

Guidelines for the

INTERNAL AUDIT OF CLINICAL AREAS

June 2017

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Foreword

This guideline document has been developed to provide practical guidelines and resources to support health care organisations in ensuring a mature approach to internal audits that reflects sector priorities and risks. This guideline supports those with responsibility for the internal audit function in an organisation to incorporate clinical areas in the internal audit program. The guideline is not intended to be a comprehensive document on internal audit and assumes an organisation has internal audit structures and functions in place. If an internal audit function is not already well established, organisations may need to seek the advice of an internal auditor or refer to the many good reference documents that exist to guide internal practice such as:

- The Institute of Internal Auditors 2012, International standards for the professional practice of internal auditing.
- Australian National Audit Office 2012, Public Sector Internal Audit: better practice guide, AGPS, Canberra

This document is structured to provide you with:

- Part One: An introduction to the internal audit of clinical areas. This area is a brief summary of the rationale for including an internal audit of the clinical domain. More detail addressing the internal audit of clinical areas and board assurance can be found in the accompanying document Assurance in the Health Sector: Overview of the Internal Audit of Clinical Areas
- Part Two: Guidelines for the internal audit of clinical areas. This main part of the document contains information about the key steps and documentation that you will need to consider in ensuring your internal audit program is inclusive of clinical areas.
- Appendices. The appendices contain useful templates that may be helpful in undertaking the internal audit of clinical areas.

Glossary

Internal Audit of Clinical Areas	A systematic and proactive process that provides the Board (and senior management) with independent and objective quality improvement advice and assurance that significant clinical risks to meeting strategic objectives are being managed. (INCITE information, 2012)
Clinical Audit	The systematic review of elements of clinical care against predetermined criteria, with the aim of identifying areas for improvement and then developing, implementing and evaluating strategies intended to achieve that improvement. (DH, 2010)
External Audit	External audits focus on the accuracy of the annual report and financial statements of an organisation and report primarily to members.
Head of Internal Audit	A manager in the health service with responsibility for managing, coordinating and reporting on the internal audit function. The head of internal audit will be, where possible, a manager with no direct responsibilities for the operational areas audited.
Internal Audit	An independent, objective assurance and consulting 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 (Institute of Internal Auditors, 2011)
Internal Auditor	Qualified internal auditor working in line with the international standards of internal auditing
Internal Audit Manager	A manager in the health service responsible for guiding the internal audit process in a specified area e.g. clinical or human resources
Internal Audit Program	A medium term plan (~3 years) of internal audits to be undertaken by an organisation
Internal Audit Work Plan	Outlines in detail the work to be completed for each year of the internal audit program

Part One: Introduction to the Internal Audit of Clinical Areas

1.1 Why undertake Internal Audit of Clinical Areas?

It is well established in the literature that healthcare interventions carry significant risks to patients and consumers. In Australia today, patients have a

'one in two chance of getting the right care, a 1:10 likelihood of being harmed in association with a hospital admission and a 1:50 possibility of system-induced death or major disability'

(Braithwaite and Coiera 2010)

Considerable attention is focused on the minimisation of harm to patients and clients in academia, government and health care settings. Health services' boards need assurance that significant clinical risks related to the core business, the delivery of health services, are being managed effectively. Best practice internal audit functions will focus their audits on the most significant risks of the organisation. The application of internal audit to areas of significant clinical risk, as part of the enterprise-wide internal audit program, is a feature of a mature internal audit function in a health service.

The internal audit of clinical areas is a systematic and proactive process that provides the board (and senior management) with independent and objective quality improvement advice and assurance that significant clinical risks to meeting strategic objectives are being managed. The internal audit of clinical areas provides a robust method for boards to drive improvement and provide assurance in regard to the effectiveness of clinical procedures and protocols to manage key clinical risks.

A variety of assurance mechanisms exists in healthcare organisations to address clinical risk, including management monitoring and reporting, external accreditation, clinical audit and external audit. An internal audit program of clinical areas can address significant clinical risks that are not covered adequately by these other assurance activity.

1.2 The Internal Audit of Clinical Areas Framework

Broadening the scope of internal audit practices to clinical areas requires ensuring appropriate responsibilities and accountability for the internal audit of clinical areas within an organisation's existing internal audit function. Internal audits are based on the principles of independence, objectivity, risk based, value adding, and being proactive, as reflected in the international standards (IIA, 2012). While the internal audit of clinical areas follows these same principles, the structures for reporting and accountability may differ to reflect the clinical expertise required and structure of the healthcare organisation.

The internal audit of clinical areas is part of the wider internal audit responsibilities of the audit committee. The internal audits of clinical and non-clinical areas are both planned and reported to the board via the audit committee. The key differences in the responsibility and accountability arrangements for the internal audit of clinical areas relate to the need for:

- clinical input into the identification of strategic clinical risks
- clinical input into the prioritisation of the organisation's three-year internal audit program
- clinical input into the internal audit of the clinical area annual work plan and individual audit plans
- clinical expertise in the internal auditor/s undertaking the audit
- oversight by a quality committee of the implementation of internal audit recommendations.

Part One: Introduction to the Internal Audit of Clinical Areas (continued)

These responsibilities and accountabilities for the internal audit of clinical areas are summarised in the governance diagram below:

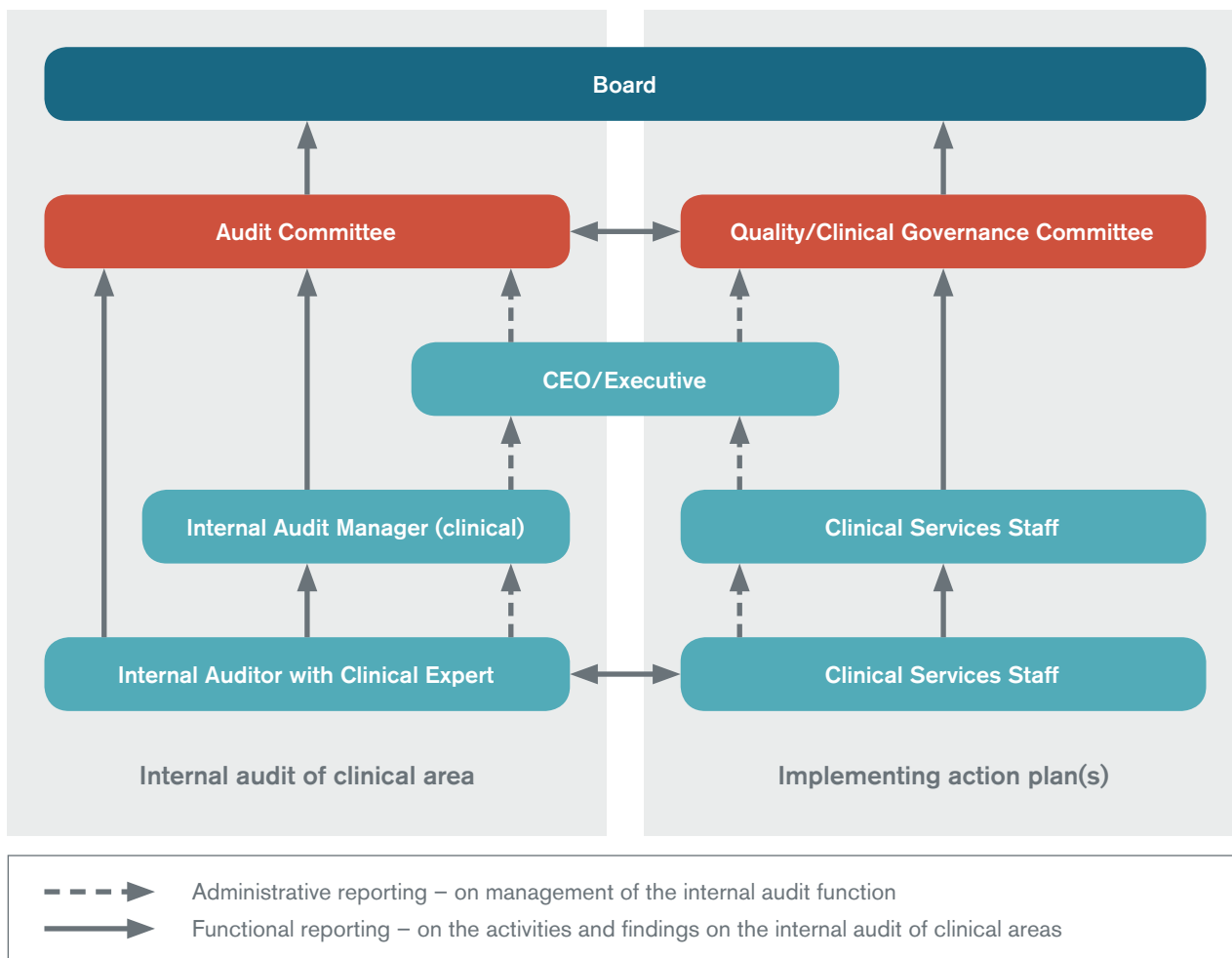


Figure 1: Governance arrangements (modified from (INCITE information 2012)

Part One: Introduction to the Internal Audit of Clinical Areas (continued)

1.3 Using these Guidelines

The guidelines in this document support health care organisations in developing a holistic approach to internal audits that reflects sector priorities and risks. It will assist those with responsibility for the internal audit function in an organisation to incorporate clinical areas into the internal audit program. The guideline is not intended to be a comprehensive document on internal audit and assumes an organisation has internal audit structures and functions in place. If an internal audit function is not already well established, organisations may need to seek the advice of an internal auditor or refer to the many reference documents that exist to guide internal practice (ANOA, 2012, IIA, 2012).

Part Two of this document will take you through the key issues in incorporating the internal audit of clinical areas into your existing internal audit system. The way in which the internal audit of clinical areas differs from a traditional internal audit is considered in each stage of the internal audit process and is summarised in the Figure Two below with each main heading corresponding to the relevant sections in Part Two.

Part Three of this document provides appendices that are suggestions for templates that may be useful in undertaking the internal audit of clinical areas.

Other key documents accompanying this guideline document are:

- INCITE Information, 2012, Clinical Internal Audit Framework
- Australian Centre for Healthcare Governance, 2013, Assurance in the Health Sector: Overview of the Internal Audit of Clinical Areas
- Internal Audit Tool for Emergency Department/Urgent Care Centres
- Generic Internal Audit Tool for Clinical Areas

Part One: Introduction to the Internal Audit of Clinical Areas (continued)

Key to Part Two of Guideline Document

<p>2.1 Review Internal Audit Policy</p>	<ul style="list-style-type: none"> ▪ Update internal audit policy scope to include the internal audit of clinical and non clinical areas <ul style="list-style-type: none"> ▪ Assign and clearly articulate role of internal audit manager in clinical area ▪ Clarify accountabilities of internal audit manager in clinical area to head of internal audit
<p>2.2 Internal Audit Program</p>	<ul style="list-style-type: none"> ▪ Review all organisation's risks (including clinical) and prioritise areas for internal audit ▪ Develop a three year program (or similar period) for enterprise wide internal audit addressing all major risks <ul style="list-style-type: none"> ▪ Develop an annual workplan including timing, costs, resources for internal audits
<p>2.3 Preparing for Internal Audit</p>	<ul style="list-style-type: none"> ▪ Internal audit manager in clinical area to inform internal auditor selection criteria re requirements for clinical expertise on internal audit team ▪ Internal audit manager in clinical area to develop/approve an internal audit tool for use in specified clinical area <ul style="list-style-type: none"> ▪ Internal auditor to develop and seek agreement on individual internal audit plan with relevant unit managers, manager of internal audit in clinical area and/or head of internal audit
<p>2.4 Conducting an Internal Audit</p>	<ul style="list-style-type: none"> ▪ Collect and analyse unit and clinical data in line with internal audit plan <ul style="list-style-type: none"> ▪ Discuss with unit managers audit progress and accuracy of findings <ul style="list-style-type: none"> ▪ Draft internal audit report
<p>2.5 Internal Audit Reporting</p>	<ul style="list-style-type: none"> ▪ Internal audit manager of clinical area to review draft report ▪ Unit manager(s) to provide response to draft audit findings and recommendations ▪ Auditor present final audit report and manager's comments to audit committee
<p>2.6 Monitoring Internal Audit</p>	<ul style="list-style-type: none"> ▪ Allocate responsibility for implementation of clinical recommendations <ul style="list-style-type: none"> ▪ Report implementation progress to board quality committee <ul style="list-style-type: none"> ▪ Re audit to determine if improvement

Figure 2: Summary of Part Two of Guidelines: Key processes in incorporating clinical areas in an internal audit program

Part Two: Guidelines for the Internal Audit of Clinical Areas

Part Two of this document provides you with practical guidelines to address the accountability and responsibility, planning, implementation, reporting, monitoring, and documentation of the internal audit of clinical areas. The intention of this section is to highlight the key steps and documentation that you will need to consider in ensuring your internal audit program is inclusive of clinical areas. The section is not intended to be a source document on internal audit and assumes an organisation has internal audit structures and functions in place.

2.1 Reviewing the Scope of Internal Audit

To ensure your internal audit program is inclusive of clinical areas, modifications may be required to documents that guide internal audits in your organisation. The key requirements in integrating the internal audit of clinical areas in internal audit policy, procedures, and position descriptions are outlined in this section.

2.1.1 Roles and Responsibilities

It is important that there is a clear articulation of the responsibilities and accountabilities in relation to all functions that support internal audit in your health service. The *Head of Internal Audit* is the manager in the health service with responsibility for managing, coordinating and reporting on the organisation-wide internal audit function. The head of internal audit will be, where possible, a manager with no direct responsibilities for the operational areas audited. This requirement supports the objectivity and independence of the organisation's internal audit functions.

The Audit Committee is responsible for reviewing the clinical and non-clinical internal audit functions of the organisation. This includes internal audit planning, oversight of the appointment of key positions, reviewing the internal audit findings and implementation of recommendations.

For the internal audit of clinical areas the following responsibilities need to be allocated:

Internal Audit Manager: A manager in the health service responsible for guiding the internal audit process in an area that is prioritised for internal audit. For example, a quality manager may have responsibilities for the management of internal audit in clinical areas. This responsibility needs to be separated from the direct operational management of a clinical area under audit. The internal audit manager of clinical areas needs to be a person with knowledge of overall clinical services. This allows them to provide the clinical perspective on risk identification, audit planning and individual audit work plans which may occur within a multidisciplinary team.

Note that not all organisations will have the resources to support the two separate responsibilities for head of internal audit and manager of internal audit and they may be merged into one role.

Quality Committee: This committee has a role in noting the findings of the internal audit of clinical areas, monitoring the actions taken by managers of clinical areas in response to internal audit recommendations and providing any advice and reports to the board for noting.

Unit Managers: managers of clinical units or programs need to have clear responsibility for supporting the implementation of internal audit function in their area.

These responsibilities can be documented in some detail in the internal audit charter or policy, and referenced in each position description with a general statement indicating the responsibility for involvement in quality assurance and improvement activities and internal audits. A statement such as:

"Responsibility to engage in quality assurance and improvement activities as directed by the board and manager which may include accreditation, monitoring, reporting and internal audit".

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.1.2 Internal Audit Charter or Policy

The International Standards for the Professional Practice of Internal Auditing requires that the purpose, authority, responsibilities and accountabilities of the internal audit activity must be formally defined in an internal audit charter (ISPPA, 2010). However charters are less commonly used in health services and many organisations may find they can outline the important issues in a board endorsed policy.

It is recommended that all agencies have an internal audit charter or policy and accompanying procedure to guide understanding, expectations and practice in relation to internal audit. The scope of the internal audit policy or charter needs to encompass all areas of significant risk for the organisation and this includes clinical areas.

Note that the internal audit policy or charter is a separate document to the audit committee terms of reference. To ensure consistency with the internal audit policy/charter, the terms of reference of the audit committee will address the roles of the committee in relation to internal audit, which are to:

- Enhance the independence and effectiveness of the internal auditors.
- Monitoring effective internal and management controls.
- Providing a communication link between management, internal audit personnel and the board.

The exact format of any policy will vary from organisation to organisation. The table in Appendix 1 provides a guide to the content of the key sections that are ideally covered in an internal audit charter or policy that is inclusive of clinical areas. The key consideration in developing or updating an internal audit charter or policy is to ensure that the scope of internal audit is described in such a way as to address any area of significant risk whether financial, clinical, or in other areas of operations.

2.1.3 Procedure

The key processes involved in implementing and conducting an internal audit function that is inclusive of clinical areas have been outlined in Figure 2 in Part One.

These key internal audit processes need to be reflected in an internal audit procedure. Inclusion of the internal audit of clinical areas into the existing internal audit procedure requires:

- Identification of an audit committee endorsed *internal audit manager* responsible for the internal audit of clinical areas. The internal audit manager of clinical areas can provide input into
 - identification of strategic clinical risks,
 - prioritisation of the organisation's three-year internal audit program
 - selection of appropriate internal auditors
 - the annual work plan of internal audit of clinical areas and individual audit plans
 - feedback on the internal audit report of clinical areasTo maintain the independence and objectivity of the organisation's internal audit function the *internal audit manager* of clinical areas will have no clinical service provision or direct management responsibility.
- Consideration of the relationship between the *head of internal audit* and the *internal audit manager* in clinical areas. Where an organisation has the need to create separate roles for the head of internal audit and the manager of internal audit in clinical areas, consideration needs to be made of the role of the *internal audit manager* in finalising the organisation's three-year internal audit program, internal auditor selection, clinical internal audit planning and reporting.
- Consideration of the linkage between both the established internal audit three-year program and the internal audit annual work plan on how planning for the internal audit of clinical areas is incorporated
- Requirements for clinical expertise in the internal auditor/s undertaking the audit
- Oversight of the implementation of internal audit recommendations by the quality committee

The exact format of the internal audit procedure will reflect each organisation's structure and processes. Suggestions for example procedure statements are shown in Appendix 2.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.2 Internal Audit Planning

Two main types of internal audit planning can occur within an organisation:

- A program of audits over the medium term (usually three years) outlining the strategic approach to internal audits, the *internal audit program*. This program should include significant risks such as those in the clinical domain.
- A detailed annual *internal audit work plan* derived from the program. This will include detail about the specific area in which clinical audit will be undertaken.

How these two related planning processes include clinical areas are described in detail in this section.

2.2.1 Developing a holistic risk-based Internal Audit Program

Developing a medium term plan of internal audits, the *internal audit program*, allows internal audits to be planned with consideration of both alignment with strategic risks and analysis of any assurance gaps. The *internal audit program* articulates the strategic risks to be addressed, the broad schedule for internal audits to be undertaken and the resources to be allocated.

As internal audit activity should be focused on where it is most useful and effective in dealing with significant organisational risk, the following sources of risk information should be considered to ensure that clinical areas are considered and included in the program:

The strategic plan: The three-year internal audit program should align with the organisational strategic direction and reflect the goals and priorities (and accompanying strategic risks) of the organisation articulated in strategy and other key plans, e.g. operational, unit, quality, and IT plans. Strategic plans would normally address, through a strategic objective, the core business of health services, clinical service delivery.

Risk register: For organisations with a mature risk management framework the organisation's risk profile will be a key source of information to understand the priorities for internal auditing. In situations where the organisation does not have a comprehensive risk profile, the internal audit will need to develop a risk profile for discussion and review by the board, audit committee and senior managers. The risk profile will need to encompass enterprise-wide strategic risks, and for health services this means that the delivery of the core business, high quality health services, would generally appear as a significant risk.

External reports: External reports and reviews can indicate sources of potential clinical risk which should be considered as part of the three-year internal audit program. Published literature and government reports may also provide useful information about potential sources of risk. Coroners' reports, accreditation recommendations, and issues identified in gap analyses can indicate areas of clinical risk for the organisation.

Assurance mapping: Internal audit is only one of the methods that exist in an organisation for providing assurance and review. A common framework for viewing the different types of risk management and assurance within an organisation is the 'Three Lines of Defence'. The first line of defence is the day to day controls in each area of the organisation. In the clinical setting these are the responsibility of clinical managers who ensure the implementation of policies, procedures and protocols in each unit/program to guide quality of care and manage risk. The second line of defence is the oversight functions of the organisation to ensure risk management and compliance. In clinical areas this is usually exercised by quality, risk and HR committees. The third line of defence is internal audit, which in clinical areas is underused in health services.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

In addition to these three internal lines of defence there are external audits and regulatory requirements in clinical areas such as accreditation, compliance reporting, and external audit (e.g. VMIA risk framework quality review) that can provide assurance to the board that risk is being managed.

The three-year internal audit program must complement not duplicate other review and assurance activities. It can be useful to develop an assurance map that provides an overview of the assurance coverage via various mechanisms and identify any risks that are not covered adequately by other assurance activity and may require internal audit.

2.2.2 Content of the Internal Audit Program

The three-year internal audit program that is inclusive of clinical areas will be outlined in a report to be considered and endorsed by the board via the audit committee. The report may include the headings shown in the table below:

Internal Audit Program Heading	Detail Required
Methodology	a brief outline of the approach taken in developing the three-year program and key stakeholders consulted (including the internal audit manager for clinical areas)
Key Strategies and Risks	an outline of the entity's key strategies and risks (including clinical), including a description of emerging external issues and trends that may impact on the entity
Assurance Map	an outline of the entity's identified business risks mapped to the various internal and external assurance and review activities with the aim of identifying assurance duplication and gaps that can inform internal audit priorities
Internal Audit Priorities	the key priorities and direction of internal audit over the period of the internal audit program (see Appendix 3 for potential prioritisation criteria in clinical areas)
Resource Allocation	an indication of the financial and human resource budgets for internal audit activities over the life of the internal audit program
Annual internal audit work plan development	the manner in which the annual internal audit work plan will be developed and the parameters for its formation, which might include: <ul style="list-style-type: none"> ▪ the balance of different types of internal audits (in clinical areas either conformance with standards or improving the performance of a unit); ▪ principles for coverage of different business and/or program and/or geographical locations; ▪ mechanisms for reliance on other review and assurance functions
Internal audit program progress and evaluation	<ul style="list-style-type: none"> ▪ performance measures to be used to evaluate the performance of internal audit ▪ arrangements for the annual review and update of the internal audit program

Table 1: Template for three-year internal audit program (modified from ANOA, 2012:23)

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

The priorities for internal audit to be addressed in the program can be represented in a table that includes the following information:

- Internal Audit themes: the potential range of all audit activities; sometimes referred to as the audit universe, this lists the main categories of enterprise-wide operations and risks
- Risk areas and ratings from the risk register
- The year the internal audit is to be conducted

An example of a table is shown below.

Potential Audit Themes	Risk Area and Risk Register ID	Risk rating	Year 1	Year 2	Year 3	Comment
Finance		High	✓			
IT and Communications		High			✓	
Risk Management		High				VMIA risk management framework quality review in Year 1
Human resources	Credentiailling	High				Credentiailling policies reviewed last year and not considered critical for internal audit coverage
Clinical Services		High	✓		✓	
Facilities management		High				
OHS		High		✓		
External relations		Medium				
Research		Low				

Table 2: Example of internal audit program priority table

2.2.3 Developing an annual work plan

An internal audit work plan outlines in detail the work to be completed for each year of the internal audit program. This involves identifying the number and scope of individual internal audits to be conducted in the broad priority areas identified in the three-year program.

Prioritising internal audits

To determine the priority of specific internal audits it is useful to develop a set of criteria that can be used to rank potential audits. Potential criteria can include (ANOA, 2012:25):

- The importance of the program to the organisation's objectives
- The risk rating identified in the risk register or identified through internal audit function
- Coverage by other assurance and review or external reporting functions
- The potential benefits of an audit
- Any relevant finding, reports, recommendations from other internal or external reviews, accreditation or audit
- The length of time since any previous internal or external audit

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

In the clinical area additional information will inform the selection of internal audits including:

- Areas of higher volume
 - minimum three years through-put data for clinical service areas to identify volumes: e.g. average total inpatient days, average number of patients, average length of stay per patient, growth trend
- Areas of higher risk
 - minimum three years incident reporting for each clinical service area to identify frequency of adverse events
 - minimum three years claims data for hospital and state-wide (VMIA) to identify emerging/high potential risk areas
 - complaints and patient satisfaction data to identify frequencies and trends by clinical service area
- Other evidence, policy directives or guidelines such as:
 - National Safety Goals
 - Coroners' reports
 - Clinical Registry Reports
 - Statement of Priorities indicators
 - My Hospital reports
- Consultation with clinical staff

A template for determining internal audit priorities can be found in Appendix 3 and includes criteria for clinical audit priorities.

Once the high priority internal audits are agreed they can be translated into the work plan with identification of timelines for each internal audit.

Developing the work plan

The internal audit work plan is for a specified period (often a year) within each three-year internal audit program and will consist of information regarding the following;

- Internal Audit theme – e.g. clinical services or human resources
- Internal Audit title
- Internal Audit description
- Internal audit manager responsible
- Rationale
- Priority
- Resources required
- Estimated start date
- Estimated report date to committee

It is useful to note in the internal audit work plan the internal audits that were considered but excluded to enable the audit committee to assess the plan against the risks and internal audits that will not be addressed.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.3 Preparing for an Internal Audit

The board endorsement of a three-year audit program and annual work plan allows the organisation to proceed with conducting the individual internal audits. This requires appointing an internal auditor/s to work with staff on the development, implementation, and reporting on individual internal audit plans. Some organisations may appoint an auditor earlier in the process to assist with the development of the three-year audit and/or annual work plan. The key processes required to conduct an internal audit in clinical areas are described below.

2.3.1. Selecting the internal auditor

The selection of an internal auditor requires careful preparation to ensure the auditor has the relevant experience. In the internal audit of clinical areas, the internal auditor may subcontract a clinical expert/s in the required clinical area/s.

The process of appointing an internal auditor in a clinical area starts with the preparation of an internal audit brief which outlines the deliverables required in the contract. These deliverables include:

- Internal audits required over the three-year period – this will comprise information from the internal audit program and work plan
- The extent of services required: assistance with internal audit work plan development, development of internal audit plans, assurance services through compliance or performance internal audits or advisory services
- The clinical standards to be followed for internal audits
- The internal audit tool to be used in the clinical area
- The timeframes for audits to be conducted and reported
- Access to personnel, patient records, and confidentiality requirements
- Key internal audit performance measures and quality measures
- Reports required : progress, draft, and final reports

Once the brief for the internal auditors is distributed the interview process can occur. Selection of the auditor in a clinical area will be based on consideration of:

- The qualifications of the internal auditor: an internal auditor will need to have either a
 - Graduate Certificate in Internal Auditing (Australian qualification),
 - Certified Internal Auditor (global qualification)or
 - Be a certified member of the Institute of Internal Auditors – Australia which, in addition to requiring the qualifications listed, requires practice in accordance with the *Institute of Internal Auditors International Professional Practices Framework*
- Relevant experience in the health sector
- Relevant knowledge of the clinical internal audit areas (or ability to team with appropriate specialist or clinical expertise)
- Reporting and communication framework
- Cost
- Referees' reports
- Review of previous audit assignment documents.

The following selection criteria need to be addressed for a clinical expert engaged by an internal auditor:

- Relevant specialist qualification in audit area
- Relevant clinical/management experience in audit area
- Previous audits undertaken in this area
- Knowledge of standards relevant to audit area.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.3.2 Internal Audit Contract Development

The contract for internal audit should include:

- Resources to be committed by internal auditor including any subcontracting arrangement (such a clinical expertise)
- Deliverables and timelines
- Performance measures to be met
- Contract payment arrangements and links to performance measures
- Communication and reporting to clinical staff, internal audit staff, and the audit committee
- Complaints mechanism.

2.3.3 Internal Audit Criteria Development

The criteria are explicit statements that define what is being measured objectively through the internal audit process. Internal auditors generally work with management and/or the board to develop appropriate audit assessment criteria if there are no established audit tools already available. In the clinical areas, if no internal audit tool exists, internal auditors will need to liaise with clinical experts to identify suitable criteria. Internal audit criteria are generally developed by identifying the key information which will inform whether objectives and goals have been met. The use of standards and guidelines is useful in informing criteria selection.

Recommendations from clinical practice guidelines can be used to develop criteria for the internal audit of clinical areas. Where there are no suitable clinical guidelines exist for developing criteria the following methods may be used:

- Prioritising the evidence from the literature
- Generating criteria based on professional consensus.

For criteria to be useful in leading to improvement they need to be

- based on evidence
- related to important aspects of operations/care
- measurable.

Criteria can be classified into those concerned with:

- structure (what you need)
- process (what you do)
- outcome (what you expect).

The internal audit of clinical areas may not use all these categories depending on the objectives and scope of the internal audit. Process data is considered to have greater sensitivity than outcome data in measuring the quality of service provision, however, process data is only of value if the process has an influence on outcomes. Measurement of outcomes can be used to identify problems in care, provided outcomes are clear, influenced by process, and occur within a short period (NICE, 2002:22).

The advantage of using all three criteria categories is that if an outcome is not achieved and the structure and processes contributing have been identified, the source of the problem should be easier to identify.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.3.4 The Internal Audit Tool

The tool to be used to collect data for the internal audit needs to be agreed between the organisation and the internal auditor. There may already be internal audit tool templates available for use but for areas where these do not exist (e.g. clinical areas) a tool will need to be developed.

Any internal audit tool developed will need to reflect the agreed criteria and be designed in a way that allows easy collection of the data by the auditors. In clinical areas consideration needs to be given to the scope of the audit and therefore the design of the tool. An internal audit tool in a clinical area may include the following:

1. Quality Systems Evaluation – a review of the main quality systems that underpin service delivery in the areas to be audited (e.g. workforce, infrastructure such as incident systems and risk systems, planning)
2. Clinical Process Evaluation – a review of the documents (policies, procedures and protocols) outlining clinical processes
3. Clinical Data Review – a review of patient-related data routinely monitored and analysed for quality improvement purposes by the service/unit under audit
4. Patient Record Review – a review of patient medical records for evidence of conformance with clinical policies and procedures. The review may examine general processes that are common to all patients in the unit and/or may identify criteria related to specific at risk populations in the audited area.

An example of a generic internal audit tool for a clinical area has been developed and is available as a separate document. IACT tools for the internal audit of specific clinical areas are also available.

Need more about scope

2.3.5 Key Methodology Considerations

The implementation of the internal audit requires consideration of a number of key methodological elements:

Sampling

Part of the internal audit of clinical areas may involve a number of observations or a review of patient health records. The first step is to precisely define the population from which the sample will be drawn by specifying the inclusion criteria. To ensure the sample examined in the audit is representative of the population the following two questions need to be answered:

- i. How many from the population do I need to select?

The sample selected should be large enough that the organisation is confident to implement changes based on the findings. However it must be remembered that this is not research and statistical significance does not need to be established. Resource considerations such as time, access to data, and costs may limit the sample size. Usually a sample of roughly 20-50 cases or 20% of the denominator, whichever is larger, is sufficient for internal audit.

- ii. How do I choose a representative sample?

Random sampling is preferable and ensures every member of the population has an equal chance of being selected. Random sampling may include approaches such as examining every 10th record in a timeframe or looking at every record created on dates with an odd number. Another key consideration in sampling of patient files is obtaining files that reflect different shifts in the clinical area such as night shifts.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

Data Sources

The data to inform an internal audit may need to be accessed from a number of sources including document review, staff interview (both planned and spontaneous with employed and visiting staff), and electronic data review. In the case of internal audit of clinical areas, patient records may be incomplete or insufficient to address all criteria and other sources may be useful, including:

1. Paper records
 - Clinical records not held on computer
2. Electronically held clinical records
 - Consultation records
 - Prescribing information
 - Use of IT tools (e.g. decision support tools)
 - Outcome data
3. Productivity Data
 - Average consultation times
 - Average triage times
 - Face to face consultations per hour/shift
4. Outcome Data
5. Feedback from patients
 - Complaints
 - Compliments
6. Feedback from colleagues
7. Incidents/ Adverse Events/Sentinel Events

2.3.6 Confidentiality of Data

Expectations in relation to confidentiality of data analysed and recorded during the internal audit require clear articulation with the internal auditor/s and staff involved with the internal audit. There are two key considerations:

Internal Audit staff

Confidentiality requirements need to be articulated clearly to the internal auditors verbally and via the internal audit brief. This may involve statements that, in line with organisation privacy and confidentiality policies, internal auditors are authorised to have full and unrestricted access to all functions, premises, assets, personnel, health records, and other documentation and information that the Head of Internal Audit considers necessary to enable internal audit to meet its responsibilities (ANOA, 2012). This would include specification that information accessed in the course of internal audits will only be used for auditing purposes. In addition, staff need to be made aware of confidentiality in respect of disclosure of discussions which take place at audit meetings.

Patient Data in Internal Audit of Clinical Areas

If information is obtained from health records there are several options to protect the confidentiality of patient information, and include:

- patients consenting to identifiable data being used,
- a member of the healthcare team making the information anonymous before it is used in audit
- internal auditors, subject to a duty of confidentiality, collect the data from the records and make it anonymous without seeking patient consent.
- Patients being made aware through rights and responsibility brochures that the information they give may be shared for the quality improvement purposes including audit.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.3.7 Developing an Internal Audit Plan

A detailed internal audit plan is required for each internal audit being conducted. The internal audit plan is developed by the internal auditor in consultation with the internal audit manager. The internal auditor will identify appropriate criteria for conducting the audit with the internal audit manager and the operational manager of the area being audited.

The following table provides a guide to the information that is recommended to be included in an internal audit plan for clinical areas.

Header	Detail Required
Internal Audit Title	
Description	e.g. An internal audit of the conformance of the emergency department with selective best practice standards and internal policies and procedures
Area of organisation	Name of audit entity in organisations e.g. clinical services, Specific / division(s) / service unit(s) affected e.g. Emergency department
Responsible internal contact	Internal audit manager and clinical unit manager (responsible for responding to audit report and implementation of recommendations)
Internal auditors	Name(s) of the internal auditor(s) involved in the audit
Objectives of audit	The objectives of the audit may be to address one or more of the following objectives: <ol style="list-style-type: none"> 1. Compliance: to determine compliance with legislation or conformance with external or internal policies, set of standards 2. Performance: to improve performance of the clinical service/ unit area 3. Advice: to provide advice on systems of internal control and policies and procedures.
Scope	Clearly define the boundaries of the audit in terms of staff involved, areas examined and documentation required In the case of the internal audit of clinical areas, the patient groups to be included, the aspects of care under review, and the time period over which the criteria apply
Audit methodology	Generally an internal audit will involve a combination of audit approaches (e.g. interviews, document reviews, data analysis) to collect sufficient reliable evidence in a cost effective manner. In this section provide a brief outline of: <ul style="list-style-type: none"> ▪ the methodology for collecting evidence including sampling approach ▪ audit tools to be used ▪ identify data sources for data collection ▪ communication and opportunities for consultation with key stakeholders (e.g. unit staff, patients) ▪ any adjustment of data e.g. case mix adjustment for outcome assessment in clinical areas ▪ confidentiality requirements.
Criteria for conducting audit	Define measurable criteria and standards against which process or outcomes of care are assessed. Can draw criteria from existing guidelines. E.g. audit criteria are based on the clinical standards for fractured neck of femur produced by the College of

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

Header	Detail Required
Deliverables	List all deliverables e.g. report on the assessment of conformance with standards including recommendation in the form of management agreed actions to address any issues identified.
Timing	Timelines for carrying out the internal audit, including expected dates for completion of key stages, including draft report, final report and re-audit.
Human resources	Names of any other staff/clinicians directly involved in carrying out the audit
Budget	List expenses in relation to audit
Accountability	Committee/staff with responsibility for review of results and ensuring actions are taken, including actual date report to be received and actions taken approved.
Communication strategies	List all planned meetings and communication strategies and contacts in implementing and reviewing the audit findings

Table 3: Internal Audit Plan Template

2.3.8 Reviewing the Draft Internal Audit Plan

Once a draft internal audit plan is developed, the internal audit manager needs to provide approval to the internal auditors to proceed with the plan. To ensure effective communication and engagement of staff in the internal audit process the internal audit plan should be reviewed by staff for comment prior to approval.

2.3.9 Registering an Internal Audit plan

Organisations may wish to develop a formal process for logging, registering, or approving an internal audit plan prior to undertaking the audit. This may involve sign off by the audit committee, head of internal audit, internal audit manager and/or unit manager.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.4 Conducting an Internal Audit

Once the plan for the internal audit is finalised and/or approved the internal audit can proceed and will generally include the activities described below.

2.4.1 Key Activities in the Internal Audit of Clinical Areas

Preliminary Meeting

A meeting between the internal auditors and the internal audit manager, operational manager/ unit manager of the unit or program to be audited, and key clinical staff prior to the final approval of the internal audit plan is recommended to:

- discuss the internal audit plan
- provide an opportunity for key staff to give their perspective on the prospective audit
- finalise details in terms of timing and staff involvement
- Arrange access to data, buildings and personnel.

A preliminary meeting between the internal auditor and the clinical expert is also necessary to ensure:

- agreement on the internal audit timetable
- clarity regarding respective tasks and responsibilities during the internal audit
- requirements for the clinical expert in recording and reporting findings

Fieldwork

The collection of data as evidence of meeting criteria may occur in several stages according to the methodology identified in the internal audit plan. The methods of data collection may include:

- Document review – offsite or onsite
- Staff interview
- Electronic system data review e.g. risk register
- Patient health records

Data Meeting

During or after the data collection and prior to the development of a draft internal audit report a meeting is useful between the internal auditor/s and the operational/unit manager of the clinical area audited and key clinical staff to discuss key findings and emerging issues. This meeting will enable practical responses to audit findings to be developed collaboratively between the operational staff and the auditors. See Internal Audit Implementation Checklist in Appendix 4 for key tasks to be undertaken in preparation for the audit.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.5 Internal Audit Reporting

Developing the Draft Report

The development of the draft internal audit report is coordinated by the internal auditor with the input of the clinical expert. To assist the internal auditor to incorporate the clinical findings and recommendations made by the clinical expert in the Part 4 of the internal audit, the patient file review, the following processes are recommended:

- Aggregation of results from all files related to a single criterion (e.g. record percentage of files that met criterion). The presentation of aggregate data allows health services to re-audit criterion at a later stage to look for evidence of improvement post implementation of internal audit recommendations.
- For each of the aggregate criterion results demonstrating a significant omission of care the clinical expert (with the assistance the internal auditor if required) needs to make a severity rating in terms of the risk, the omissions in care or documentation, represent to the organisation and the urgency with which it is required to be addressed

The rating scale used needs to be confirmed by the internal auditor but would generally follow the form of high, medium and low ratings based on consideration of the following criteria:

- likelihood of the error to potentially cause significant harm
- the likelihood to expose the health service to successful litigation
- urgency with which it needs to be addressed by the organisation

Draft Report Review

The draft report is circulated for review firstly to the head of internal audit to ensure the report responds to the objectives in the plan and the findings are clear and reasonable. The draft report is then reviewed by key staffing in the clinical area under audit to obtain feedback on the audit findings and recommendations. All feedback should be documented in the audit report. If an agreement cannot be reached on a recommendation the rationale for the auditor's recommendation should be outlined. Prior to the final report being released and presented to the audit committee by the internal auditor it should be signed off by the head of internal audit and the operational manager of the audited area.

Format of the Internal Audit Report

The internal audit report contains the major findings and recommendations arising from the internal audit. The format and timelines of the report need to be agreed with the internal auditor in advance. The format of the draft report would generally include the headings as outlined below:

- Overview of objectives and scope of internal audit: brief description
- Background of organisation and area of internal audit
- Rating scales used to rate controls and prioritise recommendations
- Names and position of staff involved in internal audit
- Summary of findings: description of key findings with allocation of control rating to reflect the risk presented to the organisation. The rating scales can be a traffic light, numeric or the use of descriptors (such as extreme, high and medium, or effective, improvement opportunity or unsatisfactory).
- Detailed findings – including identification of barriers to change
- Presentation of aggregate scores from the patient file review in Part 4 of the internal audit
- Recommendations – prioritised recommendations outlining practical actions to be taken within specified timeframe by specified staff. The recommendations developed with management should be cost effective and achievable
- Plan for re-audit if required
- Management response/auditor's opinion
- Overall audit conclusion and rating: a rating of the performance of the program against its objectives and the scope of the audit. This allows the readers of the report to understand the level of assurance that the report is providing about the audited area.

Organisations may require an internal audit reporting template to be used which allows consistency in presentation of internal audit findings from different internal auditors contracted by the organisation.

Part Two: Guidelines for the Internal Audit of Clinical Areas (continued)

2.6 Monitoring Internal Audit

The organisation will need to monitor various elements of the internal audit system including: the implementation of individual internal audit recommendations, the overall progress of the internal audit program/annual work plan, and the effectiveness of the internal audit approach itself. These different types of monitoring are each described below.

Monitoring internal audit recommendations

The responsibility for monitoring the implementation of internal audit recommendations and actions by nominated staff needs to be allocated to the appropriate committee, whether this is the audit committee or other. In the case of the internal audit of clinical areas this may be the quality or similar committee. The audit committee would be responsible for reviewing any re-audit results conducted by the internal auditor.

Reporting the progress on implementation of internal audit recommendations can be made via a template similar to the one found in Appendix 5.

Monitoring the internal audit program and work plan status

At least annually the head of internal audit should report to the audit committee on the progress of the organisation of its three-year internal audit program. The report would be expected to cover:

- progress on the completion of planned audits
- recommended changes from the approved program or work plan
- re-audits required
- an overview of the contribution of internal audit to reducing the strategic risks being targeted.

Monitoring the efficacy of internal audit

It is important that the organisation, as with any major system, periodically reviews the efficacy of its internal audit function. This may occur at the time of the review of the policy on internal audit or may be incorporated into the responsibilities of the audit committee. The review would usually be conducted internally but may be undertaken externally if required. The review of the internal audit function would identify issues that may require attention through examining:

- compliance with and effectiveness of the internal audit policy and procedure
- competency and capacity of the staff contributing to the internal audit function
- analysis of resource in terms of time, quality, costs and benefits of audits
- feedback from audited areas on the usefulness of the recommendations and the level of collaboration with management in developing the report
- feedback from the audit committee on efficiency and effectiveness of the reporting arrangements.
-

References

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(NICE) *National Institute of Clinical Excellence. 2002. Principles for Best Practice in Clinical Audit*

Victorian Department of Health 2010, *Understanding clinical practice toolkit: Clinical Audit, Quality, Safety and Patient Experience Branch, Hospital & Health Service Performance*, Melbourne

AS/NZS ISO 31000:2009 Risk management - Principles and guidelines

Part Three: Appendices

Appendix 1: Key content for internal audit policy

Internal Audit Policy	
<p>Policy Statement</p>	<p>This section should summarise the key policy statement the board endorses in relation to internal audit.</p> <p>Example statement <i>X Health Service</i> supports a rigorous and systematic internal audit process to optimally direct resources for risk management and quality assurance activities to areas of significant risk.</p>
<p>Purpose and Scope</p>	<p>This section should give an outline of the purpose of internal audit and the key operational areas addressed in the policy.</p> <p>Example statement The purpose of this policy is to set out the framework, roles and responsibilities for the conduct of internal audit.</p> <p>Internal audit reviews cover all programs and activities of [organisation] together with associated entities, and encompasses the review of all financial and non-financial policies and operations. Internal audit provides assurance that current processes effectively address significant risk areas which may be in the strategic, clinical, operational, financial or regulatory areas of <i>X Health Service</i>.</p> <p>This policy applies to anyone engaged in internal audit processes including:</p> <ul style="list-style-type: none"> ▪ Clinical and non-clinical staff ▪ Students ▪ Patients, carers, and members of the public
<p>Definitions</p>	<p>The Internal Audit of Clinical Areas The internal audit of clinical areas is a systematic and proactive process that provides the board (and senior management) with independent and objective quality improvement advice and assurance that significant clinical risks to meeting strategic objectives are being managed.</p> <p>INCITE information, 2012</p> <p>Internal Audit Internal audit is an independent, objective assurance and consulting 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.</p> <p>The Institute of Internal Auditors, 2011</p> <p>Risk Management Coordinated activities to direct and control an organisation with regard to risk.</p> <p>AS/NZS ISO 31000:2009</p>

Part Three: Appendices (continued)

Internal Audit Policy	
Guiding Principles	<p>Independence The internal audit activity will remain free from interference by any element in the organisation, including matters of audit selection, scope, procedures, frequency, timing, or report content. Internal auditors will have no direct operational responsibility or authority over any of the activities audited. Accordingly, they will not implement internal controls, develop procedures, install systems, prepare records, or engage in any other activity that may impair an internal auditor's judgment.</p> <p>Subject to compliance with information and privacy policies, internal auditors are authorised to have full, free, and unrestricted access to all functions, premises, assets, personnel, records, and other documentation and information that the Internal Audit Manager considers necessary to enable internal audit to meet its responsibilities.</p> <p>Objectivity Internal auditors must exhibit the highest level of professional objectivity in gathering, evaluating, and communicating information about the activity or process being examined. Internal auditors must make a balanced assessment of all the relevant circumstances and not be unduly influenced by their own interests or by others in forming judgments.</p> <p>Systematic and proactive The internal audit program and individual internal audits will be guided by a three-year internal audit schedule and individual audit work plans. The internal audit program effectiveness will be routinely evaluated.</p> <p>Risk-based Internal audit activities will be prioritised according to their risk rating based on the likelihood and consequence of risk.</p> <p>Value-adding Internal audit will contribute to improved organisational performance through the identification of areas for improvement and is complementary to other risk management and quality improvement processes.</p> <p>Proficient Internal audit will be conducted by appropriately skilled and credentialed internal auditors.</p>
Relevant Standards	<p>The internal audit activity will govern itself by adherence to The Institute of Internal Auditors' mandatory guidance, including the Definition of Internal Auditing, the Code of Ethics, and the International Standards for the Professional Practice of Internal Auditing. This mandatory guidance constitutes principles of the fundamental requirements for the professional practice of internal auditing and for evaluating the effectiveness of the internal audit activity's performance.</p> <p>For individual internal audits the audit will be conducted in line with relevant standards e.g. for the internal audit of clinical areas the criteria established for audit will be derived from the best available standards or clinical guidelines.</p>

Internal Audit Policy	
Responsibility	<p>This section should identify and summarise the key responsibilities of staff and committees in the organisation with a responsibility for internal audit.</p> <p>Board roles and responsibilities may include:</p> <ul style="list-style-type: none"> ▪ Ensuring adequate effective internal controls are in place in the organisation ▪ Considering and endorsing the internal audit policy via the audit committee ▪ Approving and reviewing the x year (three-year) audit program and annual work plan via the audit committee ▪ Adequately resourcing the internal audit program and work plan via a dedicated budget ▪ Approving the selection of the auditor ▪ Reviewing the internal audit work plan and its progress ▪ Reviewing and endorsing management response to internal audit report recommendations ▪ Reviewing progress on action plans via the relevant committee (audit or quality) ▪ Reviewing the effectiveness of the internal audit function <p>Chief Executive roles and responsibilities may include:</p> <ul style="list-style-type: none"> ▪ Managing the head of internal audit ▪ Reviewing final audit reports ▪ Assisting in preparing management's response to the internal audit report and approving advice to the audit committee ▪ Endorsing change initiatives in response to audit findings ▪ Being actively involved in internal and external communication regarding the audit process and findings. <p>The Audit Committee monitors and oversees the scope of work and performance of the internal audit function. The internal audit of clinical areas will be accountable to the audit committee as part of its wider responsibilities for internal audit. To meet its obligations in regard to internal audit the committee will be responsible for:</p> <ul style="list-style-type: none"> ▪ Reviewing the Internal Audit policy and procedure and recommending to the board for endorsement ▪ Approving the appointment and dismissal of the head of internal audit and the internal audit manager ▪ Selecting the internal auditor(s) and any clinical expert(s) and submitting a recommendation to the board for approval ▪ Approving the three-year Internal Audit and Clinical Internal Audit Program and submitting a recommendation to the board for endorsement ▪ Endorsing the annual audit plan ▪ Overseeing the operations of internal audit and ensuring the independence of the internal audit function ▪ Considering all internal audit reports (including clinical) ▪ Determining the appropriateness of management responses to recommendations ▪ Providing advice and recommendations to the board and the quality committee on internal audit reports in clinical areas and management responses to recommendations ▪ Reviewing the three-year internal audit program to assess coverage of significant risks (including clinical) for the health service ▪ Approving any update of the three-year internal audit program following review; and submitting recommendations to the board for endorsement. <p>The Quality Committee's role in relation to internal audit may include:</p> <ul style="list-style-type: none"> ▪ Noting the three-year clinical internal audit program and annual work plan and liaising with relevant staff and committees regarding the plan ▪ Considering and noting reports on findings from the Audit Committee ▪ Monitoring the actions taken by management in response to auditor recommendations and providing advice to the board for noting

Internal Audit Policy

Head of Internal Audit role may include responsibilities to:

- Review Internal Audit Policy and procedure and provide advice to the Audit Committee
- Organise, direct and monitor all Internal Audit operations in consultation with internal audit managers
- Identify audit priorities using a risk based approach commensurate with the board's risk appetite; develop the 3 Year Internal Audit Program and provide advice to the Audit & Risk Committee
- Manage the conduct of the three-year Internal Audit Program and ensure that internal audit resources are appropriate, sufficient, and effectively deployed to achieve the approved program
- Conduct a selection process for the Internal Auditor/s and provide advice to the Audit Committee
- Review and approve the scope of individual internal audits plans, standards and methodologies submitted by the Internal Auditor
- Direct the identification, development and documentation of audit issues and recommendations.
- Communicate the results of audit and consulting projects via written reports and oral presentations to the audit committee
- Liaise with internal audit managers

The internal audit manager/s¹ responsibilities include guiding the internal audit process in a specific area of the organisation. The example of an internal audit manager in a clinical area has been used.

The Internal Audit Manager for clinical areas will:

- Develop amendments to Internal Audit policy and procedure to reflect internal audit functions in clinical areas and provide advice to the Head of Internal Audit and Audit Committee
- Identify clinical audit priorities using a risk-based approach commensurate with the board's risk appetite;
- Develop an Internal Audit Program for clinical areas and provide advice to the Audit Committee
- Manage the conduct of the Internal Audit of the clinical area and ensure that internal audit resources are appropriate, sufficient, and effectively deployed to achieve the approved program
- Formally review audit priorities for clinical areas to inform for internal Audit program (at least annually) and provide advice to the Audit Committee
- Participate in the selection process for the Internal Auditor/s in clinical areas and provide advice to the Audit Committee
- Review the scope of individual internal audits of clinical areas and make recommendations to the head of internal audit
- Agree to audit plans, standards and methodologies submitted by the Internal Auditor for clinical areas
- Obtain and review management's response to the internal audit report of clinical areas and provide advice to the Audit Committee on the appropriateness of the proposed response commensurate with the board's risk appetite
- Review audit performance and provide advice to the Audit & Risk Committee
- Consider follow-up audit report and provide advice to the Quality Committee
- Share information and co-ordinate activities with other managers of risk management and quality assurance processes to ensure proper coverage and minimise duplication of efforts
- Liaise and work with clinicians and key staff, and clinical audit staff to ensure that the internal audit program in clinical areas meets all organisational requirements.
- Be actively involved in linkages to the other aspects of clinical governance to allow for the dissemination of audit information.
- Report to and liaise with Head of Internal Audit

Senior Manager(s) / Managers

Managers are responsible for ensuring that service development and delivery is underpinned by internal audit as required.

¹ There may be more than one manager with internal audit responsibilities reporting to the head of internal audit.

Part Three: Appendices (continued)

Internal Audit Policy	
Responsibility (continued)	<p>Individual Staff</p> <p>All staff are to be actively engaged in the internal audit process as directed by their manager. Clinical staff should be actively engaged in the internal audit process as they share responsibility for overall quality of care and have a key role to play in the development and implementation of action plans in response to audit findings. In this role they should:</p> <ul style="list-style-type: none"> ▪ Provide advice on the suitability of criteria for audit identified by the internal auditor ▪ Provide advice on the suitability of the methodology developed by the internal auditor ▪ Provide advice on the suitability of the project plan developed by the internal auditor ▪ Attend audit meetings and provide information as requested by the internal auditor
Internal Audit Plan	<p>This section should outline the planning process for internal audit within the organisation. Some organisations will engage the internal auditors to identify risk based priority areas.</p> <p>The Head of Internal Audit with the relevant internal audit manager (e.g. clinical) will prepare, for the Audit Committee's consideration, a three-year internal audit program and an annual internal audit work plan in a form agreed with the committee</p> <p>The internal audit plan will consist of a work schedule as well as budget and resource requirements for the next fiscal/calendar year</p>
Accountability	<p>The Head of Internal Audit and the Internal audit manager/s are accountable to the board for the efficient and effective operation of the internal audit function. Internal Audit manager reports functionally to the Audit Committee and administratively (i.e. day to day operations) to the Chief Executive Officer. The Head of Internal Audit has direct access to the Chair of the Board and the Chair and other members of the Audit Committee. Periodic 'in camera' meetings will be held between the Head of Internal Audit, the Internal audit manager/s and the Audit Committee.</p> <p>The Internal Audit Manager will report to each meeting of the Audit Committee on:</p> <ul style="list-style-type: none"> ▪ Progress in implementing the three-year audit plan and annual audit work plan, and agreed recommendations ▪ Audits completed. A written report will be prepared and issued by the Internal auditor and signed off by the head of internal audit and the operational manager of the audited area following the conclusion of each internal audit engagement and will be distributed as appropriate. <p>Internal audit results will be communicated to the board via the audit committee.</p>
Relationship with External Auditor	<p>External auditor will have full and free access to all internal audit plans, working papers and reports. Internal and external audit activities will be coordinated to help ensure the adequacy of overall audit coverage and to minimise duplication of effort.</p>
Internal Audit Evaluation	<p>This policy will be reviewed at least (insert period) by the Audit Committee. Any substantive changes will be formally approved by the board on the recommendation of the Audit Committee.</p> <p>The Internal Audit Manager will arrange for a periodic, independent review of the efficiency and effectiveness of the operations of the internal audit function at least every five years.</p>
Related Policies and Procedures	<p>In addition, the internal audit activity will adhere to <organisation> relevant policies and procedures and the internal audit activity's standard operating procedures manual.</p>
Date of Endorsement by Board	

Appendix 2: Key content for internal audit procedure

Procedure Section	Procedure
Internal Audit Three-Year Program	<ul style="list-style-type: none"> ▪ The head of internal audit will develop an internal audit program (three-year) outlining the broad direction of all clinical and non-clinical internal audit, taking into consideration all the organisation's assurance activities and identifying strategic gaps in assurance. ▪ The Audit Committee will review the three-year internal audit program to determine internal audit coverage is aligned with strategic organisational risk and recommend program for endorsement by the board. ▪ Appropriate notification/communication of internal audit program to key stakeholders
IA Annual Work Plan	<ul style="list-style-type: none"> ▪ The head of internal audit with the manager responsible for internal audit in approved priority areas (e.g. clinical internal audit manager) will prioritise internal audits to be conducted over the three-year period using a risk based approach commensurate with the board's risk appetite. A review of external and organisational data and staff consultations will inform risk identification and assessment. ▪ Detailed annual work plans for both clinical and non-clinical internal audits will be prepared by the manager responsible for internal audit in the approved priority area detailing the budget, timelines, staffing requirements .
Selection of Auditors	<ul style="list-style-type: none"> ▪ The head of internal audit with the area-specific internal audit manager will conduct competitive process to select a suitably qualified and experienced internal auditor(s) to conduct activities over the three-year cycle and provide advice to the audit committee. (The selected auditor may subcontract to access/provide skills and experience e.g. specific clinical service areas.) ▪ The audit committee selects auditor and recommends to the board for approval
Develop Audit Plans	<ul style="list-style-type: none"> ▪ The internal audit manager collaboratively develops with unit manager details of internal audit plan including scope, timing, staff involved. ▪ The internal auditor and/or internal audit manager develop a plan for each audit which includes the following <ol style="list-style-type: none"> i. objectives ii. scope iii. personnel iv. other resource allocations v. criteria for audit agreed by auditor, clinical internal audit manager and director of clinical services vi. methodology agreed by auditor, clinical internal audit manager and director of clinical services including: <ul style="list-style-type: none"> – data sources and methodology for data collection – audit tool and sample size vii. timing viii. deliverables ix. accountability x. communication strategy ▪ Plan agreed by internal audit manager and unit manager and submitted to head of internal audit.
Conduct Internal Audit and Analysis	<ul style="list-style-type: none"> ▪ Initial internal audit interview to be organised between internal auditors with unit managers to finalise the plan and arrange access to staff, buildings and data ▪ Data collection as per methodology of audit plan ▪ Internal auditor's interim verbal update to internal audit manager and unit manager on progress and any emerging audit issues ▪ Analysis of data as per methodology in workplan ▪ Confirmation of data accuracy and discussion of proposed recommendations between auditor, relevant internal audit manager and unit manager

Part Three: Appendices (continued)

Procedure Section	Procedure
<p>Reporting</p>	<p>Reporting on internal audit is required in two areas:</p> <p>1. Functional reporting:</p> <p>The internal auditor will submit a draft report to the head of internal audit and/or internal audit manager outlining the findings of each internal audit conducted.</p> <p>The internal auditor and/or the internal audit manager to obtain and review the management response to draft internal audit findings and recommendations. Management to provide formal response on the appropriateness and practicalities of the recommendations. Where management agrees with the recommendation an action plan should be developed. Where management disagrees with the recommendation the reason for the auditor's recommendation should be provided.</p> <p>The internal auditor to present final audit finding, including any amendments post review of management response, to audit committee in the following format:</p> <ul style="list-style-type: none"> i. Executive Summary ii. Audit objective(s) iii. Findings iv. Conclusions v. Management Responses / Action Plans <p>Audit committee to provide advice to the board and relevant committee (e.g. quality committee for internal audit of clinical areas) on reports and management responses and action plans.</p> <p>2. Administrative Reporting</p> <p>Administrative reporting on the internal audit function to encompass administration of the policies and procedures, appointment of auditors, communication and reports on internal audit plan progress. This includes:</p> <ul style="list-style-type: none"> ▪ Head of internal audit / internal audit manager to provide periodic reporting on progress of annual internal audit work plan with explanation of any variation ▪ Head of internal audit to present audit committee with an annual review of three-year plan: progress to date and recommendations re amendment
<p>Implementing Internal Audit Recommendations</p>	<ul style="list-style-type: none"> ▪ Allocation of responsibility to implement agreed recommendations and monitoring by the designated committee (e.g. quality committee in case of internal audit of clinical areas) ▪ Re-audit as planned and review by audit committee
<p>Quality Improvement</p>	<ul style="list-style-type: none"> ▪ Periodic review of efficiency and effectiveness of the internal audit system in the organisation (mixture of regular internal review with periodic external review). This may include a satisfaction survey of audited areas with final report to allow manager of audited areas to provide feedback on process. ▪ Report findings of internal audit system review to board via audit committee ▪ Periodic review of the internal audit policy by board via audit committee, based on recommendations of internal audit manager and responsible internal audit managers, to ensure the purpose, responsibilities, and authority and scope are appropriate (e.g. inclusive of clinical areas).

Part Three: Appendices (continued)

Appendix 3: Internal Audit Prioritisation Template

The following table may be helpful in determining internal audit priorities. In the table a proposed internal audit should be scored against agreed criteria. Multipliers can be used to weight the most important criteria. This method can help to formalise and structure discussion of internal audit priorities. Criteria useful in prioritising the internal audit of clinical areas have been included.

Criteria	No relevance (0)	Some relevance (1)	Almost met (2)	Fully met (3)	Score (and weight)
High cost					(x2)
High volume					
High risk					(x2)
Evidence of a quality problem					(x2)
Poor coverage by other assurance mechanisms					
Wide variation in practice					
Good evidence to inform internal audit standards					
Likely to improve healthcare outcomes as well as process					
Likely to have economic and efficiency benefits					(x2)
Topic is aligned with an organisational strategic priority					
Reliable sources of data readily available					
Reasonable time frame for completion					
Potential for change					(x2)
<i>other criteria</i>					
Total score					

Table adapted from HQIP, 2012 Clinical Audit Programme Guidance, Appendix Two)

The results of individual internal audit priority assessment can be presented in a table as shown below.

Criteria	Internal audit 1	Internal audit 2	Internal audit 3	Internal audit 4	Internal audit 5
High cost (x2)	6	2			
High volume					
other criteria					
Score					

Part Three: Appendices (continued)

Appendix 4: Internal Audit Checklist for undertaking an Internal Audit

Activity	Description of tasks	Timeline	Responsibility	Completed
Prior to Internal Audit				
Staff briefing	Internal auditors to discuss internal audit plan and agree staffing, resources, preparation and timing with internal audit staff and unit/area staff			
Confirmation of timing	Confirm date of internal audit fieldwork, draft report and final report submission with auditors			
Pre-audit documentation	Delivery of any pre-audit documentation to internal auditors (all data that may be reviewed offsite)			
Internal audit data	Organise sample and access to on site audit data e.g. patient files			
At Internal Audit				
Staff meeting at commencement of internal audit	Organise meeting with internal auditor/s , internal audit head and unit managers/key staff on Day 1 of audit			
Tour of area	Organise tour of audit area for internal auditors			
Internal audit resources	Organise room for auditors, staff and data access			
Staff meeting at completion of audit to discuss finding	Organise meeting with internal auditor/s, internal audit head and unit managers for progress update and at end of audit			
Post Internal Audit				
Feedback on draft internal audit report	Organise time for internal auditors to meet with internal audit head and unit managers for review and comment on recommendations			
Final report	Organise time for auditors to present final internal audit report to audit committee			

