

Healthcare Audit

[Quality Assurance and Verification]

Standards

April 2019

Healthcare Audit Standards

Contents

Foreword by the Chair of the HSE Risk Committee.....	1
SECTION 1.....	2
Introduction.....	2
SECTION 2.....	4
Definition of Healthcare Audit	4
SECTION 3.....	5
Code of Ethics	5
SECTION 4.....	7
Attribute Standards.....	7
Performance Standards	10
SECTION 5.....	13
Glossary	13
References.....	15

Foreword by the Chair of the HSE Risk Committee

The HSE's Code of Governance defines governance as the framework of rules, practices and policies by which an organisation can ensure accountability, fairness and transparency in its relationship with its stakeholders. The stakeholders of the health service include service users, their families, health service employees, the Minister and Department of Health, other Government Departments, and the general public.

Healthcare Audit is a cornerstone of good healthcare sector governance. Audits provide unbiased, objective assessments of whether the use of public resources and the delivery of services are managed responsibly and effectively to achieve the intended results. These assessments help the health services and the HSE's Risk Committee achieve accountability and integrity, improve operations, instil confidence amongst stakeholders and assist with the creation of a safety culture.

Healthcare Auditors also support the HSE Directorate and the HSE Risk Committee in their responsibilities of oversight, insight and foresight. Oversight addresses whether health services are doing what they are supposed to do, and serves to detect and deter unacceptable practices. Insight assists by providing an independent assessment of services delivered, programmes, policies, operations and results. Foresight identifies trends and emerging challenges.

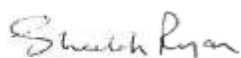
It is crucial that auditors continue to be empowered to produce reliable audit reports. Audits should continue to be conducted with unrestricted access to services, facilities and records as appropriate for the performance of audit activities.

As Chair of the Risk Committee I support the adoption and continuing use of the standards for Healthcare audit set out in this document. I am pleased to note the references in this document to the need for objectivity. Auditors must be impartial, and must be seen to be free of any conflict of interest. Continuous professional development, leadership skills, peer review and feedback from services will ensure the current high standard of service is maintained.

Risk can impact all parts of the health service, and risks have no boundaries; they can travel across internal and geographical boundaries. Risk that is not managed, or that is inadequately mitigated, can have enormous effects on an organisation's performance and reputation. While there is no way we can completely avoid risks, particularly in an organisation as large and diverse as the HSE and its partners, what we can do is position risk management high enough on the operational agenda in order to effectively identify, monitor and mitigate their impact.

Having a high-performing healthcare audit function, operating to these standards, is a critical component in the identification, assessment, and management of risk, in the prevention of adverse events, and in the improvement of outcomes for our service users.

I wish the Healthcare Audit function and its auditors continued success.



Sheelah Ryan

Chair of the HSE Risk Committee

SECTION 1

Introduction

The HSE's Healthcare Audit Team was established in 2010. Healthcare audit, in line with the design and practice of Internal Audit, is *an independent, objective assurance activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes* [The Institute of Internal Auditors].

Under the HSE's Code of Governance, Healthcare Audit sits alongside and mirrors the organisation's Internal Audit function by providing 'Third line of defence'^{1*} assurance in relation to risks and controls in care related activities in both clinical and non-clinical settings.

The HSE's Healthcare auditors are members of the Chartered Institute of Internal Auditors (CIIA) and are required to comply with the professional and general standards set by the CIIA.

The Healthcare Audit Standards have adopted, and refined from practical experience, the Institute of Internal Auditors (IIA) International Standards and the NHS Internal Audit Standards (April 2011). These Standards are amended and include additional requirements of relevance to the HSE. These additions address the specific accountability structures and associated assurance requirements of clinical and social services in the HSE.

In common with the IIA and the NHS Internal Audit Standards, on which these are based, the Healthcare Audit Standards comprise of attribute and performance standards. The attribute standards address the characteristics of the healthcare organisations and auditors performing assurance audit activities. The performance standards describe the specific nature of internal healthcare audit activities and provide quality criteria against which the performance of these services can be evaluated.

Purpose of the Healthcare Audit Standards

The objectives of the Healthcare Audit Standards are to:

- Define the nature of healthcare auditing within the HSE
- Establish a framework for providing healthcare audit services, which add value and lead to improved organisational quality processes, governance, assurance and ultimately improved patient care and safety
- Set basic principles for carrying out healthcare audit activities in the HSE
- Establish the basis for the evaluation of healthcare audit performance and to drive improvement planning.

¹ [Institute of Internal Audit: First line is operational management, Second line is internal corporate governance, Third line is Internal audit assurance on the effectiveness of the first and second lines of defence. These levels are described in the HSE Code of Governance (2015) section 9.6 "HSE Controls Assurance Framework"].

Scope

The Healthcare Audit Standards apply to all members of the Healthcare Audit Team.

All audits conducted by the Healthcare Audit Team fall within the scope of the *Definition of Healthcare Audit* (see section 2). Therefore the Healthcare Audit Standards are applicable to all assurance services performed by the Healthcare Audit Team.

The *Code of Ethics* promotes an ethical and professional culture (see section 3) and applies to all members of the Healthcare Audit team.

The specific *Standards* (attributes and performance) apply to all members of the Healthcare Audit Team (see section 4).

Terms with a specific meaning are used throughout this document and their interpretation in the context of healthcare auditing is provided in the main body of the text. Other terms are included in the Glossary (see section 5).

Key Governance Elements

HSE Healthcare Audit requirement

The annual Healthcare Audit Schedule is informed by information from the following sources:

- The Risk Register
- The Controls Assurance Process
- Analysis of incident investigation reports
- Analysis of complaint reports
- The National Patient Experience Survey.

Other audits may arise where there is an emerging concern about a safety matter and where assurance through audit is sought. This ensures that audits focus on seeking assurance about organisational compliance with standards that are in place to achieve key corporate priorities.

Within the *Standards*, the term 'senior most accountable person' (SMAP)² needs to be interpreted in the context of the governance arrangements within each HSE Corporate, Hospital Group and Community Healthcare Organisation (CHO) structure.

It is necessary for the Assistant National Director (AND) for Healthcare Audit to understand the accountabilities and authority of the HSE National Directors, Hospital Group Chief Executive Officers (CEOs), CHO Chief Officers and the Risk Committee.

Healthcare audit is applicable to all HSE healthcare organisations and any voluntary or private body that has a service level agreement with the HSE.

Healthcare audit activity must evaluate and contribute to the improvement of governance, risk management and control processes, using a systematic and disciplined approach.

Healthcare audit is an essential tool for continuous quality improvement. The findings from healthcare audit are a key element of the assurance framework that the SMAP within a healthcare organisation has to inform the completion of the annual Statement of Internal Control.

² Senior Most Accountable Person (SMAP): The person appointed to be accountable for an organisation. This designation is usually attributable to the CEO of an organisation. Within this document the term 'SMAP' needs to be interpreted in the context of the governance arrangements within each corporate, hospital group and community healthcare organisation.

SECTION 2

Definition of Healthcare Audit

The HSE's Healthcare Audit Team was established in 2010. Healthcare audit, in line with the design and practice of Internal Audit, is *an independent, objective assurance activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes* [The Institute of Internal Auditors].

Under the HSE's Code of Governance, Healthcare Audit sits alongside and mirrors the organisation's Internal Audit function by providing 'Third line of defence' assurance in relation to risks and controls in care related activities in both clinical and non-clinical settings.

The HSE's Healthcare auditors are members of the Chartered Institute of Internal Auditors (CIIA) and are required to comply with the professional and general standards set by the CIIA.

The core aim of healthcare audit is to seek sufficient evidence to provide assurance that standards for health and social care activity are met across the system. Healthcare audit provides recommendations on evidence based findings which are addressed to the SMAP.

Healthcare audit supports the HSE in achieving the goals set out in the HSEs Corporate Plan by:

- Providing valuable and reliable information to inform decision making
- Testing the effectiveness of internal controls that are identified to manage risk
- Providing evidence for managers in relation to signing the Statement of Internal Control
- Identifying good practice for sharing, learning and implementation across the system.

SECTION 3

Code of Ethics

Ethics in healthcare audit includes two essential components:

1. Principles that are relevant to the profession and practice of healthcare auditing, and
2. Rules of Conduct that describe the behaviour norms expected of healthcare auditors. These rules are an aid to interpreting the principle into practical application and are intended to guide the ethical conduct of healthcare auditors.

HSE Healthcare Audit requirement

Healthcare auditors must conform to a code of ethics. Healthcare audit endorses the IIA and NHS Internal Audit Standards code of ethics as set out below. The code of ethics refers to the standard required to which all healthcare auditors perform to and includes a code of conduct based on the four principles of integrity, objectivity, confidentiality and competency. If individual healthcare auditors have membership of a professional body then they must also comply with those specific requirements.

1. Integrity

Principle: The integrity of healthcare auditors establishes trust and thus provides the basis for reliance on their judgement.

Rules of Conduct: Healthcare auditors shall:

- Perform their work with honesty, diligence and responsibility.
- Observe the law and make disclosures expected by the law and the HSE.
- Not knowingly be a party to any illegal activity, or engage in acts that are a discredit to their profession or to the organisation.
- Respect and contribute to the legitimate and ethical objectives of the organisation.

2. Objectivity

Principle: Healthcare auditors exhibit the highest level of professional objectivity in gathering, evaluating and communicating evidence about the activity or process being audited. Auditors must make a balanced assessment of all the relevant circumstances and are not unduly influenced by their own interests or by others when forming a judgement.

Rules of Conduct: Healthcare auditors shall:

- Not participate in any activity or relationship that may impair or be presumed to impair their unbiased assessment. Such participation includes activities and relationships that may be in conflict with the interests of the organisation.
- Not accept anything that may impair or be presumed to impair their professional judgement.
- Disclose all material facts known to them that, if not disclosed, may distort the reporting of activities being audited.

3. Confidentiality

HSE Healthcare Audit requirement

Healthcare audit has taken advice in relation to the General Data Protection Regulation (2018) and from the Data Protection Commissioner (2012) to be reasonably assured that audit activity is in line with the requirements of the Data Protection Acts 1988 and 2003.

The 'Data Protection Guidelines on Research in the Health Sector' (Hawkes 2007) offers some advice in this regard. Section 2.8 'Persons Accessing Patient Identifiable Data' questions whether a staff member, who is not a health professional but who can access patient identifiable information without consent, can be considered to owe an equivalent duty of confidentiality to the patient. All staff members of Quality Assurance and Verification (QAV), including healthcare auditors, are employees of the HSE and have a HSE contractual duty of confidentiality and as such have a duty of confidentiality to the data subject that is equivalent to those who provide direct professional care. Therefore, healthcare auditor's duty of confidentiality extends to all HSE patients, clients, service users and staff.

Principle: Healthcare auditors respect the value and ownership of the evidence they receive and do not disclose information without appropriate authority unless there is a legal or professional obligation to do so.

Rules of Conduct: Healthcare auditors shall:

- Be prudent in the use and protection of information acquired in the course of their duties.
- Not use information for any personal gain or in any manner that would be contrary to the law or detrimental to the legitimate and ethical objectives of the organisation.

4. Competency

Principle: Healthcare auditors possess the knowledge, skills and experience needed in the performance of healthcare audits.

Rules of Conduct: Healthcare auditors shall:

- Only engage in audit when they have attained the necessary level of training, knowledge, skills and experience.
- Perform audit in accordance with these *Standards* and the Healthcare Audit Standard Operating Procedure.
- Continually improve their proficiency, effectiveness and the quality of audit.

HSE Healthcare Audit requirement

Healthcare auditors are also required to adhere to the HSE Code of Standards and Behaviour.

The HSE Code of Standards and Behaviour is an important element of the overall framework within which all employees are expected to work. It sets out the standards required of employees in the discharge of their duties in order to support a high quality public service, based on high levels of personal performance and responsibility. This policy is part of a suite of HSE policies and should be read in conjunction with the HSE Policy on Good Faith Reporting, the HSE Policy on Protected Disclosures and the HSE Policy on Fraud. Healthcare auditors should also read the Department of Health (2018) Code of Conduct for Health and Social Care Providers.

SECTION 4

Attribute Standards

Attribute standards define the healthcare audit activity's position and scope within the HSE.

1. Purpose, Authority and Responsibility

The purpose of healthcare audit is to act as an internal independent, objective assurance activity designed to add value and lead to improved healthcare organisational quality processes, governance, assurance and ultimately improved patient care and safety. It helps a healthcare organisation accomplish its quality and safety objectives by bringing a systematic, disciplined approach to evaluating and improving the effectiveness of the governance, accountability, control and risk management processes in place.

HSE Healthcare Audit requirement

The National Director (ND) of Quality Assurance and Verification (QAV) is accountable and responsible for Healthcare Audit.

The AND for Healthcare Audit is accountable and responsible for the overall operational and strategic development and direction of Healthcare Audit, including the development of an annual Healthcare Audit Schedule. The identification of audit priorities is led by the AND for Healthcare Audit in partnership with identified stakeholders including the ND QAV. The annual Healthcare Audit Schedule is approved by the HSE Risk Committee. The AND for Healthcare Audit must ensure that healthcare auditors are familiar with these *Standards*.

It is the responsibility of all healthcare auditors to ensure that they adhere to these *Standards*. It is the responsibility of the Healthcare Audit Team to achieve their objectives by making a positive contribution and working towards the professional expectations of the Healthcare Audit Team.

2. Independence and Objectivity

Healthcare audit activity must be independent and healthcare auditors must be objective in performing their work.

Independence is the freedom from conditions that threaten the ability of the Healthcare Audit Team to carry out healthcare audit responsibilities in an unbiased manner. To achieve the degree of independence necessary to carry out the responsibilities of healthcare audit activity, the ND QAV with the assistance of the AND for Healthcare Audit will have direct access to the senior HSE management team and the HSE Risk Committee as issues arise that require them to be informed. Threats to independence must be managed at the individual healthcare auditor, audit function and organisational level.

Healthcare audit should be sufficiently independent of the activities which it audits to enable auditors to perform their duties in a manner which facilitates impartial and effective professional judgements and recommendations. Accountability for the response to the findings and recommendations of healthcare audit lies with the line managers who accept, implement or formally reject them.

Objectivity is an unbiased mental attitude that allows healthcare auditors to perform audits in such a manner that provides a balanced assessment of all the relevant circumstances when

forming a judgement and does not compromise on quality. Objectivity requires that healthcare auditors do not subordinate/lower their judgement on audit matters. See also the principles of objectivity and rules of conduct outlined in the Code of Ethics (Section 2).

2.1 Organisational Independence

HSE Healthcare Audit requirement

The ND QAV with the assistance of the AND for Healthcare Audit is required to establish effective communication with, and have free and unfettered access to, the HSE Director General (or equivalent) and the chair of the HSE Risk Committee.

The independent nature of healthcare audit must be respected by all levels of management within the organisation in order to maintain the status and profile of the healthcare audit function.

HSE Healthcare Audit requirement

Healthcare audit activity must be free from interference in determining the scope of healthcare auditing, performing work and communicating findings.

2.2 Direct Interaction with the HSE Risk Committee

The ND QAV with the assistance of the AND for Healthcare Audit is required to communicate and interact with the HSE Risk Committee in relation to the annual Healthcare Audit Schedule and audit activity.

2.3 Individual Objectivity

Healthcare auditors must have an impartial, unbiased attitude and avoid any conflict of interest.

Conflict of interest is a situation in which a healthcare auditor, who is in a position of trust, has a competing professional or personal interest. Such competing interests can make it difficult to fulfil his/her duties impartially. A conflict of interest can exist even if no unethical or improper act results. A conflict of interest can create an appearance of impropriety that can undermine confidence in the healthcare auditor and the healthcare audit activity. A conflict of interest could impair an individual's ability to perform his/her duties and responsibilities objectively.

2.4 Impairment to Independence or Objectivity

If independence or objectivity is impaired in fact or appearance, the details of the impairment must be disclosed to all appropriate parties.

The determination of appropriate parties to which the details of an impairment to independence or objectivity must be disclosed is dependent upon the expectations of the healthcare audit activity and the responsibilities to senior management.

Impairment to independence and objectivity may include, but is not limited to, personal conflict of interest and any restriction to accessing records, documentary evidence and personnel.

Healthcare auditors must refrain from assessing specific operations for which they were previously responsible. Objectivity is presumed to be impaired if a healthcare auditor provides assurance services for an activity for which the healthcare auditor had responsibility within the previous year.

2.5 Proficiency and Due Professional Care

Audits must be performed with proficiency and due professional care.

Proficiency is the collective term that refers to the knowledge, skills and other competencies required of healthcare auditors to effectively carry out their professional responsibilities.

Due professional care refers to the application of the care and skills expected of a reasonably prudent and competent healthcare auditor.

Due professional care does not imply infallibility. Healthcare auditors must be alert to significant risks that might affect objectives. However, audit alone, even when performed with due professional care, does not guarantee that all significant risks will be identified.

Healthcare auditors must also enhance their knowledge, skills and other competencies through continuing professional development.

See also Section 2 *Code of Ethics* for principles and rules of conduct.

2.6 Quality Assurance and Improvement Programme

The AND for Healthcare Audit is required to develop and maintain a quality assurance and improvement programme that covers all aspects of healthcare audit activity.

Such a programme is designed to enable an evaluation and internal assessment of healthcare audit activity's conformance with the *Definition of Healthcare Audit* and the *Standards* and an evaluation of whether healthcare auditors apply the *Code of Ethics*. The programme will also assess the efficiency and effectiveness of the healthcare audit activity and identify opportunities for improvement through ongoing internal monitoring of the performance of healthcare audit activity.

Ongoing monitoring is an integral part of the day-to-day supervision, review and measurement of healthcare audit activity. It is incorporated into the routine policies and practices used to manage healthcare audit activity and uses processes, tools and information considered necessary to evaluate conformance with the *Definition of Healthcare Audit*, the *Code of Ethics* and the *Standards*.

External assessments must be conducted at least once every five years by a qualified independent assessor or assessment team from outside the organisation.

Performance Standards

1. Managing Healthcare Audit Activity

The AND for Healthcare Audit must effectively manage healthcare audit activity to ensure it adds value to the organisation.

Healthcare audit activity is effectively managed when:

- The results of the healthcare audit activities conforms with the *Definition of Healthcare Audit* and the *Standards*
- The auditors who are part of healthcare audit activity demonstrate conformance with the *Code of Ethics* and the *Standards*.

Healthcare audit activity adds value to the organisation (and its stakeholders) when it provides objective and relevant assurance and contributes to the effectiveness and efficiency of governance, accountability, risk management and other control processes.

1.1 Annual Healthcare Audit Schedule

The AND for Healthcare Audit must establish an annual Healthcare Audit Schedule to determine the priorities of healthcare audit activity that is consistent with the organisation's goals and assurance framework. The annual Healthcare Audit schedule and priorities are informed by information from the following sources:

1. The Risk Register
2. The Controls Assurance Process
3. Analysis of Incident Investigation Reports
4. Analysis of Complaint Reports
5. The National Patient Experience Survey.

The Schedule must be adjusted, as necessary, in response to changes in the organisation's business, risks, operations, programs, systems and controls. The Schedule of audit activity must be reviewed at least annually and input from senior management and the HSE Risk Committee are considered in this process. If other activities are required, these must be added to the annual Healthcare Audit Schedule.

1.2 Communication and Approval

The AND for Healthcare Audit must communicate the annual Healthcare Audit Schedule, resource requirements, including significant interim changes, to the ND QAV for review and approval. The AND for Healthcare Audit must also communicate the impact of any identified resource limitations.

1.3 Resource Management

The AND for Healthcare Audit must ensure that healthcare audit resources are appropriate, sufficient and deployed effectively to achieve the approved annual Schedule. Appropriate refers to the mix of knowledge, skills and other competencies needed to perform an audit. Sufficient refers to the quantity of resources needed to accomplish the Schedule. Resources are deployed efficiently when they are used in a way that optimises the achievement of the approved Schedule. The AND for Healthcare Audit should ensure proper coverage of audit, across all service areas in order to minimise duplication of efforts.

1.4 Policies and Procedures

The AND for Healthcare Audit is required to establish policies and procedures, when relevant, to guide healthcare audit activity and ensure that these are regularly reviewed by all members of the Healthcare Audit Team.

1.5 Reporting Arrangements

The AND for Healthcare Audit is required to report periodically to relevant senior management on healthcare audit activities, purpose and performance relevant to the annual Healthcare Audit Schedule. Reporting must include significant risk exposures, control issues, governance issues and other matters needed or requested by senior management. The frequency and content of reporting may change dependent on the importance of the information to be communicated and the urgency of any related actions.

2. Nature of Work

Healthcare audit activity evaluates and contributes to the improvement of clinical governance, risk management and control processes using a systematic and disciplined approach.

2.1 Clinical Governance

Clinical governance is the system through which healthcare organisations are accountable for the quality, safety and satisfaction of patients in the care they have delivered.

Clinical governance is the corporate responsibility for clinical performance. It is based on the single point of accountability principle, i.e., that the senior most accountable person of a health or social care service or organisation is responsible for the quality of patient care and the patient's health outcome. For healthcare managers this means specifying the clinical standards that are expected to be delivered and demonstrating the measurements taken to achieve these standards.

Healthcare audit activity assesses and makes appropriate recommendations for improving the governance process by communicating risk and control information to appropriate areas of the organisation.

2.2 Risk Management

Healthcare audit is required to evaluate the effectiveness and contribute to the improvement of risk management.

2.3 Internal Control/Control assurance

Healthcare audit activity adds value by testing the effectiveness of the controls to assist organisations to achieve their objectives in delivering services in an effective and safe manner. This incorporates compliance with all legal and regulatory obligations including adherence to regulations, policies, procedures and standards and ensuring the delivery of quality services in an environment which minimises risk to patients, service users and staff alike.

3. Performing the Audit

Healthcare auditors must adhere to the Healthcare Audit Standard Operating Procedure when performing an audit.

3.1 Healthcare Audit Standard Operating Procedure

The Healthcare Audit Standard Operating Procedure outlines the specific actions associated with conducting an audit according to the following headings:

- Audit Scoping

- Audit File
- Audit Plan
- Audit Fieldwork:
 - Audit Evidence
 - Audit Notification Letters
 - Audit Site Selection and Site Visits
 - Audit Alert
 - HSE Protected Disclosure Policy
- Post Fieldwork:
 - Audit reports
 - Quality of Reports
 - Summary Report
 - Disseminating Audit Reports
 - Errors and Omissions
 - Audit Opinion
 - Data Management and Ethics
 - Audit Recommendations
 - Difference of Opinion within the Assigned Audit Team.

All audits must adhere to the above actions when performing an audit.

SECTION 5

Glossary

Assurance: Confidence that controls are in place based on sufficient evidence and are operating efficiently and that the objectives are being met.

Assurance Framework: This is the primary tool used by the HSE to ensure that it is properly informed on the risks of not meeting its objectives or delivering appropriate outcomes and that it has adequate assurances on the design and operation of the systems in place to mitigate those risks.

Assurance Services: An objective examination of evidence for the purpose of providing an independent assessment on governance, accountability, risk management and control processes within an organisation. Examples may include compliance with a national standard, policy or guideline.

Clinical Governance: A system through which healthcare organisations are accountable for continuously improving the quality of services; it ensures that there are clean lines of accountability within the HSE and that there is a comprehensive programme of quality improvement systems. The six pillars of clinical governance are: clinical effectiveness, research and development, openness, risk management, education and training and clinical audit.

Code of Ethics: The purpose of the Code of Ethics is to promote an ethical culture in the profession of healthcare auditing.

Conflict of Interest: Any relationship that is, or appears to be, not in the best interest of the organisation. A conflict of interest would prejudice an individual's ability to perform his/her duties and responsibilities objectively.

Consulting Activities: Generally advisory in nature and are performed at the specific request of an engagement client. The nature and scope of the consulting activity are subject to agreement with the client.

Control: Any action taken by management to manage risk and increase the likelihood that established objectives and goals will be achieved. Management must plan, organise and direct the performance of sufficient actions to provide reasonable assurance that objectives and goals will be achieved.

Control Processes: The policies, procedures and activities that are part of the control framework designed to ensure that risks are contained within the level of risk that an organisation is willing to accept.

Engagement: A specific healthcare audit assignment, consultancy activity or other relevant project. An engagement may include multiple tasks or activities designed to accomplish a specific set of related objectives.

Governance: The combination of processes and structures implemented in an organisation to inform, direct, manage and monitor the activities of the organisation toward the achievement of objectives.

Reasonable Assurance: Confidence based on sufficient evidence that is available during the audit, at a point of time, to allow the Healthcare Audit Team to draw reasonable conclusions and provide a positively worded assurance opinion.

Risk: The effect of uncertainty on objectives. An effect is a deviation from the expected and may be positive or negative. Risk is often expressed in terms of a combination of the consequences of an event and the associated likelihood of occurrence.

Risk Management: A process to identify, assess, manage and control potential events or situations to provide reasonable assurance regarding the achievement of the organisation's objectives.

Scope: The scope is a statement that specifies the focus, extent, and boundary of a particular audit.

Senior Most Accountable Person: The person appointed to be accountable for the operations of an organisation. This designation is usually attributable to the CEO of the organisation.

Service User: A member of the public who uses health and social care services as patients, or organisations that represent the interests of these people.

Statement on Internal Control: A public accountability document that describes the effectiveness of internal controls in an organisation and is personally signed by the senior most accountable person.

References

Data Protection Acts 1988 and 2003.

Available at: <http://www.welfare.ie/en/downloads/dsfadataprotectionguide.pdf>

Department of Health (April 2011). National Health Service Internal Audit Standards.

Available at: <https://www.gov.uk>

Department of Health (May 2018). Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers.

Available at: <https://health.gov.ie/wp-content/uploads/2018/07/Code-of-Conduct-15062018.pdf>

General Data Protection Regulation (2018)

Available at: <https://www.dataprotection.ie/docs/GDPR/1623.htm>

Hawkes (2007). Data Protection Guidelines on Research in the Health Sector.

Available at: https://www.dataprotection.ie/documents/guidance/Health_research.pdf

HSE (October 2015). Code of Governance. Available at:

<https://www.hse.ie/eng/about/who/directoratemembers/codeofgovernance/hsecodeofgovernance2015.pdf>

HSE Controls Assurance Framework

Available at: <https://www.hse.ie/eng/about/who/acute-hospitals-division/about/hse-accountability-framework.pdf>

HSE Corporate Plan 2015-2017

Available at: <https://www.hse.ie/eng/services/publications/corporateplan/>

HSE Code of Standards and Behaviour

Available at: <http://www.hse.ie/eng/staff/Resources/Codeofstandards.pdf>

HSE (2011). Good Faith Reporting Policy.

Available at: <https://www.hse.ie/eng/staff/resources/hrppg/good-faith-reporting-policy-2011.pdf>

HSE Policy on Protected Disclosures

Available at: <https://www.hse.ie/eng/staff/resources/hrppg/protected-disclosures-of-information-in-the-workplace.html>

HSE (2006). Framework for the Corporate and Financial Governance of the Health Service Executive Policy Statement on Fraud. *Information and Guidelines for Staff*. Document 2.3. (Version 1: Created September 2006. Version 2: Updated November 2007. Version 3: Published June 2009). Available at: <https://www.hse.ie/eng/staff/resources/hrppg/fraud-policy.pdf>

Institute of Internal Auditors (2017). International Standards.

Available at: <https://www.iaa.org.uk/resources/ippf/international-standards/>

HSE: Quality Assurance and Verification (2018). Healthcare Audit Standard Operating Procedure (Document Reference number: QAV01).