Once the Recall stage has been completed the Serious Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Review Process. This report will include:

- ❖ The Results/ Findings of the Recall stage
- ❖ Actions taken to date to address findings
- ❖ Further recommended actions to address findings

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a look-back review process will be fully protected from legal discovery and / or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Commissioner of the Look-back Review.
The identification of learning and recommended changes to practice and procedures locally and systemically will be included in the Look-back Review Report.
The Commissioner of the Look-back Review Process will ensure that local managers, responsible for the services included in the Look-back Review, will implement the recommendations of the Look-back Review.
The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.
Peer review publication of issues relating to the Look-back Review, for instance; the development of an audit tool, logistics, communications etc. may be required.

Communication Strategy for the Recall stage of the Look-back Review.

A communication strategy will be determined. (Give the name of an individual, who is not directly involved in the recall process but who understands the process and is continually updated on the progress of the process - here), will be appointed for the purpose of communicating information pertaining to the Recall stage to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Recall Stage (delete as appropriate).

Reference:

- HSE Incident Management Framework
- HSE Guideline for Conducting a Look-back Review

Appendix 7: Look-back Review Report Template

Look-back Review Report
Confidential

Date of Incident	
NIMS NUMBER (for Look-back Review)	
Hospital Group/CHO/NAS/Other	
Look-back Review Commissioner	
Chair of Look-back Review	
Date Report Completed	
Date report uploaded on to NIMS	

Contents

1.0 Executive Summary

2.0 Acknowledgement

To the persons affected e.g. service user/relevant person(s) staff, service(s) for their participation in the process.

3.0 Introduction

Including:

- Details of Terms of Reference(s) (include Terms of Reference(s) in the Appendices section of the report)
- Composition and roles of the SIMT
- Composition and roles of the Audit Team
- Composition and roles of the Recall Team
- NIMS reference number(s)

4.0 Background

Including:

- Description of the incident(s) prompting the Look-back Review
- Details of the standards / policy/ procedures etc., informing current practice
- Overview of the service(s) included in the Look-back Review
- Details of any immediate actions taken to ameliorate and/or mitigate harm
- Details of the Preliminary Assessment and SIMT actions
- Open Disclosure
- Communications

5.0 Look-back Review Methodology

Including:

- Methodology applied to the Look-back Review Risk Assessment and the decision to proceed to the Audit and Recall Stage of the Look-back Review.
- Clear audit methodology for the Audit Stage including:
  - Audit Criteria
  - Scope of Audit
  - Audit Methodology
  - Audit Tool
- Procedures for ensuring the validity and reliability of the Audit Stage to ensure that all auditors interpret and apply audit criteria in the same way.
- Recall Stage methodology
- Communications Plan
- Information and Help Line Plan
- Plans for follow up for persons affected following both the Audit and Recall Stages, including the application of Open Disclosure.
- Quality and Safety Improvement Plan.

6.0 Results/Findings from each Stage of Look-back Review

- Results/ Findings of the Preliminary Risk Assessment
- Results/ Findings of the Audit stage
- Results/ Findings of the Recall Stage

7.0 Actions taken to address Findings

- Actions identified to address findings of the Look-back Review Process

- Altered treatment plans/ follow up etc.

8.0 Conclusion

Including:

- Outcome of Lookback Review
- Learning points for patient safety improvement

Including

  - learning from the patient/ service user/staff experience
  - learning obtained from each stage of the Look-back Review

9.0 Recommendations

10.0 References

11.0 Appendices

May include (but not exclusive to):

- Terms of Reference, including:
  - SIMT
  - Preliminary Risk Assessment
  - Audit Stage
  - Look-back Review Stage
- SIMT Membership and membership of Audit and Recall Teams
- Communication Procedure(s) for each stage including:
  - Dialogue/ scripts
  - Call logging process
  - Telephone communications
- Information Governance Procedure
- Template Letters used at each stage of the process
- Procedure for Risk Assessment, Audit and Recall Stages
- Schedule of Meetings
- Definitions and Abbreviations used in the report

Appendix 8: Look-back Review Guideline Process Checklist

Look-back Review Guideline Process Checklist **The purpose of the checklist is to act as an aide memoir to managers and staff to assist them to ensure compliance with the HSE Guideline for Conducting a Look-back Review.** **The checklist must always be used in conjunction with the HSE Guideline for Conducting a Look-back Review.** **References to the relevant sections of the Guideline have been included in the checklist.**	**Please refer to the relevant Guideline Section(s) for guidance on each stage of the process.**	**Tick as appropriate**		
Stage 1: SIMT and Preliminary Assessment Form	**Section**	**Yes**	**No**	**N/A**
Senior Accountable Officer (SAO) was notified that a Look-back Review Process may be required	**7.2**			
SAO notified the Serious Incident Management Team (SIMT) of the indication for a Look-back Review within 24 hours	**7.2**			
SIMT convened by SAO within 5 working days of the indication that a Look-back Review is required	**7.2**			
The Preliminary Assessment Form was completed in advance of the SIMT meeting and included any available information, including preliminary audit data if necessary in order to inform decision making by the SIMT	**7.2**			
The Preliminary Assessment Form and any supporting information was discussed and considered at the SIMT meeting and a decision is made by the SIMT to undertake a Look-back Review	**7.2**			
The SAO commissions a Look-back Review and a Terms of reference is agreed by the SIMT	**7.2**			
Additional information:				
Stage 2: Look-back Review Risk Assessment	**Section**	**Yes**	**No**	**N/A**
SIMT commission relevant experts to carry out Look-back Review Risk Assessment	**7.3**			
Look-back Review Risk Assessment was carried out by experts to identify if the Audit and Recall stage of the Look-back Review is required	**7.3**			
Using the information obtained from the Preliminary Risk Assessment, the SIMT made a decision to progress to the Audit and Recall stages of the Look-back Review	**7.3**			
The SIMT informed the relevant National Director of the decision to progress with the Audit and Recall Stages of the Look-back Review	**7.3**			
Additional information:				

Stage 3: Audit Stage	Section	Yes	No	N/A
The SIMT agreed the Scope and the Terms of Reference of the Audit and Recall stages of the Look-back Review	**7.4**			
The SIMT developed a Look-back Review Work Plan to inform the Audit and Recall Stages of the Look-back Review	**7.4**			
A data collation tool was established collate and track the information gathered by the Look-back Review	**7.4**			
The Audit was undertaken by Service Providers or experts commissioned by the Service Providers	**7.4**			
The Audit identified persons affected to be included in the Recall stage	**7.4**			
The Communication Plan was agreed and rolled out by the SIMT	**7.4**			
The Information Line was established by the SIMT	**7.4**			
The SIMT established Recall Team(s)	**7.4**			
Additional Information:				

Stage 4: Recall Stage and Look Back Review Report	Section	Yes	No	N/A
The Recall stage was announced by the relevant National Director	**7.5**			
The Recall stage was announced after persons affected had been informed of their inclusion in the Recall stage of the Look-back Review	**7.5**			
The Recall Team(s) implemented the Recall stage as per the Look-back Review Work Plan	**7.5**			
The Recall Team identified actions to be taken to address any deviations from required standards of care	**7.5**			
The Recall Team implemented actions and/ or communicated required actions to the SIMT	**7.5**			
The SIMT developed an anonymised report of the Look-back Review	**7.6**			
The Chair of the SIMT submitted the anonymised report and Recommendations of the Look-back Review through the appropriate governance pathway to the National Director and the HSE as per the Look-back Review Action Plan	**7.6**			
Additional Information:				

Completed by:	
Date:	

Appendix 9: Key Changes to this Guideline

Changes have been made to wording throughout this entire document with the aim of providing greater clarification and definition to users of this guideline. The layout of the sections of this guideline has also been changed to facilitate easier implementation of the 4 key phases of the Look-back Review process: Preliminary Assessment by SIMT, Look-back Review Risk Assessment Phase, Audit Phase and Recall Phase. As every change cannot be detailed below, it is vital that this newly revised draft guideline is read in its entirety.

The following outlines the main changes made to this guideline:

Section	Outline of Change
All sections	Amendments throughout to reflect the HSE Incident Management Framework which replaced the Incident Management Policy (2014) and associated guidelines
All sections	Replaced Safety Incident Management Team to Serious Incident Management Team (SIMT)
Foreword	Inclusion of new section
1.0	Policy Statement: amendments to link this guideline to the IMF Highlights that Look-back Review does not replace the requirement for an incident review
3.0	Scope: Inclusion of NIRP
4.0	Policy and Legislative context: Updated to reflect current policy and legislation
5.0	Glossary: New definitions added in line with the HSE Incident Management Framework
6.0	Amendments to the responsibilities of all staff in undertaking a Look-back Review Process Addition of new QPS roles and NQOSD roles Reference to Patient Safety Notification Protocol and governance structures
7.0	Process Map: New addition to give overview of 4 stage look-back review process. Includes a new Stage 1 i.e. Preliminary Risk Assessment in line with the IMF
7.1 -7.4	Description of 4 stage process of Look-back Review Reference to Patient Safety Notification Protocol and describes enhanced governance structures and processes
Open Disclosure	Increased reference to Open Disclosure throughout document to ensure that this process is adhered to as necessary throughout the Look-back Review Process.
NIMS	Reference to documentation of the Look-back Review and associated cases on NIMS
Appendices	• templates amended to reflect changes in guideline and to align with IMF • Addition of Look-back Review Report Template

Appendix 10: Overview of Look-back Review Process